



**Salvia Stakeholders REDUX**

**Stephanie Szick** to: Jocelyn Kula, Frank Cesa, Jacqueline DaSilva

2011-02-18 01:09 PM

Cc: Louis Proulx, CSTD-DGO, Michael Assad, Suzanne Desjardins, Jacqueline DaSilva, Frank Cesa

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History: This message has been forwarded.

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Frank and Jackie - can you also check with RAPB re: their stakeholders that may suit this requirement.

This is quite pressing. I've attached here the template that we have been provided to complete for this request. If you could add the stakeholders to that.

How does it look to have something by 2:00 pm at latest to share with Jocelyn, Suzanne and Louis?

Thanks very much, S



Stakeholder Template.doc

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**Stephanie Szick**

hi again Jackie DaSilva in the policy shop has to...

2011-02-18 12:03:48 PM

From: Stephanie Szick/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC, Louis Proulx/HC-SC/GC/CA@HWC  
Cc: CSTD-DGO, Jocelyn Kula/HC-SC/GC/CA@HWC, Louis Proulx/HC-SC/GC/CA@HWC, Michael Assad/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC, Jacqueline DaSilva/HC-SC/GC/CA@HWC, Frank Cesa/HC-SC/GC/CA@HWC  
Date: 2011-02-18 12:03 PM  
Subject: Salvia Stakeholders REDUX

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hi again

Jackie DaSilva in the policy shop has touched base with PACCB - she is pulling together a youth/parent et al list that we might be able to put forward.

Frank - please note.

Stephanie

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**Stephanie Szick**

Please see reply from Jesse below. This is non...

2011-02-18 11:51:32 AM

From: Stephanie Szick/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC, Louis Proulx/HC-SC/GC/CA@HWC  
Cc: CSTD-DGO, Michael Assad/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC  
Date: 2011-02-18 11:51 AM  
Subject: Salvia Stakeholders MECS request

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Please see reply from Jesse below.

This is non-negotiable -- we are to provide names of stakeholder groups who we would anticipate would be supportive of this action.

Can we tap PACCB and/or RAPB - through their networks?



----- Forwarded by Stephanie Szick/HC-SC/GC/CA on 2011-02-18 11:48 AM -----

From: Jesse Arnup-Blondin/HC-SC/GC/CA  
To: Stephanie Szick/HC-SC/GC/CA@HWC  
Date: 2011-02-18 11:46 AM  
Subject: Re:

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We must id stakeholders - eg parents or students against drugs, local law enforcement etc. Just saying rcmp will not suffice.  
Stephanie Szick

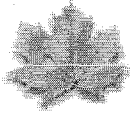
----- Original Message -----

**From:** Stephanie Szick  
**Sent:** 2011-02-18 11:40 AM EST  
**To:** Jesse Arnup-Blondin

I missed you before your meeting

Short of the RCMP, we have no stakeholders to provide

Jocelyn Kula and Suzanne Desjardins would be the Dept. spokes (at Winnipeg and Mtl respectively)....  
Louis has asked to meet with both of them today at 12:30



**Contact Info for NDPAC Stakeholders - NADS Announcement**

**Jacqueline DaSilva** to: Stephanie Szick

2011-02-18 02:01 PM

Cc: Frank Cesa, Michael Assad

Here is what PACCB has sent me. Tim Peters is working on a list from his DSCIF stakeholders.

Jackie

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Jackie DaSilva

Policy Analyst | Analyste de politique

Office of Policy and Strategic Planning | Bureau des politiques et de la planification stratégique

Controlled Substances and Tobacco Directorate | Direction des substances contrôlées et de la lutte au tabagisme

Health Canada | Santé Canada

T. (613) 946-3598

F. (613) 948-7977

jacqueline.dasilva@hc-sc.gc.ca

----- Forwarded by Jacqueline DaSilva/HC-SC/GC/CA on 2011-02-18 02:01 PM -----

From: Katharina Simioni/HC-SC/GC/CA

To: Jacqueline DaSilva/HC-SC/GC/CA@HWC


Cc: Lucie-Anne Besner/HC-SC/GC/CA@HWC, Michael Byrne/HC-SC/GC/CA@HWC, Barb Kennedy/HC-SC/GC/CA@HWC

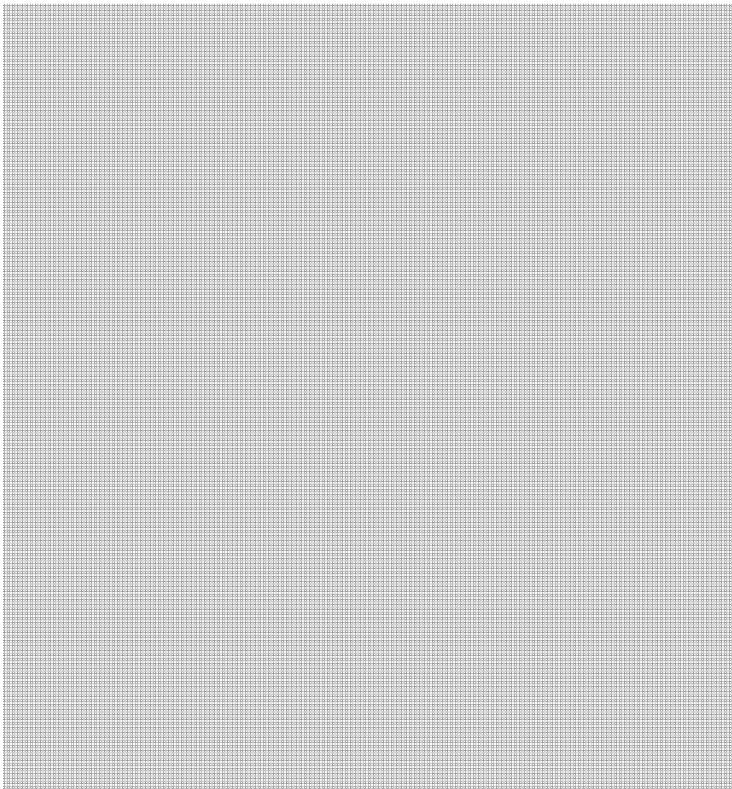
Date: 2011-02-18 01:48 PM

Subject: Contact Info for NDPAC Stakeholders - NADS Announcement

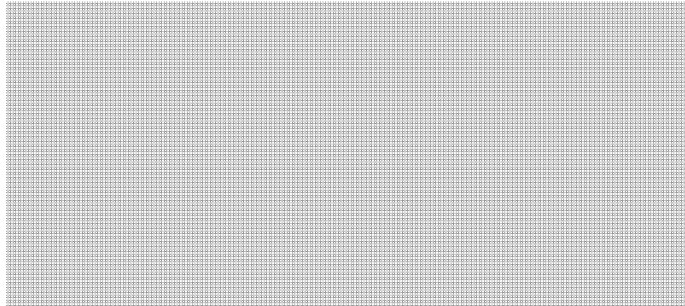
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Hi Jackie,

Here is the info that you are seeking, you are including  correct?



**s.19(1)**



s.19(1)

Katharina Simioni  
Senior Marketing Advisor / Conseillère principale en marketing  
Marketing and Communications Services Directorate / Direction des services de marketing et de communication  
Public Affairs, Consultation and Communications Branch / Direction générale des affaires publiques, de la consultation et des communications  
Health Canada / Santé Canada  
Tel/Tél: (613) 941-5356  
Fax/Télé: (613) 954-9713  
www.healthcanada.gc.ca / www.santecanada.gc.ca  
Government of Canada / Gouvernement du Canada

Jacqueline DaSilva

Hi Kathy, We're looking to contact potential sta...

2011-02-18 12:04:53 PM

From: Jacqueline DaSilva/HC-SC/GC/CA  
To: Katharina Simioni/HC-SC/GC/CA@HWC  
Date: 2011-02-18 12:04 PM  
Subject: Contact Info for NDPAC Stakeholders

Hi Kathy,

We're looking to contact potential stakeholder groups that could be interested in appearing with MO on Monday for a media release. On Monday MO will be announcing Health Canada's release of a Notice of Intent to schedule Salvia in the CDSA.

Based on the members of the NDPAC, would you have contact info for these groups so we may contact them?

- Centre of Excellence for Youth Engagement
- Canadian Association for School Health
- NECHI Training, Research and Health Promotions Institute
- Media Awareness Network
- Canadian Association of Family Resource Programs
- Canadian Executive Council on Addictions
- Alberta Alcohol and Drug Abuse Commission
- Drug Prevention Network of Canada (past President)

Thank you,  
Jackie

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Jackie DaSilva

Policy Analyst | Analyste de politique  
Office of Policy and Strategic Planning | Bureau des politiques et de la planification stratégique  
Controlled Substances and Tobacco Directorate | Direction des substances contrôlées et de la lutte au  
tabagisme  
Health Canada | Santé Canada  
T. (613) 946-3598  
F. (613) 948-7977  
[jacqueline.dasilva@hc-sc.gc.ca](mailto:jacqueline.dasilva@hc-sc.gc.ca)

Re: URGENT AR 11-103679-138 Ministerial Announcements on Salvia - February 21



Frank Cesa to: Stephanie Szick

2011-02-21 07:30 AM

Anna Roberts, Brenda Paine, Denis Arsenault, Gisele Osta, Jocelyn Kula,  
Cc: Michael Assad, Paula Robert, SoniaH Lindblad1, Stephanie Chandler, Matthieu  
Winter, Jacqueline DaSilva, Lyse Champagne, Cesare Spadaccini

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History: This message has been replied to.

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We will take the last four on the list if Denis takes the first four.

Matthieu, Anna, Jackie, Lyse - Since you are all in well before 9, can you each call one of the 4 organizations using the script and fill in the template below?

Denis - if you send your information you collect to us, we can collate it and get it in to DGO for the deadline. Please send to Anna and she will pull it all together.

I will try and be in by 9 this morning but will also have my blackberry on if anything comes up.

Frank

Frank Cesa, M.A.  
Manager, Substance Abuse Policy  
Office of Policy and Strategic Planning  
Controlled Substances and Tobacco Directorate  
Healthy Environments and Consumer Safety Branch  
Health Canada  
Phone #: 613-957-8332  
Fax #: 613-946-6460  
Frank.Cesa@hc-sc.gc.ca

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Stephanie Szick hi all, Further to my earlier emails of today regar... 2011-02-20 08:47:04 PM

From: Stephanie Szick/HC-SC/GC/CA  
To: Frank Cesa/HC-SC/GC/CA@HWC, Brenda Paine/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC  
Cc: Paula Robert/HC-SC/GC/CA@HWC, SoniaH Lindblad1/HC-SC/GC/CA@HWC, Michael Assad/HC-SC/GC/CA@HWC, Anna Roberts/HC-SC/GC/CA@HWC, Gisele Osta/HC-SC/GC/CA@HWC  
Date: 2011-02-20 08:47 PM  
Subject: URGENT AR 11-103679-138 Ministerial Announcements on Salvia - February 21

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hi all,  
Further to my earlier emails of today regarding this urgent request.

Unfortunately, we have no flexibility with this request or the deadline. ADMO wants to hear from us by 9:50 Monday morning.

This means these calls need to be made first thing Monday morning.

Recognizing we are up against a terrible time crunch and family day (we may not even get

people on the phone), these calls MUST be made - must be shown we have done this outreach.

Frank and Denis --

- **There are 8 stakeholders in the attached table listing list - please divide these among your teams and provide to DGO a consolidated report no later than 9:40 Monday morning** (some are an obvious fit for the given office - for example CCSA -- ideally OPSP call as there is a relationship there)
- Please use the table listing provided -- and completing the columns in the template re:

Positive or Negative?	Interested in Event?	Willing to Issue News Release	Willing to have Media Availability
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- Please indicate that a call was made -- whether or not a message was left or if you were able to speak with someone? with whom did you speak? did they give the impression of being supportive of this announcement by the govt. etc (per the columns as pasted above and in the template.)

For reference, I've also pasted here the communications products and the final DG-signed NOI in both languages re: the announcement of the publication of the NOI to CG1 this past weekend.

---- I suggest a very simple, high level "script" using the key messages from these materials, something along the lines of the following (definitely feel free to edit - I may have too much re: what the scheduling means and the question about making a public statement of support could use some nuancing...I defer to subject experts on the content!). Keeping in mind, everything will be online - so there will be public info. available, and the NOI is already online.

**Brenda** - are you fine with the proposed "script" below? - this is based on the news release.

Hello, my name is XXXXXX and I work at Health Canada.

I am calling to let you know about an announcement Health Canada will be making this morning regarding its proposal to schedule the substance Salvia to the Controlled Drugs and Substances Act.

A Notice to Interested Parties outlining Health Canada's proposal was published in *Canada Gazette*, Part I, this past Saturday, February 19, 2011. There is a 30-day period for people to provide their comments, which ends March 21, 2011.

The Department is taking this steps following a review of Canadian surveillance data and scientific reports which suggest that this substance

has the potential for abuse, especially among young people.

Salvia is a species of sage belonging to the mint family.

Stories about Salvia use, especially by youth, have often come up in the media.

We know that the risks of salvia use include hallucinations, loss of consciousness and short-term memory loss.

The scheduling of Salvia as a controlled substance would mean that activities such as possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation) would be illegal unless authorized by regulation.

Also, the scheduling of Salvia would enable law enforcement to take action against suspected illegal activities involving the substance.

More information about Salvia and details about the government's proposal is available at the Health Canada web site -- [www.hc-sc.gc.ca](http://www.hc-sc.gc.ca)

Part of the reason for my call this morning is also to get an understanding from you if this is an proposal your organization would support - in general terms but also through a public statement, such as a news release.

Is this something your organization would consider?

Thank you for your time this morning.

Thank you.

NOI



11-101374-981 Salvia NOI letter eng.pdf 11-101374-981 Salvia NOI letter fr.pdf

English

DEPARTMENT OF HEALTH

CONTROLLED DRUGS AND SUBSTANCES ACT

*Notice to interested parties - Proposal regarding the addition of Salvia divinorum and salvinorin A to Schedule III to the Controlled Drugs and Substances Act*

This notice provides interested stakeholders with the opportunity to provide comments on Health Canada's proposal to add the plant *Salvia divinorum* (*S. divinorum*) and its main active ingredient salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA). Stakeholders may also identify themselves for inclusion in any future consultation.

*S. divinorum* is a species of sage belonging to the mint family. Its leaves are generally chewed or smoked to obtain psychotropic effects. While uncertainty remains surrounding the health risks of *S. divinorum*, known effects are reported to be short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant. Neither *S. divinorum* nor salvinorin A are currently included in any of the Schedules to the CDSA.








Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. *S. divinorum* is widely touted as a "legal" hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs.<sup>1</sup> Results from the *Canadian Alcohol and Drug Use Monitoring Survey* (CADUMS) reveal that, in 2009, 1.6% of Canadians aged 15 years and older reported having used *S. divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24 years. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *S. divinorum* in the past year. Moreover, the 2009 *Ontario Student Drug Use and Health Survey* (OSDUHS) indicated that 5.4% of Ontario students in grades 7-12 reported ever using *S. divinorum* and 4.4% of these students reported using this substance in the past year. Because its psychoactive effects resemble those of other substances included in Schedule III to the CDSA such as lysergic acid diethylamide (LSD) and psilocybin, Health Canada is concerned that the ready availability and use of *S. divinorum* poses a risk to the health and safety of Canadians, particularly youth.

While *S. divinorum* and salvinorin A are not currently included in any of the United Nations Drug Control Conventions, a number of countries have chosen to regulate one or both as controlled substances. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden have all placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. Some American states have also implemented laws restricting their use, sale and/or distribution.






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<sup>1</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.



 HECS\_FS\_Salvia\_FINAL.DOC  HECS\_Salvia\_NTM\_Feb18\_Winnipeg-FINAL-bil.doc  HECS\_ML\_Salvia\_Feb17\_1411.doc  
 SN - MP Glover - Salvia - Feb 21.doc  HECS\_SP for SG bilingual Final.doc  HECS\_SP for SG\_Salvia\_FINAL.DOC  
 HECS\_NR\_Salvia\_FINAL.DOC

**French**

 HECS\_FS\_Salvia\_FINAL-fr.DOC  HECS\_Salvia\_NTM\_Feb19 Montreal.doc  HECS\_NR\_Salvia\_FINAL- fr.DOC  
 HECS\_SP for Fr Rep\_Salvia\_FINAL-fr.DOC  HECS\_SP for Fr Rep\_Salvia\_FINAL.DOC

----- Forwarded by Stephanie Szick/HC-SC/GC/CA on 02/20/2011 07:55 PM -----

From: Jesse Arnup-Blondin/HC-SC/GC/CA  
To: Frank Cesa/HC-SC/GC/CA@HWC, Brenda.Paine@hc-sc.gc.ca, michael.assad@hc-sc.gc.ca, stephanie.szick@hc-sc.gc.ca  
Cc: Paula Robert/HC-SC/GC/CA@HWC, SoniaH Lindblad1/HC-SC/GC/CA@HWC, Linda Corrigan/HC-SC/GC/CA@HWC, LeAnne Middler/HC-SC/GC/CA@HWC  
Date: 02/18/2011 05:31 PM  
Subject: URGENT AR 11-103679-138 Ministerial Annoucements on Salvia - February 21

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Please advise HECSB ADMO by **9:50 on Monday morning** which stakeholders have been contacted and which will issue a positive news release. As the events are happening on Monday, we do not have any flexibility with the timelines.

Thank you,

Jesse

----- Forwarded by Jesse Arnup-Blondin/HC-SC/GC/CA on 2011-02-18 05:25 PM -----

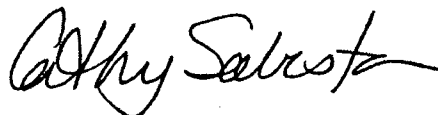
From: Meghan Lax/HC-SC/GC/CA  
To: Jesse Arnup-Blondin/HC-SC/GC/CA@HWC, Lisa Whittleton/HC-SC/GC/CA@HWC  
Cc: Linda Corrigan/HC-SC/GC/CA@HWC, Sandra Rose Roy/HC-SC/GC/CA@HWC, HECSB\_Action Request\_48h, HECSB\_Briefing, "Alexis M Tervo" <Alexis.M.Tervo@hc-sc.gc.ca>, PACCB-ADMO, RAPB-ADMO  
Date: 2011-02-18 05:18 PM  
Subject: Re: URGENT AR 11-103679-138 Ministerial Annoucements on Salvia - February 21

Including these substances within Schedule III to the CDSA would prohibit: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation). The regulation of *S. divinorum* and salvinorin A under the CDSA will also enable law enforcement agencies to take action against suspected illegal activities involving these substances.

As this action is not intended to interfere with the use and availability of *S. divinorum* and/or salvinorin A for legitimate medical, scientific or industrial purposes, Health Canada is seeking information from stakeholders on whether there are any such uses in Canada. Information received in response to this notice will be instrumental in determining appropriate regulation under the CDSA.

The publication of this notice begins a 30-day comment period. There will be additional opportunities to provide comments as the federal regulatory process progresses.

If you are interested in this process or have comments on this proposal, please contact Stephanie Chandler, Regulatory Policy Division, Office of Controlled Substances, Address Locator: 3503D, 123 Slater St., Ottawa, Ontario, Canada, K1A 1B9, by fax at (613) 946-4224 or by email at [OCS\\_Policy\\_and\\_Regulatory\\_Affairs@hc-sc.gc.ca](mailto:OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca).



Cathy A. Sabiston  
Director General  
Controlled Substances and Tobacco Directorate

Date Jan 28/11

## MINISTÈRE DE LA SANTÉ

### LOI RÉGLEMENTANT CERTAINES DROGUES ET AUTRES SUBSTANCES

*Avis aux parties intéressées - Proposition concernant l'ajout de Salvia divinorum et de la salvinorine A à l'annexe III de la Loi réglementant certaines drogues et autres substances*

Cet avis informe les parties intéressées de la possibilité de commenter la proposition de Santé Canada d'ajouter la plante *Salvia divinorum* (*S. divinorum*) et son principal ingrédient actif, la salvinorine A, à l'annexe III de la *Loi réglementant certaines drogues et autres substances* (LRCDas). Les parties intéressées ont aussi l'occasion d'ajouter leur nom pour toute consultation future.

*S. divinorum* est une espèce de sauge appartenant à la famille des menthes. Généralement, ses feuilles sont mâchées ou fumées pour obtenir des effets psychotropes. Alors qu'une incertitude subsiste quant aux risques pour la santé découlant de la consommation de *S. divinorum*, les effets de cette consommation sont connus pour être brefs et comprennent des hallucinations, une dysphorie, des expériences extra-corporel, l'inconscience et une perte de mémoire à court terme. Les effets, qui varient d'une personne à l'autre, sont également souvent décrits comme déplaisants. Ni la *S. divinorum* ni la salvinorine A ne sont actuellement incluses dans les annexes de la LRCDas.

Des rapports ont récemment été publiés indiquant que des adolescents et des jeunes adultes canadiens consomment de la *S. divinorum* pour sa capacité à produire des hallucinations. *S. divinorum* est largement vantée comme un hallucinogène "légal" sur Internet et a aussi été signalée comme l'un des produits à base d'herbes médicinales les plus courants utilisés comme option alternative aux drogues illicites.<sup>1</sup> Les conclusions tirées de l'*Enquête de surveillance canadienne de la consommation d'alcool et de drogues* (ESCCAD) révèlent que, en 2009, 1,6 % des Canadiens âgés de 15 ans ou plus ont déclaré avoir consommé de la *S. divinorum* au moins une fois dans leur vie, avec un taux de consommation plus important (7,3%) parmi les jeunes âgés de 15 à 24 ans. Les résultats de l'*Enquête sur le tabagisme chez les jeunes* de 2008-2009 au Canada montrent également que 5 % des jeunes de 15 ans ont consommé de la *S. divinorum* au cours de la dernière année. De plus, le *Sondage sur la consommation de drogues et la santé des élèves de l'Ontario* (SCDSEO) de 2009 indique que 5,4 % des élèves de l'Ontario des classes scolaires 7 à 12 ont déclaré avoir déjà consommé de la *S. divinorum* et que 4,4 % de ces élèves ont indiqué avoir consommé cette substance au cours de la dernière année. Puisque ses effets psychoactifs ressemblent à ceux d'autres substances comprises dans l'annexe III de la LRCDas, comme l'acide lysergique diéthylamide (LSD) et la psilocybine, Santé Canada craint que la disponibilité immédiate et la consommation de *S. divinorum* ne posent un risque pour la santé et la sécurité des Canadiens, en particulier pour celles des jeunes.

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<sup>1</sup>Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. Oct 2005, vol. 39, no°10, pp. 1634-1639.


Alors que la *S. divinorum* et la salvinorine A ne sont actuellement comprises dans aucune des Conventions de l'Organisation des Nations Unies sur le contrôle des drogues, de nombreux pays ont choisi de réglementer une de ces substances, ou les deux, comme substance désignée. L'Australie, la Belgique, le Danemark, la Finlande, l'Allemagne, l'Italie, le Japon, la Corée du Sud, l'Espagne et la Suède ont tous établi des contrôles sur les importations ou la vente, ou les deux, de *S. divinorum* et/ou de salvinorine A. Certains États américains ont aussi mis en oeuvre des lois restreignant son utilisation, sa vente et/ou sa distribution.

Le fait d'ajouter ces substances à l'annexe III de la LRCDas en interdirait la possession, le commerce, la possession aux fins de commerce, l'importation, l'exportation, la possession aux fins d'exportation et la production (ou la culture). La réglementation de la *S. divinorum* et de la salvinorine A conformément à la LRCDas permettrait également aux organismes d'application de la loi de prendre des mesures contre les activités illicites présumées liées à ces substances.

Étant donné que cette mesure ne vise pas à interférer avec l'utilisation et la disponibilité de la *S. divinorum* et/ou de la salvinorine A à des fins médicales, scientifiques ou industrielles légitimes, Santé Canada sollicite de l'information aux parties intéressées sur les possibilités de ces types d'utilisation au Canada. L'information reçue en réponse à cet avis sera déterminante dans la rédaction d'un règlement approprié conformément à la LRCDas.

La publication de cet avis entame une période de commentaires de 30 jours. Il y aura des occasions supplémentaires de fournir des commentaires au fur et à mesure que progresse le processus de réglementation fédéral.

Si vous êtes intéressé par ce processus ou que vous avez des commentaires sur cette proposition, veuillez communiquer avec Stephanie Chandler de la Division de la politique réglementaire, du Bureau des substances contrôlées, situé au : 3503D, 123, rue Slater, Ottawa (Ontario), Canada, K1A 1B9, par télécopieur au (613) 946-4224 ou par courriel au [OCS\\_Policy\\_and\\_Regulatory\\_Affairs@hc-sc.gc.ca](mailto:OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca).



Cathy A. Sabiston  
Directrice générale  
Direction des substances contrôlées et de la lutte au  
tabagisme

Date

Jan 28/11

## Salvia divinorum

News Release: The Government of Canada Proposes to Schedule Salvia Divinorum and Salvinorin A as Controlled Substances (insert link)

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Certain websites promote the use of *S. divinorum* as a “legal” alternative to street drugs. The products are sold in a number of forms, including fresh or dried leaves, liquids or seeds and plant cuttings for growing purposes.

Canadians should not use products containing *S. divinorum* and/or salvinorin A because they are hallucinogenic and little is known about the long-term effects of these substances on the brain and body; how it interacts with other substances, including other drugs, natural health products and alcohol; and the potential of *S. divinorum* to produce physical dependence and/or addiction.

### Risks Associated with the Use of *Salvia divinorum*

*S. divinorum* is known to have both physical and mental effects, which may include:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

### Legal Status of *Salvia divinorum*

#### In Canada

*S. divinorum* currently meets the definition of a natural health product (NHP) under the *Natural Health Products Regulations*. As of February 2011, Health Canada has not authorized for sale any natural health products which contain *S. divinorum* as an ingredient. The sale of unauthorized natural health products containing *S. divinorum* or its main active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

While *S. divinorum* and salvinorin A are not currently scheduled under the *Controlled Drugs and Substances Act* (CDSA), Health Canada has issued a Notice to Interested Parties which proposes to include *S. divinorum* and salvinorin A as controlled substances under the CDSA. This means that activities such as possession, trafficking, importation, exportation, production (or cultivation), possession for the purpose of trafficking or possession for the purposes of exporting would be illegal unless authorized by regulation.

### In Other Countries

Several countries including but not limited to Australia, Belgium, Germany, Italy and Japan, have placed similar controls on the import and/or sale of *S. divinorum* and/or salvinorin A.

In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed similar restrictions on their sale and/or import.

### **Research on the use of *Salvia divinorum* in Canada?**

Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *S. divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *S. divinorum* in the past year. The 2009 *Ontario Student Drug Use and Health Survey (OSDUHS)* indicated that 5.4% of Ontario students in grades 7-12 reported ever using *S. divinorum* and 4.4% of these students reported using this substance in the past year.

### **Need More Info?**

For information on how to submit a consumer or trade complaint about the unauthorized sale of health products containing *S. divinorum* please consult the following documents:

- Consumers: [http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_44\\_consumer\\_consommateur\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_44_consumer_consommateur_cp-pc-eng.php)
- Trade: [http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_38\\_trade-industrie\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_38_trade-industrie_cp-pc-eng.php). Or contact the **Health Products and Food Branch Inspectorate** directly by calling toll-free 1-800-267-9675.

To report an adverse reaction or interaction involving any health product, contact Health Canada at 1-866-234-2345 (toll free in Canada), or visit the [MedEffect Canada](http://www.health.gc.ca/medeffect) web section at: [www.health.gc.ca/medeffect](http://www.health.gc.ca/medeffect)

For more information on the risks of using Salvia, please see *It's Your Health* at: (insert link)



## NOTICE TO MEDIA

February 19, 2011

MP Shelly Glover (Saint Boniface) will make an announcement on behalf of the Honourable Leona Aglukkaq, Minister of Health, related to the health and safety of Canadians.

**Date**

February 21, 2011

**Time**

1:45 p.m. (CST)

**Location**

YMCA-YWCA - South Y  
5 Fermor Avenue  
Multi-purpose room 2  
Winnipeg, Manitoba

**Media Inquiries**

Health Canada  
(613) 957-2983

Jenny Van Alstyne  
Office of the Honourable Leona Aglukkaq  
Federal Minister of Health  
(613) 957-0200

## AVIS AUX MÉDIAS

Le 19 février 2011

La députée Shelly Glover (Saint-Boniface), fera une annonce sur la santé et la sécurité des Canadiens, au nom de l'honorable Leona Aglukkaq, ministre de la Santé.

**Date**

Le 21 février 2011

**Heure**

13 h 45 (HNC)

**Endroit**

YMCA-YWCA - South Y  
5, avenue Fermor  
Salle polyvalente 2  
Winnipeg (Manitoba)

**Renseignements aux médias**

Santé Canada  
613-957-2983

Jenny Van Alstyne  
Cabinet de l'honorable Leona Aglukkaq  
Ministre fédéral de la Santé  
613-957-0200



**DRAFT**  
11/02/2011

**Media Lines**  
***Salvia divinorum***

**Issue**

There is ongoing media interest regarding the availability of *Salvia divinorum* in Canada as well as Canadian surveillance data suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has concluded that *Salvia divinorum* and its main active ingredient salvinorin A should be scheduled under the *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth. A Notice to Interested Parties outlining Health Canada's proposal to regulate this substance will be published in *Canada Gazette*, Part I, on February 19, 2011 (TBC).

**Key Messages:**

- The Government of Canada is taking these steps in order to protect the health and safety of Canadians, particularly youth, from the potentially harmful effects of *Salvia divinorum* and/or salvinorin A.
- After reviewing available information and reports that suggest these substances have the potential for abuse, especially among young people, Health Canada is proposing to schedule both *Salvia divinorum* and its main active ingredient salvinorin A as controlled substances.
- Health Canada is continuing to survey the prevalence of salvia use and have based our proposed scheduling on available information and reports that suggest these substances have the potential for abuse, especially among young Canadians. The risks of salvia use include hallucinations, loss of consciousness and short-term memory loss.
- The proposed inclusion of *Salvia divinorum* and salvinorin A in Schedule III to the *Controlled Drugs and Substances Act* would make possession, trafficking, importation, exportation, production (or cultivation), possession for the purpose of trafficking or possession for the purposes of exporting illegal unless authorized by regulation.

**Supplementary Messages:**

- Though it is a hallucinogen, the plant *Salvia divinorum* is not currently scheduled under the CDSA.
- To date, Health Canada has not authorized for sale any natural health products which contain *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products containing *Salvia divinorum* or its active ingredient



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salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act and its associated regulations*.

**Questions and Answers:**

**Q1 - What are the risks associated with the use of *Salvia divinorum***

A1 - *S. divinorum* is known to have both physical and mental effects. The effects of *S. divinorum*, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

There is no way to predict what effect these substances may have on an individual. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product;
- how much is used;
- the purity of the product (products that contain *S. divinorum* may be mixed with other substances);
- how it is taken, for example, whether the product is chewed, swallowed or smoked; and
- the user's mood and expectations.

While scientists know which brain receptors are targeted by the main active ingredient, salvinorin A, very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or if it can cause permanent damage;
- how it interacts with other substances, including other drugs, natural health products and alcohol;
- the potential of *S. divinorum* to produce physical dependence and/or addiction.

For more information on *Salvia divinorum* and the risks associated with its use, please see *It's Your Health* at: (insert link to the *It's Your Health* article.)

**Q2 – What is involved in scheduling *Salvia divinorum* as a controlled substance and what stage is it at?**

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A2 - Health Canada considers several factors in determining whether the scheduling of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- Overall risk to public health and safety posed by the substance.
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- International requirements and trends in international control.

Health Canada recently concluded its assessment of *Salvia divinorum* and salvinorin A against these factors and proposes to include both substances in Schedule III to the CDSA. The first step in the process of scheduling a substance under the CDSA is the publication of a *Notice to Interested Parties* (NOI) in *Canada Gazette*, Part I, which will be published on February 19, 2011 (TBC) for a 30-day comment period. This notice provides interested stakeholders with the opportunity to provide comments on Health Canada's proposal to add *Salvia divinorum* and its main active ingredient salvinorin A to Schedule III to the CDSA. Any comments received are considered during the preparation of a regulatory proposal. There will be additional opportunities for comment as the federal regulatory process progresses, which usually takes about 18 to 24 months to complete.

**Q3. Why has the Government now decided to schedule these substances under the CDSA?**

A3. Scheduling these products will reduce the potential risks to the health and safety of Canadians associated with their ready availability, with their increased use and their unknown effects. The scheduling of *Salvia divinorum* and salvinorin A will also eliminate the current misconception that these substances are a safe alternative to other illegal drugs. Furthermore, the scheduling will also enable law enforcement agencies to take action against suspected illegal activities involving these substances.

**Q4 – Are *Salvia divinorum* and/or salvinorin A controlled internationally? How are these substances regulated in other countries?**

A4 - Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions; as a result, there is no requirement for them to be scheduled as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

The move to include *Salvia divinorum* and salvinorin A in Schedule III to the CDSA is consistent with actions taken by several countries (e.g., Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden) that have also placed similar controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A.

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Some individual U.S. states have implemented similar laws restricting their use, sale and/or distribution.

**Q5 – Is there any research on the use of *Salvia divinorum* in Canada?**

A5 - Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *Salvia divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *Salvia divinorum* in the past year. The 2009 *Ontario Student Drug Use and Health Survey (OSDUHS)* indicated that 5.4% of Ontario students in grades 7-12 reported ever using *Salvia divinorum* and 4.4% of these students reported using this substance in the past year.

**Q6 – If Health Canada is aware that the use of *Salvia divinorum* can produce negative health effects such as hallucinations, feelings of anxiety, etc., why is it not controlled under the Controlled Drugs and Substances Act?**

A6 – The move to schedule *Salvia divinorum* and salvinorin A as controlled substances is based on surveillance data from surveys such as the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)*, *Youth Smoking Survey (YSS)* and the *Ontario Student Drug Use and Health Survey (OSDUHS)*, some of which only became available in 2010.

In the interim, as *Salvia divinorum* is a plant with hallucinogenic properties, it currently meets the definition of a natural health product under the *Natural Health Products Regulations (NHPR)*. The sale of unauthorized natural health products may be subject to compliance and enforcement action in accordance with the *Food and Drugs Act* and its associated regulations.

**Q7 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A7 – Once *Salvia divinorum* and salvinorin A are included in Schedule III to the CDSA, law enforcement will be able to take appropriate action in response to suspected illegal activities with these substances.

Currently, however, *Salvia divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. For more information on how to submit a consumer complaint about the unauthorized sale of drugs containing *Salvia divinorum* and/or salvinorin A, visit: [www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_44\\_consumer\\_consommateur\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_44_consumer_consommateur_cp-pc-eng.php).

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**Q8 - Has Health Canada issued any kind of warning to Canadians about *Salvia divinorum*?**

A8 - Health Canada has developed an *It's Your Health* article about *Salvia divinorum* to help inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at: (link to come). Health Canada also issued a news release on February XX announcing the Government of Canada's intention to schedule *Salvia divinorum* and salvinorin A, as controlled substances. A Notice to Interested Parties, outlining Health Canada's proposal, was published in *Canada Gazette*, Part I, on February 19, 2011 (TBC), giving interested parties a 30-day period to submit their comments. There will be additional opportunities for comment as the federal regulatory process progresses.

**Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff, incense special, and salvia. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

Data from the 2008-2009 Youth Smoking Survey indicates that:

- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;
- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year; and
- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using Salvia in their lifetime (0.2% in the past year); and
- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that:

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;
- 5.4% of students (grades 7-12) ever used *Salvia divinorum*; and
- use of *Salvia divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

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**Prepared by:** Stephanie Chandler and Denis Arsenault, OCS, CSTD  
Reviewed and revised by: Christine Roush, Senior Communications  
Advisor, HECS, Communications

**Approved by:**

Jocelyn Kula, A/Director, OCS, CSTD, HECS (Jan 19, 2011 and Jan 27, 2011)  
Suzanne Desjardins, Director, ODARS, CSTD, HECS (Approved Jan 20, 2011)  
Cathy Sabiston, DG, CSTD, HECS  
Chris Turner, DG, MHPD  
Scott Sawler, DG, NHPD  
Diana Dowthwaite, DG, HPFB  
Sharon Mullin, Director, Compliance and Enforcement Coordination, HPFB  
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Paul Glover, ADM, HPFB  
Hillary Geller, A/ADM, HECS  
Anne Lamar, ADM, PACCB  
DMO (pending)  
MO (pending)  
PCO (pending)

**Last updated February 18, 2011 at 7:41 p.m.**

**Scenario Note for  
Shelly Glover, Member of Parliament for Saint-Boniface**

**Announcement of the Government of Canada's intention to regulate *Salvia divinorum* and salvinorin A, also known as Salvia, as controlled substances.**

**Winnipeg, Manitoba  
February 21, 2011  
1:45 p.m.**

**Purpose of Event:** On behalf of the Honourable Leona Aglukkaq, Shelly Glover, Member of Parliament for Saint-Boniface, will announce the Government of Canada's intention to regulate *Salvia divinorum* and salvinorin A, also known as Salvia, as controlled substances.

**Event Address:**

The YMCA-YWCA – South Y  
Multipurpose Room 2  
5 Fermor Avenue  
Winnipeg, Manitoba

**Contacts:**

**MP Glover's Office:**

Myrrhanda Novak  
gloves1@parl.gc.ca  
204.983.3183

**Health Canada**

Jocelyn Kula  
A/Director, Office of Controlled Substances  
Controlled Substances and Tobacco Directorate, HECS

Cell: 613-797-2103

**On-site Health Canada logistics support:**

Adele Novak  
Regional Communications Officer

Office: 204-984-7895  
Cell: 204-791-0240

Karen Christiuk  
Regional Communications Officer

Office: 204-984-7199  
Cell: 204-291-3657

**YMCA-YWCA – South Y**

Caroline Winston  
Communications Manager

Office: 204-831-2974  
Cell: 204-229-3209

Angela Hildebrand  
General Manager, YMCA, South Y

Office: 204-

**Event Emcee**

Angela Hildebrand  
General Manager, YMCA, South Y

Office: 204-

**Holding Room:**

General Manager's Office (Angela Hildebrand)  
YMCA, South Y  
5 Fermor Avenue

**Photographer (CP photographer booked by Health Canada Media Relations):**

Name David Lipnowski Cell: 204-296-3038

**Media:** Media will be invited to attend by way of a notice to media issued to the news wire by Health Canada (HQ) and posted to Health Canada's Web site. Regional Communications will make follow-up calls to media after the notice to media is issued. At the event, media will have the opportunity to ask questions following the speakers' remarks in the format of a question and answer period.

**Transcript:**

Required: Yes (Media Q booked by Health Canada Media Relations)

**Logistics (sound system, podium, flags):**

Arranged by Health Canada Regional Communications.

**Sound system (arranged by Health Canada Regional Communications)**

Tel Av  
Aaron Jakab/Tom Borsa

Office: 204-775-6198  
Cell: 204-899-5021

**Winnipeg, Manitoba**

**Monday, February 21, 2011**

**DETAILED ITINERARY**

- 1255 hrs MP Glover arrives at the front doors of the YMCA, South Y, 5 Fernor Avenue, and is greeted by Angela Hildebrand, General Manager, YMCA, South Y and event Emcee; and Adele Novak, Regional Communications Officer, Health Canada. Angela Hildebrand and Adele Novak escort MP Glover to the holding room, Angela's Office (behind the front reception).
- 1300 hrs MP Glover and Angela Hildebrand arrive at the holding room and are joined by Jocelyn Kula, A/Director, Office of Controlled Substances, Health Canada.
- A pitcher of water will be available in the briefing room.
- 1344 hrs MP Glover, Angela Hildebrand, and Jocelyn Kula depart holding room en route to the Multipurpose Room 2 where the announcement will take place.
- 1345 hrs Event begins. Angela Hildebrand welcomes everyone and introduces MP Glover.
- 
- Open to media. Media will be set up behind the audience.**
- 
- 1347 hrs MP Glover speaks.
- 1352 hrs Angela Hildebrand thanks MP Glover and introduces second speaker (TBC)
- 1353 hrs Second speaker speaks.
- 1357 hrs Angela Hildebrand thanks second speaker, and invites MP Glover and Jocelyn Kula to the podium to answer questions from the audience and media.
- 1407 hrs Event concludes. Photos may be taken.
- 1420 hrs MP Glover departs YMCA, South Y and proceeds to board her vehicle.

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**Speech for**  
**Shelly Glover**  
**Parliamentary Secretary to the Minister of Finance**  
**Member of Parliament for Saint Boniface**

**Issue: Proposal to add Salvia Divinorum and Salvinorin  
A to Schedule III to the *Controlled Drugs and  
Substances Act*.**

**Date: February 21, 2011**

Check Against Delivery

Good Morning/Afternoon:

I'd like to thank you for joining me here today for what I consider to be a very important announcement for Canadian families and safer communities.

Une substance connue sous le nom de salvia continue de gagner en popularité chez les jeunes, et certains d'entre eux en abusent. En tant que mère et que policière, je peux vous assurer qu'il s'agit d'une question qui me préoccupe

Its popularity comes from the fact that it can have some of the same effects as certain illicit drugs, and there is also a false perception that it is safe.

But it isn't safe.

Salvia has the real potential to be harmful.

It can cause hallucinations and can have other serious effects on the brain and body. At this point, very little is known about the long-term effect of this substance.

Results from the *Canadian Alcohol and Drug Use Monitoring Survey* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *S. divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24.

And, the results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *S. divinorum* in the past year.

Because of the potential risks to the health of Canadians, particularly young people, we are proposing to add Salvia

divinorum, and its main active ingredient salvinorin A, to the *Controlled Drugs and Substances Act*.

These substances should be controlled, just like other illicit drugs.

As a first step, a notice was published in the *Canada Gazette* on this past weekend. That started a process during which all Canadians will have a 30-day period to comment on our proposal. While we are consulting with Canadians, our position is clear. We want to help parents, families and communities to keep our kids safe.

L'ajout de la *salvia divinorum* à la liste des substances contrôlées rendrait illégales les activités mettant en cause la salvia, comme la possession, le trafic, l'importation et la culture.

And, these measures are in line with other countries, including but not limited to Australia, Belgium, Germany, Italy and Japan. All of these countries have placed similar controls on the import and/or sale of *salvia*.

The bottom line is that our teens face enough pressure already. And with heavily covered stories of young people in Hollywood using Salvia to get high, we have the responsibility to help protect our youth. In a fragile economy like this, Moms and Dads literally can't afford to always keep watch of what's happening. We want to help Mom and Dad.

Nous agissons rapidement dans ce dossier, parce que nous voulons protéger nos jeunes des méfaits associés à la salvia.

Nous voulons éliminer les idées fausses selon lesquelles la salvia est un substitut sécuritaire aux drogues de la rue.

It is not.

All of the steps we are taking are designed to protect the health and safety of Canadians from the potentially harmful effects of this substance. We know that parents want their children to be protected from substances like Salvia, particularly when they are in their teenage years.

I am happy to take your questions.

Thank you

**Speech for**  
**Shelly Glover**  
**Parliamentary Secretary to the Minister of Finance**  
**Member of Parliament for Saint Boniface**

**Issue: Proposal to add Salvia Divinorum and Salvinorin  
A to Schedule III to the *Controlled Drugs and  
Substances Act.***

**Date: February 21, 2011**

Check Against Delivery

Good Morning/Afternoon:

I'd like to thank you for joining me here today for what I consider to be a very important announcement for Canadian families and safer communities.

Among today's youth, a substance known as Salvia has been gaining popularity, and is being abused by some young people. As a parent and a police officer, I can tell you that it's something I'm personally concerned about.

Its popularity comes from the fact that it can have some of the same effects as certain illicit drugs, and there is also a false perception that it is safe.

But it isn't safe.

Salvia has the real potential to be harmful.

It can cause hallucinations and can have other serious effects on the brain and body. At this point, very little is known about the long-term effect of this substance.

Results from the *Canadian Alcohol and Drug Use Monitoring Survey* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *S. divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24.

And, the results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *S. divinorum* in the past year.

Because of the potential risks to the health of Canadians, particularly young people, we are proposing to add *Salvia divinorum*, and its main active ingredient *salvinorin A*, to the *Controlled Drugs and Substances Act*.

These substances should be controlled, just like other illicit drugs.

As a first step, a notice was published in the *Canada Gazette* on this past weekend. That started a process during which all Canadians will

have a 30-day period to comment on our proposal. While we are consulting with Canadians, our position is clear. We want to help parents, families and communities to keep our kids safe.

Adding *salvia divinorum* to the list of controlled drugs and substances would make activities with *salvia*, such as possession, trafficking, importing or cultivating illegal.

And, these measures are in line with other countries, including but not limited to Australia, Belgium, Germany, Italy and Japan. All of these countries have placed similar controls on the import and/or sale of *salvia*.

The bottom line is that our teens face enough pressure already. And with heavily covered stories of young people in Hollywood using *Salvia* to get high, we have the responsibility to help protect our youth. In a fragile economy like this, Moms and Dads literally can't afford to always keep watch of what's happening. We want to help Mom and Dad.

We're acting quickly on this because we want to protect our young people from the harms associated with *Salvia*.

We want to eliminate the misconceptions that *Salvia* is a safe alternative to street drugs.

It is not.

All of the steps we are taking are designed to protect the health and safety of Canadians from the potentially harmful effects of this substance. We know that parents want their children to be protected from substances like *Salvia*, particularly when they are in their teenage years.

I am happy to take your questions.

Thank you.

Health Canada

2011-XX

# News Release

## Harper Government Takes Action to Protect Families

February 21, 2011

For immediate release

Factsheet: *Salvia Divinorum* (insert link)

**OTTAWA** – Today, MP Shelly Glover (Saint Boniface), Parliamentary Secretary to the Minister of Finance, and the Honourable Christian Paradis, Minister of Natural Resources, announced on behalf of the Honourable Leona Aglukkaq, Minister of Health, the Harper Government's proposed intention to include *Salvia divinorum* and salvinorin A, also known as Salvia, as controlled substances. A Notice to Interested Parties outlining Health Canada's proposal was published in *Canada Gazette*, Part I, on February 19, 2011.

"As a mother and police officer, I am pleased to see our Government take action to help parents protect their children from this dangerous substance," said P.S. Glover.

"After reviewing Canadian surveillance data and scientific reports that suggest this substance has the potential for abuse, especially among young people, we are taking these steps to protect the health and safety of Canadians from the harmful effects of this substance," said Minister Paradis.

The Notice to Interested Parties proposes that *Salvia divinorum* and its main active ingredient salvinorin A be added to Schedule III to the *Controlled Drugs and Substances Act*. This means that activities such as possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation) would be illegal unless authorized by regulation. The scheduling of *Salvia divinorum* and salvinorin A as a controlled substance would also enable law enforcement agencies to take action against suspected illegal activities involving these substances.

Interested parties are encouraged to submit any comments regarding the Notice to Interested Parties by March 21, 2011.

For more information on *Salvia divinorum* and the risks associated with its use, please see *It's Your Health* at: (insert link to the *It's Your Health* article.)



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**Media Enquiries:**

Health Canada  
(613) 957-2983

*Également disponible en français*

Jenny Van Alstyné  
Office of the Honourable Leona Aglukkaq  
Federal Minister of Health  
(613) 957-0200

**Public Enquiries:**

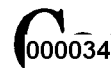
(613) 957-2991  
1-866 225-0709

Health Canada news releases are available on the Internet at  
[www.healthcanada.gc.ca/media](http://www.healthcanada.gc.ca/media)



Government  
of Canada

Gouvernement  
du Canada





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## Fiche de renseignements Février 2011

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### ***Salvia divinorum***

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Communiqué de presse : Le gouvernement du Canada propose d'ajouter la salvia et la salvinorine A à la liste des substances contrôlées (insérer le lien)

La *salvia divinorum* (la salvia) est une espèce de sauge de la famille des labiacées. Certains sites Web encouragent la consommation de salvia comme substitut légal aux drogues de la rue. Les produits se vendent sous plusieurs formes, notamment en feuilles fraîches ou séchées, en liquides ou en graines et en boutures pour la culture.

Les Canadiens doivent éviter de consommer des produits contenant de la salvia, car il s'agit d'une substance hallucinogène dont on connaît mal les effets à long terme sur le cerveau et l'organisme, la façon dont elle interagit avec d'autres substances, comme d'autres drogues, des produits de santé naturel et l'alcool, et le risque de dépendance physique ou de toxicomanie associé à la consommation de la salvia.

#### **Risques associés à la consommation de salvia**

La salvia a des effets physiques et mentaux connus qui peuvent comprendre les suivants :

- hallucinations
- dysphorie (sentiment d'angoisse, de dépression ou d'agitation)
- expériences extracorporelles
- rire incontrôlable
- évanouissement
- perte de mémoire immédiate
- manque de coordination des mouvements
- trouble de l'élocution et phrases maladroites

#### **Statut juridique de la salvia**

##### Au Canada

La salvia correspond présentement à la définition d'un produit de santé naturel que donne le *Règlement sur les produits de santé naturels*. En février 2011, Santé Canada n'avait toujours pas homologué de produit de santé naturel contenant de la salvia. Conformément à la *Loi sur les aliments et drogues*, Santé Canada peut prendre des mesures coercitives à l'égard de quiconque vend des produits de santé naturels non homologués contenant de la salvia ou son principal ingrédient actif, la salvinorine A.

Si la salvia et la salvinorine A ne sont pas, à l'heure actuelle, considérées comme des substances contrôlées en vertu de la *Loi réglementant certaines drogues et autres substances*, Santé Canada a toutefois émis un avis aux parties intéressées dans lequel il propose de les ajouter à l'annexe III de la *Loi*. Cela signifie que les activités comme la possession, le trafic, l'importation, l'exportation, la production (ou la culture), la

possession en vue du trafic ou la possession en vue de l'exportation seraient illégales à moins d'être autorisées par réglementation.

#### À l'étranger

Plusieurs pays, notamment l'Australie, la Belgique, l'Allemagne, l'Italie et le Japon, réglementent l'importation et la vente de la salvia et de la salvinorine A.

Aux États-Unis, la salvia et la salvinorine A ne sont pas réglementées en vertu de la *Loi sur les substances contrôlées*, mais certains États ont adopté des mesures visant à en restreindre la vente et l'importation.

#### **Recherche sur l'utilisation de la *Salvia divinorum* au Canada**

L'Enquête de surveillance canadienne de la consommation d'alcool et de drogues révèle qu'en 2009, 1,6 % des Canadiens ont déclaré avoir consommé de la salvia au moins une fois et que la consommation est beaucoup plus élevée (7,3 %) chez les jeunes de 15 à 24 ans. L'Enquête canadienne 2008-2009 sur le tabagisme chez les jeunes montre que 5 % des jeunes de 15 ans avaient consommé de la salvia au cours de l'année précédente. Selon le Sondage 2009 sur la consommation de drogues et la santé des étudiants de l'Ontario, 5,4 % des étudiants ontariens de la 7<sup>e</sup> à la 12<sup>e</sup> année ont déclaré avoir déjà consommé de la salvia, et 4,4 % d'entre eux ont affirmé en avoir consommée au cours au cours de l'année précédente.

#### **Pour en savoir plus**

Pour savoir comment présenter une plainte concernant la vente non autorisée de produits de santé contenant de la salvia, veuillez consulter le document pertinent ci-dessous :

- Consommateurs : [http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_44\\_consumer\\_consommateur\\_cp-pc-fra.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_44_consumer_consommateur_cp-pc-fra.php)
- Industrie : [http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_38\\_trade-industrie\\_cp-pc-fra.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_38_trade-industrie_cp-pc-fra.php)

ou communiquer directement avec l'**Inspectorat de la Direction générale des produits de santé et des aliments**, en composant sans frais le 1-800-267-9675.

Pour signaler un effet indésirable ou une interaction mettant en cause un produit de santé, communiquez avec Santé Canada, au 1-866-234-2345 (sans frais au Canada), ou consultez la section *MedEffet Canada* dans le site [www.sante.gc.ca/medeffet](http://www.sante.gc.ca/medeffet)

Pour de plus amples informations sur le risque associé à l'utilisation de la salvia, veuillez consulter *Votre santé et vous* à (insérer le lien)



## NOTICE TO MEDIA

**February 19, 2011**

The Honourable Christian Paradis, Minister of Natural Resources make an announcement on behalf of the Honourable Leona Aglukkaq, Minister of Health, related to the health and safety of Canadians.

## AVIS AUX MÉDIAS

**Le 19 février 2011**

L'honorable Christian Paradis, ministre des Ressources naturelles, fera une annonce sur la santé et la sécurité des Canadiens, au nom de l'honorable Leona Aglukkaq, ministre de la Santé.

**Date**

February 21, 2011

**Date**

Le 21 février 2011

**Time**

TBC

**Heure**

TBC

**Location**

TBC

**Endroit**

TBC

### Media Inquiries

Health Canada  
(613) 957-2983

Jenny Van Alstyne  
Office of the Honourable Leona Aglukkaq  
Federal Minister of Health  
(613) 957-0200

### Renseignements aux médias

Santé Canada  
613-957-2983

Jenny Van Alstyne  
Cabinet de l'honorable Leona Aglukkaq  
Ministre fédéral de la Santé  
613-957-0200



# News Release

## Le gouvernement Harper prend des mesures pour protéger les familles

Le 21 février 2011

Pour diffusion immédiate

Fiche de renseignements : *Salvia divinorum* ([insert link](#))

**OTTAWA** – Aujourd’hui, la députée Shelly Glover (Saint-Boniface), Secrétaire parlementaire du ministre des Finances, et l’honorable Christian Paradis, ministre des Ressources naturelles, ont annoncé, au nom de l’honorable Leona Aglukkaq, ministre de la Santé, que le gouvernement Harper avait l’intention d’ajouter la *salvia divinorum* et la salvinorine A à la liste des substances contrôlées. Un Avis aux intéressés décrivant la proposition de Santé Canada a été publié dans la *Gazette du Canada*, Partie I, le 19 février 2011.

« En tant que mère et que policière, je suis heureuse que le gouvernement intervienne pour aider les parents à protéger leurs enfants contre cette substance dangereuse », a indiqué M<sup>me</sup> Glover.

« Après avoir pris connaissance des données de surveillance et des rapports scientifiques canadiens indiquant que certaines personnes, surtout les jeunes, pourraient abuser de la salvia, nous entendons protéger les Canadiens contre les effets dangereux de cette substance », a déclaré la ministre Paradis.

L’Avis aux intéressés propose d’ajouter la *salvia divinorum* et son principal ingrédient actif, la salvinorine A, à l’annexe III de la *Loi réglementant certaines drogues et autres substances*. Cela signifie que les activités comme la possession, le trafic, la possession en vue du trafic, l’importation, l’exportation, la possession en vue de l’exportation et la production (ou la culture) seraient illégales à moins d’être autorisées par réglementation. L’ajout de la *salvia divinorum* et de la salvinorine A à la liste des substances contrôlées permettrait aux organismes d’application de la loi de lutter contre les activités présumées illégales impliquant ces substances.

Les intervenants sont invités à faire parvenir leurs commentaires sur l’Avis aux intéressés d’ici le 14 mars 2011.

Pour de plus amples renseignements sur la salvia et les risques associés à son utilisation, veuillez consulter l'article de *Votre santé et vous* à : (insert link to the *It's Your Health* article.)

-30-

**Renseignements aux médias**

Santé Canada  
613-957-2983

*Also available in English*

Jenny Van Alstyne  
Cabinet de l'honorable Leona Aglukkaq  
Ministre fédérale de la Santé  
613-957-0200

**Renseignements au public**

613-957-2991  
1-866-225-0709

On peut consulter les communiqués de Santé Canada dans le site  
[www.santecanada.gc.ca/media](http://www.santecanada.gc.ca/media)



**Discours de  
l'honorable Christian Paradis,  
ministre des Ressources naturelles**

**Question : Proposition d'ajouter la *salvia divinorum* et la  
salvinorine A à l'annexe III de la *Loi réglementant  
certaines drogues et autres substances***

**Date : le 21 février 2011**

Seul le texte prononcé fait foi

Bonjour,

Je tiens à vous remercier de vous être joints à moi aujourd'hui pour ce que je considère une annonce très importante pour les familles canadiennes, annonce qui contribuera à la sécurité des collectivités.

Une substance connue sous le nom de salvia continue de gagner en popularité chez les jeunes, et certains d'entre eux en abusent.

Cette substance est populaire, car elle peut avoir les mêmes effets que certaines drogues illicites. Il y a aussi une fausse impression selon laquelle elle est sans danger.

Mais ce n'est pas le cas.

La salvia peut être très dangereuse.

Elle cause parfois des hallucinations et peut avoir d'autres effets néfastes sur le cerveau et l'organisme. À l'heure actuelle, les effets à long terme de cette substance sont peu connus.

L'Enquête de surveillance canadienne de la consommation d'alcool et de drogues de 2009 révèle qu'en 2009, 1,6 % des Canadiens de 15 ans et plus ont consommé de la *salvia divinorum* au moins une fois dans leur vie et que la consommation est beaucoup plus élevée (7,3 %) chez les jeunes de 15 à 24 ans.

De plus, les résultats de l'Enquête sur le tabagisme chez les jeunes 2008-2009, menée au Canada, révèlent que 5 % des jeunes de 15 ans ont consommé de la *salvia divinorum* au cours de l'année précédent l'enquête.

En raison des risques possibles pour la santé des Canadiens, en particulier celle des jeunes, nous proposons d'ajouter la *salvia divinorum*, et son principal ingrédient actif, la salvinorine A, à la *Loi réglementant certaines drogues et autres substances*.

Ces substances doivent être réglementées, tout comme les autres drogues illicites.



Dans un premier temps, un avis a été publié dans la *Gazette du Canada* au cours de la fin de semaine dernière, de sorte que tous les Canadiens disposent de 30 jours pour émettre leurs commentaires au sujet de notre proposition. Alors que nous consultons les Canadiens, notre position est claire. Nous voulons aider les parents, les familles et les collectivités à assurer la sécurité de nos enfants.

L'ajout de la *salvia divinorum* à la liste des substances contrôlées rendrait illégales les activités mettant en cause la salvia, comme la possession, le trafic, l'importation et la culture.

Ces mesures vont dans le sens de celles adoptés par d'autres pays, notamment l'Australie, la Belgique, l'Allemagne, l'Italie et le Japon, qui ont tous mis en place des contrôles semblables qui s'appliquent à l'importation ou à la vente de la *salvia*.

Le fait est que nos adolescents subissent déjà suffisamment de pression. Et, avec des histoires dans les médias de jeunes gens à Hollywood qui utilisent la salvia pour son effet euphorique, nous avons la responsabilité de faire ce qu'il faut pour protéger nos jeunes. Dans une économie aussi fragile que celle que nous connaissons présentement, les mères et les pères ne peuvent tout simplement pas se permettre de toujours surveiller ce que leurs jeunes font.

Ce que nous voulons, c'est aider ces parents.

Nous agissons rapidement dans ce dossier, parce que nous voulons protéger nos jeunes des méfaits associés à la salvia.

Nous voulons éliminer les idées fausses selon lesquelles la salvia est un substitut sécuritaire aux drogues de la rue.

Ce n'est pas le cas.

Toutes les mesures que nous prenons visent à protéger la santé et la sécurité des Canadiens des effets néfastes que peut avoir cette substance. Nous savons que les parents veulent que leurs enfants soient protégés contre les substances comme la salvia, surtout pendant leur adolescence.

C'est avec plaisir que je répondrai maintenant à vos questions.

Merci.

**Speech for  
The Honourable Christian Paradis,  
Minister of Natural Resources**

**Issue: Proposal to add Salvia Divinorum and Salvinorin  
A to Schedule III to the *Controlled Drugs and  
Substances Act*.**

**Date: February 21, 2011**

Check Against Delivery

Good Morning/Afternoon:

I'd like to thank you for joining me here today for what I consider to be a very important announcement for Canadian families and safer communities.

Among today's youth, a substance known as Salvia has been gaining popularity, and is being abused by some young people.

Its popularity comes from the fact that it can have some of the same effects as certain illicit drugs, and there is also a false perception that it is safe.

But it isn't safe.

Salvia has the real potential to be harmful.

It can cause hallucinations and can have other serious effects on the brain and body. At this point, very little is known about the long-term effect of this substance.

Results from the *Canadian Alcohol and Drug Use Monitoring Survey* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *S. divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24.

And, the results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *S. divinorum* in the past year.

Because of the potential risks to the health of Canadians, particularly young people, we are proposing to add *Salvia divinorum*, and its main active ingredient salvinorin A, to the *Controlled Drugs and Substances Act*.

These substances should be controlled, just like other illicit drugs.

As a first step, a notice was published in the *Canada Gazette* on this past weekend. That started a process during which all Canadians will have a 30-day period to comment on our proposal. While we are

consulting with Canadians, our position is clear. We want to help parents, families and communities to keep our kids safe.

Adding *salvia divinorum* to the list of controlled drugs and substances would make activities with *salvia*, such as possession, trafficking, importing or cultivating illegal.

And, these measures are in line with other countries, including but not limited to Australia, Belgium, Germany, Italy and Japan. All of these countries have placed similar controls on the import and/or sale of *salvia*.

The bottom line is that our teens face enough pressure already. And with heavily covered stories of young Hollywood using this *salvia* to get high, we have the responsibility to help protect our youth. In a fragile economy like this, Moms and Dads literally can't afford to always keep watch of what's happening.

We want to help Mom and Dad.

We're acting quickly on this because we want to protect our young people from the harms associated with *Salvia*.

We want to eliminate the misconceptions that *Salvia* is a safe alternative to street drugs.

It is not.

All of the steps we are taking are designed to protect the health and safety of Canadians from the potentially harmful effects of this substance. We know that parents want their children to be protected from substances like *Salvia*, particularly when they are in their teenage years.

I would now be happy to take your questions.

Thank you.

Hello,

The stakeholder list below has been MO approved.

HeCSB- please contact all stakeholders to advise them of this announcement.

Also please advise mbu by 10AM monday morning, which stakeholders will issue a positive news release.

Thank you,

Meghan Lax

----- Original Message -----

**From:** Sandra Rose Roy

**Sent:** 2011-02-17 05:05 PM EST

**To:** Jesse Arnup-Blondin; HECSB\_Action Request\_48h

**Cc:** Lisa Whittleton; Christine Gillis; Christine Shea; Diane Laplante;  
HECSB\_Briefing; Ian Hobler; Joan Kennedy; Jonathan Loan; Meghan Lax; Natalie  
Racine; PACCB-ADMO; Sarah-Emily Carle

**Subject:** Re: URGENT AR 11-103679-138 Ministerial Annoucements on Salvia  
- February 21

Thank you Jesse, Lisa left for the day, but she meant to say Friday, February 18, for the BF date.

Merci.

Sandra Rose Roy  
Briefing Analyst / Analyste de l'information  
Ministerial Invitations ministérielles  
Ministerial Briefing Unit / Unité d'information ministérielle  
DMO / CSM  
Health Canada/Santé Canada  
Tel.: (613) 948-5889  
Fax: (613) 952-3679

From: Jesse Arnup-Blondin/HC-SC/GC/CA

To: Lisa Whittleton/HC-SC/GC/CA@HWC

Cc: Christine Gillis/HC-SC/GC/CA@HWC, Christine Shea/HC-SC/GC/CA@HWC, Diane Laplante/HC-SC/GC/CA@HWC,  
HECSB\_Briefing, Ian Hobler/HC-SC/GC/CA@HWC, Joan Kennedy/HC-SC/GC/CA@HWC, Jonathan Loan/HC-SC/GC/CA@HWC,

000047

Meghan Lax/HC-SC/GC/CA@HWC, Natalie Racine/HC-SC/GC/CA@HWC, PACCB-ADMO, Sandra Rose  
Roy/HC-SC/GC/CA@HWC, Sarah-Emily Carle/HC-SC/GC/CA@HWC, HECSB\_Action Request\_48h

Date: 2011-02-17 04:55 PM

Subject: Re: URGENT AR 11-103679-138 Ministerial Annoucements on Salvia - February 21

Hi Lisa -

There is no template attached to this email. As well, the deadline given for the Stakeholder list is in  
January. Can you please clarify.

This request should be sent to HECSB\_Action Request\_48h, rather than HECSB\_Briefing.

Thank you,

Jesse

From: Lisa Whittleton/HC-SC/GC/CA

To: HECSB\_Briefing, Natalie Racine/HC-SC/GC/CA@HWC, PACCB-ADMO

Cc: Joan Kennedy/HC-SC/GC/CA@HWC, Jonathan Loan/HC-SC/GC/CA@HWC, Diane Laplante/HC-SC/GC/CA@HWC, Ian  
Hobler/HC-SC/GC/CA@HWC, Sarah-Emily Carle/HC-SC/GC/CA@HWC, Christine Gillis/HC-SC/GC/CA@HWC, Meghan  
Lax/HC-SC/GC/CA@HWC, Sandra Rose Roy/HC-SC/GC/CA@HWC, Christine Shea/HC-SC/GC/CA@HWC

Date: 2011-02-17 04:46 PM

Subject: URGENT AR 11-103679-138 Ministerial Annoucements on Salvia - February 21

Good morning,

Please see the action request appended below.

Thank you.

---

Lisa Whittleton  
Briefing Analyst | Analyste de l'information  
Ministerial Briefing Unit (MBU) | Unité d'information Ministérielle (UIM)  
Departmental Secretariat | Secrétariat du ministère  
Deputy Minister's Office | Cabinet du sous-ministre  
Health Canada | Santé Canada  
Phone | Téléphone: (613) 954-1637

----- Forwarded by Lisa Whittleton/HC-SC/GC/CA on 2011-02-17 04:45 PM -----

Status: Open/Ouvert

000048

**ACTION REQUEST - DEMANDE D'ACTION**

<b>REQUESTOR'S NAME - NOM DU DEMANDEUR</b> Lisa Whittleton	<b>DATE</b> 2011-02-17	<b>NUMBER - NUMÉRO</b> 11-103679-138
---	---------------------------	---

**REQUEST ORIGIN - ORIGINE DE LA DEMANDE**

**SUBJECT - OBJET**

Tim Vail  
  
Salvia Announcements

**REQUEST - DEMANDE (YYYY-MM-DD)**

**(1)Date:** 2011-02-17

There will be two concurrent Announcements on Salvia taking place on Monday, February 21, 2011 in Quebec and in Manitoba (location and time TBC).

MO Requested Products for Binder Development:

Tasked to COMMS:

- MEP
- Scenario Note
- Speech
- Media advisory
- Press release
- Media lines with Q&As
- Fact sheet

\*\* All products requested in both official languages \*\*

Tasked to Programs (HECSB LEAD with HPFB input):

-Stakeholder list - MO is interested in having non-government stakeholders such as parental groups etc. that would support this announcement present at each location. Once MO has approved the stakeholder list, program branch will be responsible for contacting the stakeholders.

\*Please use the template below and flag interested/supportive stakeholders as well as those who may be willing to issue a positive news release or have media availability. Please also flag any stakeholders who may have a negative response to the Announcement.

\*\*DEADLINE FOR ALL PRODUCTS TASKED TO COMMS WILL BE COMMUNICATED BY DGO COMMS \*\*

\*\*STAKEHOLDER LIST IS DUE IN MBU ON FRIDAY, JANUARY 12 FEBRUARY 18 AT NOON FOR MO APPROVAL \*\*

**(2)Date:**

**(3)Date:**

<b>REQUIRED ON - REQUIS LE</b> Date: 2011-02-18	<b>AT - À</b> Time: 12:00 PM
--	---------------------------------

<b>DEPARTMENTAL CONTACT - AGENT DE LIAISON DU MINISTÈRE</b> Lisa Whittleton	<b>TELEPHONE NUMBER - NUMÉRO DE TÉLÉPHONE</b> 954-1637
--	---





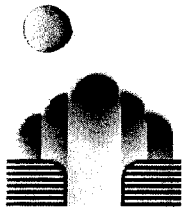
EDMS - 80653 - 1 - SALVIA ANNOUNCEMENT - STAKEHOLDER LIST.DOC

**Stakeholder List – Salvia Announcement**

Stakeholder	Positive or Negative?	Interested in Event?	Willing to Issue News Release	Willing to have Media Availability
Centre of Excellence for Youth Engagement [Redacted]	Expected to be positive	Unknown	Unknown	Unknown
Canadian Association for School Health [Redacted]	Expected to be positive	Unknown	Unknown	Unknown
Media Awareness Network [Redacted]	Expected to be positive	Unknown	Unknown	Unknown
Canadian Association of Family Resource Programs [Redacted]	Expected to be positive	Unknown	Unknown	Unknown

s.19(1)

Stakeholder	Positive or Negative?	Interested in Event?	Willing to Issue News Release	Willing to have Media Availability
Drug Prevention Network of Canada (past President)	Expected to be positive	Unknown	Unknown	Unknown
Royal Canadian Mounted Police (RCMP) Eric Slinn, Superintendent 613-949-4265 <a href="mailto:Eric.slinn@rcmp-grc.gc.ca">Eric.slinn@rcmp-grc.gc.ca</a>	Expected to be positive	Unknown	Unknown	Unknown
Canadian Centre on Substance Abuse	Expected to be positive	Unknown	Unknown	Unknown
Canada Border Services Agency (CBSA) Bente Baklid Director, Program Evaluation Division 613-954-7280 <a href="mailto:Bente.baklid@cbsa-asfc.gc.ca">Bente.baklid@cbsa-asfc.gc.ca</a>	Expected to be positive	Unknown	Unknown	Unknown



Jocelyn Kula/HC-SC/GC/CA

2009-01-02 09:28 AM

To Cheryl Tremblay/HC-SC/GC/CA@HWC

cc

bcc

Subject Fw: Top 5 Recreational Drug Experiments-Salvia

Ronald sent me this, and I wonder if you can confirm that the Neuropharmacology paper mentioned below is one we have in our files; just means we perhaps have to be less equivocal with respect to mechanism of action now, i.e., not sure what our media lines say but I thought we had something in there about not being sure how salvia works??

pls follow up and change lines if necessary- now is the time given that they are still in approvals.....

will also be important for IAS

JK

---

Jocelyn Kula  
Manager, Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Healthy Environments and Consumer Safety Branch  
Health Canada

Tel: (613) 946-0125 Fax: (613) 946-4224

----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2009-01-02 09:26 AM -----



Ronald  
Denault/HC-SC/GC/CA

2008-12-31 01:34 PM

To Jocelyn Kula/HC-SC/GC/CA

cc

Subject Top 5 Recreational Drug Experiments-Salvia

<http://blog.wired.com/wiredscience/2008/04/top-5-recreatio.html#previouspost>

Check #3

Ronald

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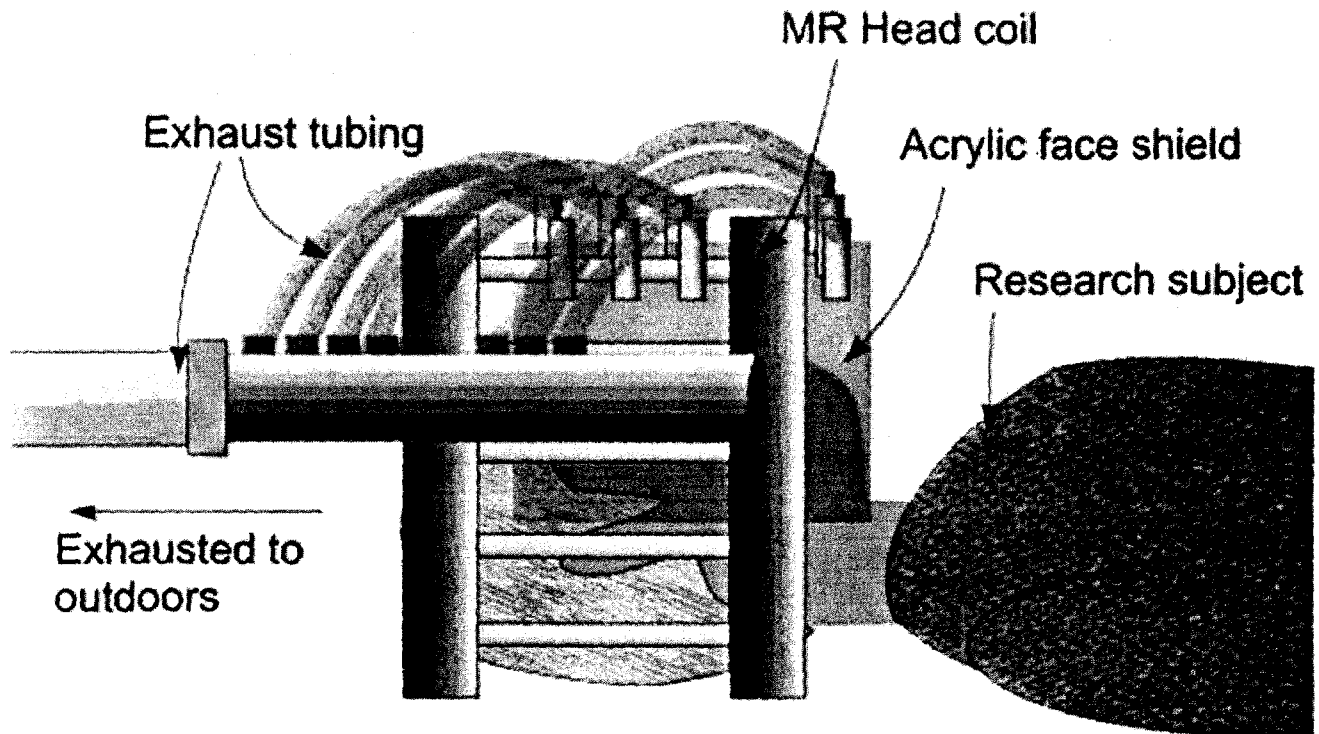
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« Europeans Show Off Possibly Useful, Definitely Bizarre Inventions | Main | Seeds of Life Came From Space »

# Top 5 Recreational Drug Experiments

By Aaron Rowe  April 05, 2008 | 11:46:38 AM Categories: Chem Lab, Drugs & Alcohol, Neuroscience



Recreational drugs are a ridiculously fun topic for scientific research. They could also be the inspiration for powerful new medications. We are often amazed by the fascinating, and sometimes hilarious, stories that make their way into peer-reviewed journals. Here are some of our very favorites:

## 5. Harvard Scientists Build a Device to Smoke Weed During a Brain Scan

To better understand addiction, and how to treat it, scientists need to get a better look at the human brain as it is under the influence of weed. Unfortunately, smoking weed inside the narrow chamber of a functional MRI is not easy. To prevent smoke damage and allow their research subjects to puff without

moving around too much, Blaise Frederick and his team at Harvard built what amounts to a giant bong

#### 4. Stanford Chemists make THC from Scratch

Since 1965, chemists have been trying to make the active ingredient of marijuana [pdf]from scratch. Back then, the researchers could only make tetrahydrocannabinol along with its enantiomers -- impurities that have the same chemical composition, but a different shape. Then, in 2006, a pair of chemists from Stanford University used a Molybdenum catalyst and other sophisticated techniques to produce the coveted molecule in its pure form. Despite their discovery, mother nature is still the best chemist and closets with high-intensity lamps will outperform the most sophisticated laboratories.

#### 3. Researchers Learn How Salvia Works

Diviner's sage contains a powerful hallucinogen that may someday inspire a new class of depression, pain, and addiction medications. In at least one instance, a woman has used the substance to rid herself of depression. Tests on animals have shown that the Oxaccan plant, a relative of the culinary herb, can also control pain.

Last year, Catherine Willmore and her colleagues at Ohio Northern University ended a controversy about how the drug works. In the Sep. 2007 issue of *Neuropharmacology*, she confirmed that the active chemical, Salvinorin A, binds to signal-carrying proteins called kappa opioid receptors.

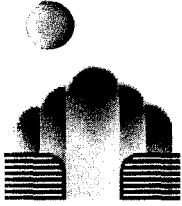
Willmore and her team trained rats to recognize the sensations caused by a well-understood drug that also targets kappa opioid receptors. It is impossible to know exactly how the rats felt during the test, but they could not tell the difference between the active chemical in sage and the one they had been trained to identify. Since the drugs feel the same, both of them must activate the same target.

#### 2. British Army Tests LSD on Soldiers



#### 1. Researchers Combine Chemicals from Sea Urchin Eggs and Weed to Make Powerful Painkillers

Scientists at organix, a small research and development firm, made hybrid molecules which resemble the euphoria-causing compounds THC and anandamide. In the Dec. 2007 issue of *Bioorganic and Medicinal*



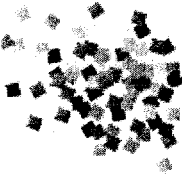
Jocelyn Kula/HC-SC/GC/CA  
2009-01-02 09:59 AM

To Cheryl Tremblay/HC-SC/GC/CA@HWC  
cc Jasmin Kragtwyk/HC-SC/GC/CA@HWC  
bcc  
Subject Fw: It's Your Health - article template

for salvia file as predates our conversation with the writer....  
Jasmin- pls print for my salvia file too

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Jocelyn Kula  
Manager, Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Healthy Environments and Consumer Safety Branch  
Health Canada  
Tel: (613) 946-0125 Fax: (613) 946-4224  
---- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2009-01-02 09:58 AM ----



Lisa Holmes/HC-SC/GC/CA  
2008-10-20 03:12 PM

To Jocelyn Kula/HC-SC/GC/CA@HWC  
cc Stephanie Mitchell/HC-SC/GC/CA@HWC  
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Proposed Article Template - IYH for Salvia-D.wpd

Many thanks,  
Lisa

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Lisa Holmes  
Senior Communications Advisor | Conseillère principale en communications  
PACRB | DGAPCR  
Strategic Communications Directorate | Direction des communications stratégiques  
Health Canada | Santé Canada  
T: (613) 957-3431  
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**Author and Date of Proposal** - *Lisa Holmes - October 17, 2008*

**Proposed Title** - *Salvia divinorum*

**The Issue** - *Salvia Divinorum is a species of sage which belongs to the mint family. It is found in the form of dried leaves, extract and plant cuttings. Salvia Divinorum, also known as "diviner's sage" and/or "magic mint", is chewed or smoked and can induce illusions and hallucinations.*

*Salvia Divinorum continues to attract moderate media attention. It will be beneficial to have an It's Your Health article available on the internet so that the general public can be better informed about the issue, and so that reporters can refer to this article, should they have questions about the issue.*

**Health Canada's Role** - *There are no regulations or laws prohibiting the possession, use or sale of Salvia divinorum in Canada. While many countries across the globe have prohibited Salvia, it remains legal in Canada. Health Canada is currently exploring our options for prohibiting Salvia in Canada.*

**Why is this article needed and why It's Your Health ?-** *The target audience is the general public. It's Your Health is a good vehicle to use to inform individuals about Salvia because the articles are written in plain language and are easily understood by the vast majority of Canadians.*

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Blossom Leung

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Louise McCoy

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Eleanor Cameron

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Caroline Hares

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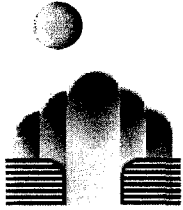
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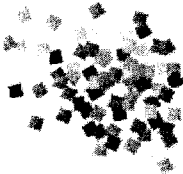
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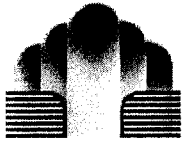
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Proposed Article: IYH Salvia-D  
2008-11-27

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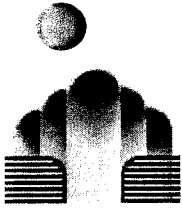
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Jocelyn Kula/HC-SC/GC/CA  
2009-01-05 09:31 AM

To Cheryl Tremblay/HC-SC/GC/CA@HWC  
cc  
bcc  
Subject Fw: FYI: Salvia divinorum.doc

thought maybe you should save the e-copy of this somewhere- paper from RCMP on salvia that we talked to Doug about

---

Jocelyn Kula  
Manager, Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Healthy Environments and Consumer Safety Branch  
Health Canada  
Tel: (613) 946-0125 Fax: (613) 946-4224

----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2009-01-04 05:33 PM -----

Nathan  
Lockhart/HC-SC/GC/CA  
2008-07-31 04:25 PM

To Jocelyn Kula/HC-SC/GC/CA@HWC  
cc  
Subject FYI: Salvia divinorum.doc

See email below from Michel. Apparently his colleague, Doug, prepared the attachment.

Nathan  
613-948-2158

----- Forwarded by Nathan Lockhart/HC-SC/GC/CA on 2008-07-31 04:24 PM -----



"Michel Pelletier"  
<Michel.Pelletier@rcmp-grc.gc.ca>  
2008-07-31 03:57 PM

To <Nathan\_Lockhart@hc-sc.gc.ca>  
cc "Liam Gerofsky" <Liam.Gerofsky@rcmp-grc.gc.ca>  
Subject Fwd: Salvia divinorum.doc

Nathan, this is what Sgt. Doug Culver our Clan Lab National Coord. provided for this substance but would also appreciate Health Canada' official stance so that our Division Drugs & Organized Crime Awareness Service Coordinators can provide their communities with appropriate News Release.

Latest, to ask for this information is Whitehorse, Yukon where this is being sold in the stores.

Michel Pelletier, S/Sgt.  
National Coordinator  
Drugs and Organized Crime Awareness Service  
Tel: (613) 993-2501  
E-mail: Michel.Pelletier@rcmp-grc.gc.ca

Date: Thu, 31 Jul 2008 14:48:04 -0400  
From: "Doug Culver" <Douglas.Culver@rcmp-grc.gc.ca>  
To: "Michel Pelletier" <Michel.Pelletier@rcmp-grc.gc.ca>  
Subject: Salvia divinorum.doc

Content-Type: multipart/mixed; boundary="=\_Part4E6799F4.1\_="

Mime-Version: 1.0

There is no action by HC to control this substance at the present time.

D

Doug W. CULVER  
National Coordinator  
Synthetic Drug Operations  
Drugs and Organized Crime  
Fed. & Int. Ser., HQ  
Office (613) 993 8241  
Fax (613) 993 5454  
Cell. (613) 859 1252



- Salvia divinorum.doc

# *Salvia divinorum*

## INFORMATION CONCERNING THE PLANT AND ITS ACTIVE PRINCIPLES

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Scheduling Issues .....	4
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### EXECUTIVE SUMMARY

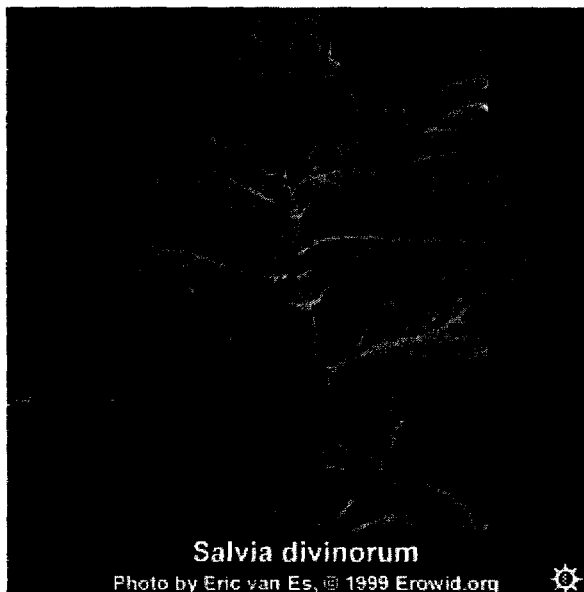
The plant *Salvia divinorum* was virtually unknown to North Americans until recently. A New York Times article (Jones 2001) created a spike of interest in the plant as a legal hallucinogen along with internet sites such as [www.erowid.org](http://www.erowid.org). There has been a resurgence of public interest in ethnobotanical hallucinogens that are yet to be scheduled under the Controlled Drugs and Substances Act. Studies indicate that *S. divinorum* and/or its active principle may have "significant research and therapeutic potential in fields such as psychopharmacology, psychiatry and complementary disciplines such as herbal medicine" (Hanes 2001). Because its abuse potential is low and its medical potential significant, placement of *S. divinorum* or its active principle, salvinorin A, in a Schedule of the Controlled Drugs and Substances Act is currently unwarranted.

### BACKGROUND

Global flora is rife with species exhibiting psychoactive properties. A recent survey listed 250 plants that naturally produce either controlled drugs and/or substances (Ott 1993), and the overall number of psychoactive plant species is undoubtedly much larger. One among a multitude of lesser known psychoactive plants is *Salvia divinorum*, a plant native to the Sierra Mazateca in Mexico, and first introduced to the United States in 1962 (Hofmann 1990, Wasson 1962). *Salvia divinorum* is a member of the Labiatae or Mint family, one of the largest families of angiosperms, which includes many ornamental, culinary and medicinal herbs in common use throughout the world. Close relatives include the spices basil, mint (*Mentha*), common sage (*Salvia officianalis*), rosemary and thyme. This family is also a rich source of essential oils, including isomenthone, isopinocampnone, carvone, menthol, and methyl acetate. Many related species have been valued throughout history by the Assyrians, Babylonians, Chinese, Arabs, Greeks and Romans for their medicinal properties. These species are still utilized in this capacity by indigenous cultures around the globe, including Native Mexicans. As its name reflects, *Salvia divinorum* (translation: "Diviner's Sage" or "Sage of Seers") is traditionally employed by the Mazatec Indians in medico- magical- divination ceremonies (Epling & Játiva 1962). To the Mazatec, *S. divinorum* provides numerous therapeutic applications. Infusions of the plant are administered in a ceremonial context and are used for a variety of complaints, including diarrhea, headache, rheumatism and anemia. Mazatec shamans use *S. divinorum* as a vision inducing plant. They say it "allows them to travel to heaven and talk to God and the Saints about divination, diagnosis, and healing" (Rovinsky & Civadlo 1998).

### DESCRIPTION, COMPOSITION & EFFECTS

*Salvia divinorum* is also known, in Mazatec, as Ska Pastora or Ska María Pastora, meaning "Leaves of the Shepherdess" or "Leaves of Mary the Shepherdess." In Náhuatl it is named Pipiltzintzintli, and in Spanish, la Hembra or Hojas de Pastora. In English, it is commonly referred to as Magic Mint, or more properly by its direct translation from Latin, "Diviner's Sage" or "Seer's Sage." The plant is a sprawling perennial herb with flowering stems growing two or even three meters tall. This plant has never been observed to set seed in the wild, and can be found to flower, from May to September, in white with a light blue tinge.



#### AVAILABILITY & ABUSE POTENTIAL

*Salvia divinorum* is endemic only to the Mazatec zone of the Sierra Madre Oriental, in the Mexican state of Oaxaca. It is propagated vegetatively, and because the only specimens observed in its native habitat were known to be planted by Mazatecs, it is assumed by most to be a cultigen. Cultivation in more northern latitudes has been accomplished, but it is difficult, demanding a high degree of technical skill. The plant requires rich soil and abundant moisture, tolerating sun only if soil moisture remains high and humidity is sustained. Numerous Internet sites provide descriptions of *S. divinorum* and its mind altering powers. Some of the sites accentuate the unpleasant and antisocial effects of using *S. divinorum*, while others describe the "spiritual dimension" of its traditional use. Some Internet sites are used to post information about its cultivation and use, and a few herbalists conduct business online selling cuttings and leaf. Interestingly, many Internet postings recounting personal experiences include stern warnings regarding the plant's potentially disturbing psychoactive effects.

Accounts of serious medical consequences or statistics on emergency visits related to use of the plant or chemical are virtually nonexistent. No citations were uncovered in a search of the Morbidity and Mortality Weekly Report. The Toxic Exposure Surveillance System (TESS) maintained by the American Association of Poison Control Centers has no reports of *S. divinorum* specific poisonings. (Litovitz 2000). No cases of dependency on *S. divinorum* or salvinorin A are reported in the literature. Aside from rare reports of pervasive anxiety associated "bad" experiences with their usage, no cases of psychotic deterioration or other medical complications are known. Any danger from the use of the plant or chemical arises from anxiety reactions, or the possibility of accidents secondary to users ambulating or pursuing other activities while visually impaired. Anxiety reactions are generally self-limited due to the brief duration of effects, and respond to quiet reassurance. Additionally, extraneous noise or even opening the eyes may totally terminate the psychoactive effects. Unlike other dissociative plant agents subject to occasional recreational use, such as *Brugmansia* spp. (Angel's Trumpet) or *Ipomoea* spp. (Morning Glory), *Salvia divinorum* and its active ingredient salvinorin A are short acting and lack any known tissue toxicity, gastrointestinal or cardiovascular sequelae.

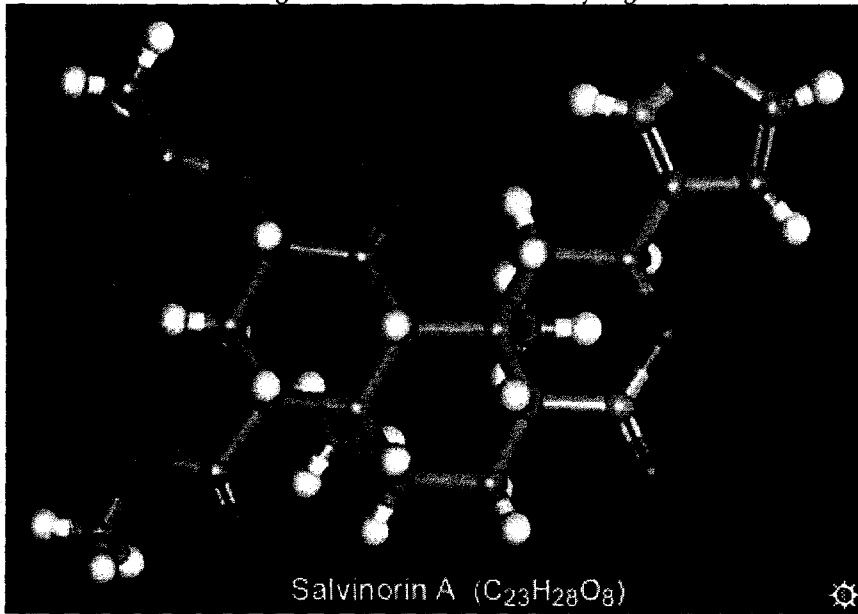
## ACTUAL & POTENTIAL MEDICAL USE

For centuries, the Mazatec Indians have used the plant *Salvia divinorum* in healing ceremonies, gaining relief from anaemia, headache, and rheumatism (Valdés 1983). Until very recently, the precise neurotransmitter receptors used by salvinorin A were unknown, despite a battery of NovaScreen® tests. However, in Fall 2002 a team of researchers published their findings that Salvinorin A is a potent kappa opioid receptor agonist (Roth 2002). The researchers noted that salvinorin A's affinity for kappa opioid receptors was surprising and that this held promise for developing entirely new psychiatric medicines: Salvinorin A thus represents, to our knowledge, the first naturally occurring nonnitrogenous opioid- receptor subtype selective agonist. Kappa opioid receptor interactions produce spina analgesia, sedation, miosis, diuresis, mild respiratory depression, and low addiction liability. Because Salvinorin A is a psychotomimetic selective for kappa opioid receptors, kappa opioid- selective antagonists may represent novel psychotherapeutic compounds for diseases manifested by perceptual distortions (e.g., schizophrenia, dementia, and bipolar disorders) (Roth 2002). An article in the Journal of Clinical Psychopharmacology reported on "Ms. G" a 26- year- old woman with a history of unrelenting depression, who eventually found relief in *Salvia divinorum*. Having found that other medications failed to provide satisfactory relief, Ms. G self-medicated with an oral dose of *Salvia divinorum* leaves three times per week. As a result of her use of *Salvia divinorum*, "she has continued to show a total remission of her symptoms of depression and has maintained this improvement for the last 6 months, showing no signs of relapse and reporting only minimal side effects, such as occasional lightheadedness for up to 1 hour after using the herb" (Hanes 2001). The author of the Case Report concluded .it is not inconceivable that research using the active ingredients from this herb may pinpoint a unique mechanism of antidepressant action for these compounds. This, in turn, could lead to methods for the management of depression or of treatment resistant subtypes of this condition. . We may be dealing with a highly novel agent that has significant research and therapeutic potential in fields such as psychopharmacology, psychiatry and complementary disciplines such as herbal medicine" (Hanes 2001).

Despite its availability to science over the last few decades, investigation and use of *S. divinorum* or its primary psychoactive substance, salvinorin A (a diterpenoid agent devoid of nitrogen), remain quite limited. Salvinorin A is a complex molecule made up of some 59 molecules in its structure. Examination of the PubMed database of the National Library of Medicine results in only five citations (Giroud 2000, Valdés 1994, Siebert 1994, Valdés 1986, and Valdés 1983). There are several reasons why so little information about either *S. divinorum* or salvinorin A exists in the medical literature. Firstly, until August 2002, the precise neurotransmitter receptors with an affinity for salvinorin A were unknown. In August 2002, however, a team of researchers published their findings that salvinorin A binds to kappa opioid receptors. (Roth 2002). Secondly, cultivation of *S. divinorum* is relatively exacting, and commerce in the plant is presently limited. Thirdly, the plant and chemical seem to have little innate toxicity. Animal studies stimulate decreases in movements without sedation (Valdés 1994). Administration of huge doses of salvinorin A to rats produced no observable subsequent sequelae on behavior (Valdés 1987). More importantly, *S. divinorum* is uniformly acknowledged as a difficult agent to employ, with a steep "learning curve." It is virtually inactive orally because salvinorin A is insoluble in water. The intense bitterness of the leaves is a hindrance to many, while smoking the leaves requires rapid inhalation of large volumes of smoke. The plant's psychoactive effects are inconsistent and fleeting. Even the isolated chemical is associated with very transient effects in humans. Few consider the psychoactive effects pleasurable, and most people choose not to repeat the experience after one exposure. Many describe the appearance of geometric shapes in the vision, while at higher doses, a brief dissociative effect, "out- of- body experience," or true hallucination may be produced.

### SCHEDULING ISSUES

*Salvia divinorum* is not scheduled under the Controlled Drugs and Substances Act, nor is it controlled under any regulations. Its active principle, salvinorin A, is likewise unscheduled under Federal law. The diterpene that is responsible for the action of the plant is totally dissimilar from any other scheduled drug or substance. Salvinorin A's chemical structure appears to be unique among other psychoactive molecules, and among existing controlled substances (Valdés 1994). Because it is not "substantially similar" in chemical structure to an existing controlled substance, salvinorin A can not be classified as an analogue under the CDSA or any regulations.



### SUMMARY & RECOMMENDATIONS

*Salvia divinorum* is a psychoactive plant, which until recently remained unknown to all but a specialized division of ethnobotanists. The plant's bitter taste, unpredictable and occasionally disturbing short term psychoactive effects, combined with exacting cultivation parameters; make it an unlikely candidate for widespread use. While news coverage periodically produces a spike of interest in the plant as a "legal hallucinogen," use of the plant is not expected to ever reach the level experienced with other illegal drugs. Neither *S. divinorum* nor salvinorin A have a "high potential for abuse," and recent scientific studies, supported by ethnobotanical data, strongly suggest possible therapeutic applications. Accordingly, neither the plant nor its active principle, are appropriate candidates for placement in the CDSA. Monitoring of abuse patterns should continue, however, education aimed at raising awareness of the plant's unpredictable and occasionally upsetting psychoactive effects, rather than criminal prohibition, is key to reducing individual and social harm with respect to *Salvia divinorum* and its active component.

In order to place *S. divinorum* or salvinorin A in a schedule of the Controlled Drugs and Substances Act, several criteria must be satisfied. The CDSA provides a legislative framework for the control of substances that can alter mental processes and that may produce harm to the health of an individual and to society when diverted or misused. In determining whether a substance should be added to the CDSA, and into which schedule, HC considers several factors including: (1) international requirements regarding the control of the substance; (2) dependence potential and likelihood of abuse/misuse of the substance; (3) extent of actual abuse/misuse in Canada and elsewhere; (4) danger the substance represents to the safety of the public; (5) usefulness of the substance as a therapeutic agent; (6) industrial and commercial usefulness; and (7) chemical similarity with

substances currently scheduled in the CDSA. *Salvia divinorum* remains un-scheduled in many countries including the United States and the United Kingdom. Placement of the plant or chemical in the CDSA cannot be scientifically justified. The plant and chemical have minimal abuse potential and no addictive potential. Recent studies published in scientific journals have emphasized that further studies with salvinorin A and/or *S. divinorum* may lead to the development of "novel psychotherapeutic compounds" (Roth 2002) with "significant research and therapeutic potential in fields such as psychopharmacology, psychiatry and complementary disciplines such as herbal medicine" (Hanes 2001). These findings are supported by ethnobotanical data. Available data supports the safety of using *S. divinorum* or salvinorin A under medical supervision. CDSA status for salvinorin A or its parent plant could inhibit scientific research that has the potential to understand novel neurotransmitter systems of great importance to neuropharmacological research and the treatment of disease.

Doug Culver, Sgt.  
R.C.M.Police

Primary Authors:  
Richard Glen Boire, J. D.  
Ethan Russo, M. D.  
Adam Richard Fish  
Jake Bowman

#### BIBLIOGRAPHY

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Giroud, C., et al . 2000. *Salvia divinorum* : a hallucinogenic mint which might become a new recreational drug in Switzerland. Forensic Sci Int 112( 2- 3): 143- 50.

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Valdés III, L. J. et al. 1983. Ethnopharmacology of Ska María Pastora (*Salvia divinorum*, Epling and Játiva- M.). *J Ethnopharmacol* 7 (3): 287- 312.

Wasson, R. G. 1962. A new Mexican psychotropic drug from the mint family, *Botanical Museum Leaflets Harvard University* 20 (3): 77- 84.

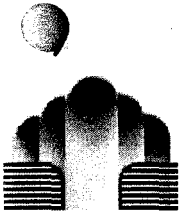
#### SOURCES FOR MORE INFORMATION

Toxic Exposure Surveillance System (TESS)  
American Association of Poison Control Centers  
Telephone: (202) 362- 7217  
E- mail: [aapcc@poison.org](mailto:aapcc@poison.org)  
Web site: [www.aapcc.org/poison1.htm](http://www.aapcc.org/poison1.htm)

PubMed (National Library of Medicine)  
Web site: <http://www4.ncbi.nlm.nih.gov/PubMed/>

Medical Use & Abuse Potential  
Ethan Russo, M. D.  
Montana Neurobehavioral Specialists  
Telephone: (406) 327- 3372  
E- mail: [erusso@blackfoot.net](mailto:erusso@blackfoot.net)

Law & Public Policy  
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Jocelyn Kula/HC-SC/GC/CA  
2009-01-29 09:37 AM

To Cheryl Tremblay/HC-SC/GC/CA@HWC  
cc  
bcc  
Subject Fw: It's Your Health article on Salvia divinorum

---

Jocelyn Kula  
Manager, Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Healthy Environments and Consumer Safety Branch  
Health Canada  
Tel: (613) 946-0125 Fax: (613) 946-4224

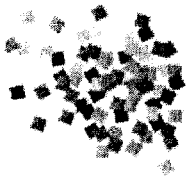
----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2009-01-29 09:37 AM -----

Stephanie  
Szick/HC-SC/GC/CA  
2009-01-29 09:21 AM

To Jocelyn Kula/HC-SC/GC/CA@HWC  
cc  
Subject Fw: It's Your Health article on Salvia divinorum

FYI -

----- Forwarded by Stephanie Szick/HC-SC/GC/CA on 2009-01-29 09:21 AM -----



Lisa Holmes/HC-SC/GC/CA  
2009-01-29 09:18 AM

To Ray Edwards/HC-SC/GC/CA@HWC, Andrew  
Adams/HC-SC/GC/CA@HWC, Pamela  
Arnott/HC-SC/GC/CA@HWC, Stephanie  
Szick/HC-SC/GC/CA@HWC  
cc Paula Robert/HC-SC/GC/CA@HWC,  
stephanie\_mitchell@hc-sc.gc.ca  
Subject Fw: It's Your Health article on Salvia divinorum

Good news - looks like the first draft of the Salvia It's Your Health will be ready to circulate next week!


---

Lisa Holmes  
Senior Communications Advisor | Conseillère principale en communications  
PACRB | DGAPCR  
Strategic Communications Directorate | Direction des communications stratégiques  
Health Canada | Santé Canada  
T: (613) 957-3431  
F: (613) 948-8085  
C: (613) 601-0215

----- Forwarded by Lisa Holmes/HC-SC/GC/CA on 2009-01-29 09:15 AM -----

Lisa MacKay/HC-SC/GC/CA  
2009-01-28 11:44 AM

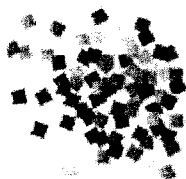
To Lisa Holmes/HC-SC/GC/CA@HWC

cc Darrin Denne/HC-SC/GC/CA@HWC,  
stephanie\_mitchell@hc-sc.gc.ca  
Subject Re: Fw: It's Your Health article on Salvia divinorum 

Hello all,


s.19(1) Sue was waiting to hear back from Darrin regarding Shahid but apparently Shahid is now gone on leave so I've told her to proceed. She should have a draft to start passing around for comment by early next week.

Lisa  
Lisa Holmes/HC-SC/GC/CA



Lisa Holmes/HC-SC/GC/CA

2009-01-28 10:18 AM

To Darrin Denne/HC-SC/GC/CA@HWC  
cc Lisa MacKay/HC-SC/GC/CA@HWC,  
stephanie\_mitchell@hc-sc.gc.ca  
Subject Re: Fw: It's Your Health article on Salvia divinorum 

Hi Darrin,

Has Sue Lumsden touched base with you? Just checking in to make sure we are moving forward with the IYH. I know the the Drug Strategy group here is very anxious to move forward with this...

Please let me know.

Thanks,  
Lisa


---

Lisa Holmes  
Senior Communications Advisor | Conseillère principale en communications  
PACRB | DGAPCR  
Strategic Communications Directorate | Direction des communications stratégiques  
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Darrin Denne/HC-SC/GC/CA



Darrin Denne/HC-SC/GC/CA

2008-12-02 03:34 PM

To Lisa Holmes/HC-SC/GC/CA@HWC  
cc Lisa MacKay/HC-SC/GC/CA@HWC  
Subject Re: Fw: It's Your Health article on Salvia divinorum 

No they didn't, but I'm not surprised at their input. This has cropped up in relation to a couple of other risk communications over the years. I always counter by saying that it is better to tell people about the risks. If

they read our advice and ignore it, that's their decision. Better than them saying they had no idea it was a potential danger. And in this case, information about the effects of salvia is already widely available to anyone on the Internet.

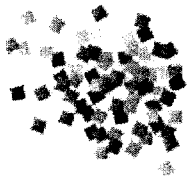
How do you want to proceed? Would you like me to talk to Shahid?

Cheers,  
Darrin

---

Darrin Denne  
Senior Communications Advisor - HPFB / Conseiller principal en communications - DGPSA  
Strategic Communications Directorate / Direction des communications stratégique  
Public Affairs, Consultation and Communications Branch (PACCB) /  
Direction générale des affaires publiques, de la consultation et des communications (DGAPCC)  
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Tel: (613) 946-0648  
Cel: (613) 282-6588  
Fax: (613) 957-8805

Lisa Holmes/HC-SC/GC/CA



Lisa Holmes/HC-SC/GC/CA

2008-12-02 12:44 PM

To Darrin Denne/HC-SC/GC/CA@HWC

cc Lisa MacKay/HC-SC/GC/CA@HWC

Subject Fw: It's Your Health article on Salvia divinorum

Hi Darrin,

Did your clients in MHPD raise this concern with you?

Thanks,  
Lisa

---

Lisa Holmes  
Senior Communications Advisor | Conseillère principale en communications  
PACRB | DGAPCR  
Strategic Communications Directorate | Direction des communications stratégiques  
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----- Forwarded by Lisa Holmes/HC-SC/GC/CA on 2008-12-02 12:42 PM -----

s.19(1)



"Sue Lumsden"

2008-12-02 12:20 PM

To "Lisa MacKay" <Lisa\_MacKay@hc-sc.gc.ca>

cc "Shahid Perwaiz" <shahid\_perwaiz@hc-sc.gc.ca>, "Lisa Holmes" <Lisa\_Holmes@hc-sc.gc.ca>

Subject Fw: It's Your Health article on Salvia divinorum

Hi Lisa,

The email message below from Shahid Perwaiz (MHPD) outlines his concern that posting an It's Your Health article on Salvia divinorum, which would feature information about its hallucinogenic properties and the current legal status, might result in more teenagers finding out about / seeking out this substance.

I gather that when you circulated the Proposal to the IYH Editorial Board, no one raised this issue as a potential downside to producing the article. However, as you'll see below, Shahid believes that the Editorial Board should be made aware of this possibility so that they may further consider whether or not the article should go forward.

Thanks.

Sue

[Redacted]

s.19(1)

----- Original Message -----

From: "Shahid Perwaiz" <shahid\_perwaiz@hc-sc.gc.ca>

To: [Redacted]

Cc: <Duc\_Vu@hc-sc.gc.ca>; "Scott Jordan" <Scott\_Jordan@hc-sc.gc.ca>

Sent: Tuesday, December 02, 2008 11:59 AM

Subject: It's Your Health article on Salvia divinorum

> Hi Sue,

>

> As I indicated to you during our telephonic conversation that my only concern regarding issuing an IYH on Salvia divinorum would be if we choose to inform public about its hallucinogenic properties and its legal status in Canada, this would likely create a promotional effect and could result in more adolescents seeking out Salvia from its currently easy access.

>

> I know that the proposal for the It's Your Health (IYH) article on Salvia divinorum has already been approved by the IYH Editorial Board, but it would be appropriate to bring the above-mentioned concern to the Editorial Board attention for their consideration.

>

> Thanks,

>

>

> Shahid Perwaiz, Ph.D.

> Evaluator

> Marketed Biologicals, Biotechnology and Natural Health Products Bureau

> Marketed Health Products Directorate

> Address Locator 0701 A, Ottawa, Ontario K1A 0K9

> Tel: (613) 948-8540 Fax: (613) 954-2354

>

>

>

> "Sue Lumsden"

>

>

>

> 2008-11-27 12:35

>

>

>

>

PM

<Shahid\_Perwaiz@hc-sc.gc.ca>

To

cc

<Ranjan\_Bose@hc-sc.gc.ca> ,

<Scott\_Jordan@hc-sc.gc.ca> ,

<Duc\_Vu@hc-sc.gc.ca>

Subject

It's Your Health article on Salvia  
divinorum

> Hi Dr. Perwaiz,

> As a follow-up to our brief discussion earlier today, I'm sending this  
> message along with two attachments: the Proposal for the It's Your Health  
> (IYH) article on Salvia divinorum, which was approved by the IYH Editorial  
> Board, and the general template for IYH, which outlines the kind of  
> information I would be looking for from you for the article.

> As you'll see, the Proposal for the article was written by Lisa Holmes  
> (Strategic Communications). She gave me your name as a program contact  
> for  
> the article. I'm also contacting Valerie Hurray (NHPD) and Jocelyn Kula  
> and  
> Brittany Sauve from the HECSB Office of Controlled Substances.

> I'm hoping you can put aside 20 minutes to half an hour in the near future  
> for a telephone interview to provide input for this article.

> I can be available during any of the following windows:

> Friday November 28th between 9:30 a.m. and 5:00 p.m.

> Monday December 1st between 10:30 a.m. and 12:45 p.m. or between 2:30 p.m.  
> and 5:30 p.m.


> Tuesday December 2nd between 8:00 a.m. and 4:30 p.m.

> Please let me know if any of these windows works for you, and if so, what  
> your preferred date and time would be for the interview.

> When I've gathered input from everyone on the list, I'll write a first  
> draft and will circulate it to all program contacts for further input,  
> revisions, etc. This process will go back and forth until the program  
> contacts are satisfied with the tone and content of the article, at which  
> point it will go into "formal approvals."

> Please let me know if you have any questions or concerns after reviewing  
> this message and the attached documents.

> Thank you,  
> Sue Lumsden

>  (See attached file: Proposed Article IYH Salvia-D.wpd) (See  
> attached file: IYH - Template 2008.wpd)

s.19(1)



- Proposed Article IYH Salvia-D.wpd



- IYH - Template 2008.wpd

DRAFT v03  
February 3, 2009

## **Media Lines**

### **Regulatory Control of *Salvia Divinorum***

#### **Issue**

Since 2006, Health Canada has observed a steady increase in the amount of media interest regarding the availability of *Salvia divinorum* on the Canadian market. Health Canada has also received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum*, particularly given reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties.

#### **Key Messages:**

- Health Canada continues to collect relevant information about *Salvia divinorum* and its active ingredient, Salvinorin A, from both national and international sources in order to help determine what, if any, regulatory controls are needed.
- While the media has reported that use of *Salvia divinorum* is on the rise in certain parts of the country, Health Canada does not currently have statistics on its use across the Canadian population.
- Health Canada is taking steps to address this lack of data. Questions regarding the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. A general open-ended question about the use of other substances has also been included in the 2008 Canadian Alcohol and Drug Use Monitoring Survey.

#### **Supplementary Messages:**

##### ***On the classification of *Salvia divinorum*:***

- In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, Salvinorin A, is controlled under the *Controlled Drugs and Substances Act* (CDSA).
- *Salvia divinorum* is not listed under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these conventions.
- Several countries (Australia, Belgium, Denmark, Sweden, Italy, Spain, Finland and South Korea) have placed controls on the import and/or sale of *Salvia divinorum*. Although some individual U.S. states have implemented laws restricting its use,

sale and/or distribution, *Salvia divinorum* is not federally regulated under the *Controlled Substances Act* in the United States.

- In Canada, *Salvia divinorum* under some conditions of use meets the definition of a natural health product under the *Natural Health Products Regulations*. This means that a product making health claims that contains *Salvia divinorum* must be approved by Health Canada prior to being sold in Canada. Products that don't comply with the regulations may be subject to compliance and enforcement actions.
- As of January 2009, Health Canada had not approved any *Salvia divinorum* products for sale in Canada.

***If asked for specifics on when the survey data will be available:***

- Data from the Canadian Alcohol and Drug Use Monitoring Survey will be available in summer 2009, while the results of the Youth Smoking Survey and the Ontario Student Drug Use and Health Survey likely will not be available until 2010.

**Questions and Answers**

**Q1 – If Health Canada is aware of *Salvia divinorum*'s ill-effects, why isn't it illegal?**

A1 – There are very few controlled scientific studies of the physical and psychotropic effects of *Salvia divinorum* on humans, and using these studies to predict its potential for addiction and abuse is difficult. The mechanism of action by which *Salvia divinorum* works is still not fully understood from the existing information, and more controlled systematic research in this area is needed.

Health Canada has only received a limited number of communications regarding *Salvia divinorum* from law enforcement agencies, and none has advised that the use of *Salvia divinorum* poses any particular threat to public safety.

**Q2 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?**

A2 – The *Natural Health Products Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *Salvia divinorum*.

**Q3 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum*. What does that involve and what stage is it at?**

A - Health Canada considers several factors in determining whether scheduling a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in control and scheduling;



- Chemical and pharmacological similarity to other substances already scheduled under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Addiction liability and potential for abuse/misuse of the substance;
- Extent of actual abuse and misuse of the substance in Canada and internationally;  
and
- Overall risk to public health and safety posed by the substance.

Health Canada has only anecdotal information about the last three of the above-mentioned factors.

Health Canada will continue to collect and consider information regarding *Salvia divinorum* as it becomes available, in order to determine whether the controls imposed by the CDSA are an appropriate strategy for managing the risks associated with *Salvia divinorum*'s use and controlling its availability.

**Q4 – Didn't an internal report from Health Canada's Marketed Health Products Directorate recommend that *Salvia divinorum* be scheduled under the CDSA? Why has that recommendation not been acted upon?**

A4 – Health Canada maintains an active file on this topic. Health Canada will continue to collect and consider information regarding *Salvia divinorum* as it becomes available, in order to determine whether the controls imposed by the CDSA are an appropriate strategy for managing the risks associated with *Salvia divinorum*'s use and controlling its availability.

**Q5 – Has Health Canada received any reports of adverse reactions related to the use of *Salvia divinorum*?**

A5 -- Since 2005, Health Canada has received four reports of adverse reactions associated with the use of *Salvia divinorum* as a hallucinogen, with three being considered non-serious (requiring no medical attention) and the fourth being considered serious (medical intervention was required).

Where did these reports come from?

**Background**

*Salvia divinorum* is a species of sage belonging to the mint family that is chewed or smoked in order to induce its psychotropic effects. The effects are short-acting in nature and include hallucinations, out-of-body experiences, unconsciousness and short-term memory loss.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. While no validated data exist regarding usage in Canada, data from a 2006 National Survey on Drug Use and Health Report, published by the U.S. Substance Abuse and Mental Health Services Administration has estimated that:

- 1.8 million persons aged 12 or older used *Salvia divinorum* at least once in their lifetime, and approximately 750,000 did so in the past year.
- Use was more common among young adults (18 to 25 years old) as opposed to older adults (>26 years of age).
- Young adults were 3 times more likely than youths aged 12 to 17 to have used *Salvia divinorum* in the past year.
- Use was more common in males than females.

~~*Salvia divinorum* is widely touted on the Internet as a "legal" alternative to street drugs.~~

The mechanism of action by which *Salvia divinorum* works is not fully understood. While some users have reported that the psychotropic effects of *Salvia divinorum* resemble those induced by other hallucinogens, such as LSD and phencyclidine, the overall experience is quite unique.

**Prepared by:** Cheryl Tremblay, Policy and Regulatory Affairs Division, DSCSD  
Stephanie Mitchell, Communications Advisor (HECSB)  
Darrin Denne, Communications Officer (HPFB)

**Approved by :**

Approved

Andrew Adams, Director, OCS, DSCSD  
Nancy Richards, Director, Bureau of Policy and Regulatory Affairs, NHPD (January 23, 2009)  
Duc Vu, Director, Marketed Biologics, Biotechnology and Natural Health Products Bureau, MHPD (February 3, 2009)

Pending

Ray Edwards, A/DG, DSCSD

Pending

Chris Turner, DG, MHPD

Pending

Michelle Boudreau, DG, NHPD

Pending

Diana Dowthwaite, DG, HPFBI

Pending

Ken Polk, Communications Executive, HPFB

Pending

Kathleen Malone, Senior Communications Executive, HECSB

Pending

Peter Yendall, Director, Public Affairs, PACCB

Pending

Paul Glover, ADM, HECSB

Pending

Meena Ballantyne, ADM, HPFB

Pending

DMO

Pending

MO

Pending

PCO

DRAFT v03  
February 3, 2009

~~Additional comment 2~~

## **Media Lines**

### **Regulatory Control of Salvia Divinorum**

#### **Issue**

Since 2006, Health Canada has observed a steady increase in the amount of media interest regarding the availability of *Salvia divinorum* on the Canadian market. Health Canada has also received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum*, particularly given reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties.

#### **Key Messages:**

- Health Canada continues to collect relevant information about *Salvia divinorum* and its active ingredient, Salvinorin A, from both national and international sources in order to help determine what, if any, regulatory controls are needed.
- While the media has reported that use of *Salvia divinorum* is on the rise in certain parts of the country, Health Canada does not currently have statistics on its use across the Canadian population.
- Health Canada is taking steps to address this lack of data. Questions regarding the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. A general open-ended question about the use of other substances has also been included in the 2008 Canadian Alcohol and Drug Use Monitoring Survey.
- Results from these surveys should start becoming available in summer 2009.

#### **Supplementary Messages:**

##### ***On the classification of Salvia divinorum:***

- In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, Salvinorin A, is controlled under the *Controlled Drugs and Substances Act* (CDSA).
- *Salvia divinorum* is not listed under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these conventions.

- Several countries (Australia, Belgium, Denmark, Sweden, Italy, Spain, Finland and South Korea) have placed controls on the import and/or sale of *Salvia divinorum*. Although some individual U.S. states have implemented laws restricting its use, sale and/or distribution, *Salvia divinorum* is not federally regulated under the *Controlled Substances Act* in the United States.
- In Canada, *Salvia divinorum* under some conditions of use meets the definition of a natural health product under the *Natural Health Products Regulations*. This means that a product making health claims that contains *Salvia divinorum* must be approved by Health Canada prior to being sold in Canada. Products that don't comply with the Regulations may be subject to compliance and enforcement actions.
- As of January 2009, Health Canada had not approved any *Salvia divinorum* products for sale in Canada.

***If asked for specifics on when the survey data will be available:***

- Data from the Canadian Alcohol and Drug Use Monitoring Survey will be available in summer 2009, while the results of the Youth Smoking Survey and the Ontario Student Drug Use and Health Survey likely will not be available until 2010.

**Questions and Answers**

**Q1 – If Health Canada is aware of *Salvia divinorum*'s ill-effects, why isn't it illegal?**

A1 – There are very few controlled scientific studies of the physical and psychotropic effects of *Salvia divinorum* on humans, and using these studies to predict its potential for addiction and abuse is difficult. The mechanism of action by which *Salvia divinorum* works is still not fully understood from the existing information, and more controlled systematic research in this area is needed.

Health Canada has only received a limited number of communications regarding *Salvia divinorum* from law enforcement agencies, and none has advised that the use of *Salvia divinorum* poses any particular threat to public safety [REDACTED]

**Q2 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?**

A2 – The *Natural Health Products Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials such as the plant, *Salvia divinorum*.

**Q3 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum*. What does that involve and what stage is it at?**

A - Health Canada considers several factors carefully in determining whether scheduling a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in control and scheduling;
- Chemical and pharmacological similarity to other substances already scheduled under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Addiction liability and potential for abuse/misuse of the substance;
- Extent of actual abuse and misuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada has only anecdotal information about the last three of the above-mentioned factors.

Health Canada will continue to collect and consider information regarding *Salvia divinorum* as it becomes available, in order to determine whether the controls imposed by the CDSA are an appropriate strategy for managing the risks associated with *Salvia divinorum*'s use and controlling its availability.

**Q4 – Didn't an internal report from Health Canada's Marketed Health Products Directorate recommend that *Salvia divinorum* be scheduled under the CDSA? Why has that recommendation not been acted upon?**

A4 – Health Canada maintains an active file and discussions on this topic. Health Canada will continue to collect and consider information regarding *Salvia divinorum* as it becomes available, in order to determine whether the controls imposed by the CDSA are an appropriate strategy for managing the risks associated with *Salvia divinorum*'s use and controlling its availability.

**Q5 – Has Health Canada received any reports of adverse reactions related to the use of *Salvia divinorum*?**

A5 -- Since 2005, Health Canada has received four reports of adverse reactions associated with the use of *Salvia divinorum* as a hallucinogen, with three being considered non-serious (requiring no medical attention) and the fourth being considered serious (medical intervention was required).

**Background**

*Salvia divinorum* is a species of sage belonging to the mint family that is chewed or smoked in order to induce its psychotropic effects. The effects are short-acting in nature

*Handwritten mark: a scribble with a question mark.*

and include hallucinations, out-of-body experiences, unconsciousness and short-term memory loss.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. While no validated data exist regarding usage in Canada, data from a 2006 National Survey on Drug Use and Health Report, published by the U.S. Substance Abuse and Mental Health Services Administration has estimated that:

- 1.8 million persons aged 12 or older used *Salvia divinorum* at least once in their lifetime, and approximately 750,000 did so in the past year.
- Use was more common among young adults (18 to 25 years old) as opposed to older adults (>26 years of age).
- Young adults were 3 times more likely than youths aged 12 to 17 to have used *Salvia divinorum* in the past year.
- Use was more common in males than females.

*Salvia divinorum* is widely touted on the Internet as a "legal" alternative to street drugs.

The mechanism of action by which *Salvia divinorum* works is not fully understood. While some users have reported that the psychotropic effects of *Salvia divinorum* resemble those induced by other hallucinogens, such as LSD and phencyclidine, the overall experience is quite unique.

**Prepared by:** Cheryl Tremblay, Policy and Regulatory Affairs Division, DSCSD  
Stephanie Mitchell, Communications Officer (HECSB)  
Darrin Denne, Communications Officer (HPFB)

**Approved by :**

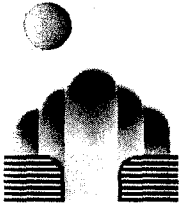
Approved	Andrew Adams, Director, OCS, DSCSD Nancy Richards, Director, Bureau of Policy and Regulatory Affairs, NHPD (January 23, 2009) Duc Vu, Director, Marketed Biologics, Biotechnology and Natural Health Products Bureau, MHPD (February 3, 2009)
Pending	Ray Edwards, A/DG, DSCSD
Pending	Chris Turner, DG, MHPD
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Pending	Ken Polk, Communications Executive, HPFB
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Pending	Paul Glover, ADM, HECSB
Pending	Meena Ballantyne, ADM, HPFB
Pending	DMO
Pending	MO

Pending

PCO

---

---



Jocelyn Kula/HC-SC/GC/CA

2009-02-05 12:38 PM

To Cheryl Tremblay/HC-SC/GC/CA@HWC, Brittany  
Sauvé/HC-SC/GC/CA@HWC, Valerie  
Hurry/HC-SC/GC/CA@HWC

cc

bcc

Subject Fw: It's Your Health - Salvia divinorum - Draft One

May I suggest that we try and provide one set of comments for Sue to work from? Perhaps if everyone could provide comments to Cheryl, she can collate and then circulate for all to agree on before we pass on to Sue. Just might be easier for Sue to work from.

Let me know.

Jocelyn

---

Jocelyn Kula  
Manager, Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Healthy Environments and Consumer Safety Branch  
Health Canada  
Tel: (613) 946-0125 Fax: (613) 946-4224

----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2009-02-05 12:36 PM -----



"Sue Lumsden"

2009-02-05 12:34 PM

To "Jocelyn Kula" <jocelyn\_kula@hc-sc.gc.ca>, "Cheryl  
Tremblay" <Cheryl\_Tremblay@hc-sc.gc.ca>, Brittany Sauvé  
<brittany\_sauve@hc-sc.gc.ca>, "Valerie Hurry"  
<Valerie\_Hurry@hc-sc.gc.ca>  
cc <Scott\_Jordan@hc-sc.gc.ca>

Subject It's Your Health - Salvia divinorum - Draft One

Good afternoon,

With apologies for the delay since we spoke about this issue, I'm forwarding a first draft of the It's Your Health (IYH) article on Salvia Divinorum.

When reviewing this document, please keep in mind that IYH is geared towards an audience with grade 10-12 literacy skills. We try to use plain language and a conversational tone. I realize this draft is quite simplistic in content, especially when compared to Brittany's research paper.

The usual process with IYH is for the draft to go back and forth between the writer and the Program contacts until you are satisfied with the content and tone of the article, at which point it is forwarded to the IYH Manager (Lisa Mackay) to begin the formal approvals process.

I'll be happy to work with you on revisions via e-mail or telephone, whichever you prefer.

Thank you. I look forward to seeing or hearing your comments on this first draft.

Sue



6130835-2878  - IYH - Salvia Divinorum - Draft One.wpd

s.19(1)



"Sue Lumsden"

2009-02-05 12:47 PM

To "Jocelyn Kula" <jocelyn\_kula@hc-sc.gc.ca>  
cc "Cheryl Tremblay" <Cheryl\_Tremblay@hc-sc.gc.ca>  
bcc

Subject Re: It's Your Health - Salvia divinorum - Draft One

Hi Jocelyn and Cheryl,

Please do whatever works best for you. I'd be happy to deal with either a list of comments or direct edits to text. I do like your idea of streamlined feedback, however. That would be very helpful.

Sue

----- Original Message -----

From: "Jocelyn Kula" <jocelyn\_kula@hc-sc.gc.ca>  
To: [REDACTED]  
Cc: "Cheryl Tremblay" <Cheryl\_Tremblay@hc-sc.gc.ca>  
Sent: Thursday, February 05, 2009 12:40 PM  
Subject: Re: It's Your Health - Salvia divinorum - Draft One

Hi Sue,

Thanks for this. Can I ask how you would like to receive feedback, i.e., a list of comments to be addressed or edits to the text directly? FYI, I have also suggested to the others that we try and collate comments so that the feedback is more streamlined.....

Jocelyn

---

Jocelyn Kula  
Manager, Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Healthy Environments and Consumer Safety Branch  
Health Canada  
Tel: (613) 946-0125 Fax: (613) 946-4224

"Sue Lumsden"

2009-02-05 12:34  
PM

To  
"Jocelyn Kula"  
<jocelyn\_kula@hc-sc.gc.ca>, "Cheryl  
Tremblay"  
<Cheryl\_Tremblay@hc-sc.gc.ca>,  
Brittany Sauvé  
<brittany\_sauve@hc-sc.gc.ca>,  
"Valerie Hurry"  
<Valerie\_Hurry@hc-sc.gc.ca>

cc  
<Scott\_Jordan@hc-sc.gc.ca>  
Subject  
It's Your Health - Salvia divinorum  
- Draft One

000091

s.19(1)

Good afternoon,

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I'll be happy to work with you on revisions via e-mail or telephone, whichever you prefer.

Thank you. I look forward to seeing or hearing your comments on this first draft.

Sue

(See attached file: IYH - Salvia Divinorum - Draft One.wpd)

## **Salvia Divinorum**

### **The Issue**

Certain Web sites are promoting the use of *Salvia divinorum* as a “legal” alternative to street drugs. Health Canada recommends that you avoid using this substance because very little is known about the extent of adverse effects, and there is no way to predict how it will affect you.

### **Background**

*Salvia divinorum* is a species of sage that belongs to the mint family. It is known to have psychotropic effects, which means it is capable of acting on the mind.

The leaves of this plant are used traditionally by the Mazatec Indians in Mexico for medicinal and spiritual purposes. Traditional use involves chewing the leaves or using them to make tea to treat such conditions as headache or stomach upset, or to produce a “mystical” experience.

Products that claim to contain *Salvia divinorum* – or its main active ingredient, Salvinorin A – are widely available on the Internet and are sold in various “head shops” and corner stores. These products are sold in a number of formats, including seeds, plant cuttings, fresh or dried leaves and liquid extracts, and are intended to be either chewed, swallowed or smoked. Street names for *Salvia divinorum* include: diviner’s sage, Magic mint, Maria pastra, puff encens special, ska pastora, ska Maria pastora, Sally D, Lady Sally and Salvia.

Recently, there have been reports suggesting that Canadian teens and young adults are using *Salvia divinorum* to get “high,” but so far, there has been no solid research in Canada on actual use.

Health Canada has not approved any *Salvia* products for sale in Canada. However, neither *Salvia divinorum* nor Salvinorin A is controlled in Canada under the *Controlled Drugs and Substances Act*.

Several countries (e.g., Australia, Belgium, Denmark, Sweden, Italy, Spain, Finland and South Korea) have placed controls on the import and/or sale of *Salvia divinorum*. A number of individual states have done this as well, but *Salvia divinorum* is not regulated under the *Controlled Substances Act* in the United States.

### **Risks associated with using *Salvia Divinorum***

The use of *Salvia divinorum* distorts reality. The effects vary from person to person, and may include the following:

- hallucinations (“seeing” objects that are not there)
- out-of-body experiences
- loss of consciousness
- short-term memory loss

- uncontrollable laughter
- loss of ability to speak

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one experience to the next, depending on such factors as the potency of the product, how much was used, whether it was ingested or smoked, and the user's mood and expectations.

A major concern about *Salvia divinorum* is the fact that there have been so few scientific studies about the way it affects the body and the brain. For example, very little is known about the following issues:

- whether it is toxic
- precisely how it acts on the brain
- how long it acts on the brain and whether there are permanent effects
- whether it causes physical or psychological dependence
- how it interacts with other substances (including drugs and alcohol)

Also, since no *Salvia divinorum* products have been approved for sale in Canada, products that claim to contain this substance have not been reviewed by Health Canada. As such, they may be counterfeit or may contain other ingredients that pose risks to health. In cases like this, it is always a matter of "buyer beware."

### **The Legal Status of *Salvia Divinorum***

From time to time, Health Canada is asked why *Salvia divinorum* and Salvinorin A are not prohibited under the *Controlled Drugs and Substances Act* (CDSA). When assessing whether to regulate a substance under the CDSA, Health Canada considers many factors, including the following:

- international requirements and trends in controlling the substance
- similarity to other substances already regulated under the CDSA
- whether there may be legitimate uses of the substance (e.g., potential health benefits)
- the potential for addiction and abuse/misuse of the substance
- the extent of actual abuse and misuse of the substance in Canada and elsewhere
- overall risk to public health and safety posed by the substance

In the case of *Salvia divinorum*, there is simply not enough information available to determine whether prohibition is the best option to manage risks. To date, no law enforcement agencies have advised Health Canada that the use of *Salvia divinorum* poses any particular threat to public safety. However, as noted earlier, very little is known about the potential for addiction or the extent of actual use.

Questions about the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. The survey results will help fill some of the information gaps, but the data will not likely be available until 2010.

## **Minimizing Your Risk**

Health Canada recommends that you avoid using *Salvia divinorum*. Also, if you have children, talk to them about peer pressure and the risks of using drugs and other substances that distort reality. (See the "Need More Info?" section below for links to resources that can help you with this.)

Also, remember that just because a product is "natural," this does not mean it is safe. Natural Health Products that have been approved by Health Canada will have one of the following:

- a Drug Identification Number - Homeopathic Medicine (DIN-HM) or
- a Natural Product Number (NPN)

These numbers let you know that the products have undergone and passed a review of their formulation, labelling and instructions for use. As stated earlier, no *Salvia* products have been approved by Health Canada.

## **Health Canada's Role**

Health Canada continues to collect and consider information regarding *Salvia divinorum* and continues to consult with key stakeholders, including health officials in other countries, and law enforcement officials here at home. This will assist in determining the most appropriate strategy to manage the risks associated with the use of *Salvia divinorum* and to control the availability of this substance.

## **Need More Info?**

For information about Health Canada's Drug Strategy and Controlled Substances Programme, go to: <http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hecs-dgsesc/dscsp-psasc/index-eng.php>

Also, see the section on Prevention on the Government of Canada's National Anti-Drug Strategy Web site at: <http://www.nationalantidrugstrategy.gc.ca/>. This site has a number of helpful resources for parents, including "Tips on Talking to Your Teenager" and "What to do if Your Teen is using Drugs."

For more on the surveys that are collecting information about *Salvia divinorum* use in Canada, see:

The Ontario Student Drug Use and Health Survey, at: <http://www.camh.net/Research/osdus.html>  
The 2008-2009 Youth Smoking Survey, at:  
[http://www.yss.uwaterloo.ca/ysss/site\\_app/controller/index.cfm](http://www.yss.uwaterloo.ca/ysss/site_app/controller/index.cfm)

Also, see the following Web sites:

U.S. Drug Enforcement Administration: Drugs and Chemicals of Concern: *Salvia divinorum* and Salvinorin A at: [http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)

U.S. Department of Health & Human Services, National Survey on Drug Use and Health: Use of  
Specific Hallucinogens: 2006 at:

<http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf>

For additional articles on health and safety issues go to the *It's Your Health* Web site at:

<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/index-eng.php>

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

Original:

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Catalogue#

**s.19(1)**

ISBN#

----- 0 -----

Writer: Sue Lumsden

Version/date: Draft One, February 5, 2009

Contacts: Jocelyn Kula, Cheryl Tremblay, Brittany Sauvé (HECSB)  
Valery Hurry (NHPD - HPFB)  
No input from MHPD, but draft is being sent to Scott Jordan for review



"Sue Lumsden"

2009-02-05 12:47 PM

To "Jocelyn Kula" <jocelyn\_kula@hc-sc.gc.ca>  
cc "Cheryl Tremblay" <Cheryl\_Tremblay@hc-sc.gc.ca>  
bcc

Subject Re: It's Your Health - Salvia divinorum - Draft One

Hi Jocelyn and Cheryl,

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----- Original Message -----

From: "Jocelyn Kula" <jocelyn\_kula@hc-sc.gc.ca>  
To: [REDACTED]  
Cc: "Cheryl Tremblay" <Cheryl\_Tremblay@hc-sc.gc.ca>  
Sent: Thursday, February 05, 2009 12:40 PM  
Subject: Re: It's Your Health - Salvia divinorum - Draft One

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Jocelyn

---

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Manager, Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Healthy Environments and Consumer Safety Branch  
Health Canada  
Tel: (613) 946-0125 Fax: (613) 946-4224

"Sue Lumsden"

2009-02-05 12:34  
PM

To  
"Jocelyn Kula"  
<jocelyn\_kula@hc-sc.gc.ca>, "Cheryl  
Tremblay"  
<Cheryl\_Tremblay@hc-sc.gc.ca>,  
Brittany Sauvé  
<brittany\_sauve@hc-sc.gc.ca>,  
"Valerie Hurry"  
<Valerie\_Hurry@hc-sc.gc.ca>

cc

<Scott\_Jordan@hc-sc.gc.ca>  
Subject  
It's Your Health - Salvia divinorum  
- Draft One



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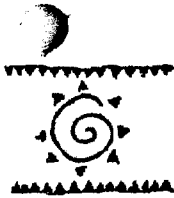
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Sue

(See attached file: IYH - Salvia Divinorum - Draft One.wpd)



Brittany  
Sauvé/HC-SC/GC/CA  
2009-02-05 02:48 PM

To Cheryl Tremblay/HC-SC/GC/CA@HWC  
cc  
bcc

Subject Re: Fw: Top 5 Recreational Drug Experiments-Salvia

History: This message has been forwarded.

**Yeah, I remember going over that in my head the last chance we got before these were finalized and what I should do in regards to that... But in hindsight, I would take it out. See my comments below.**

**Q1 – If Health Canada is aware of *Salvia divinorum* 's ill-effects, why isn't it illegal?**

A - Human studies that demonstrate reliable, systematic and controlled observations on the physical and psychotropic effects of *Salvia divinorum* are sparse, and using these studies to predict its potential for addiction and abuse is difficult . The information currently available to Health Canada indicates that the likelihood of abuse/misuse of *Salvia divinorum* is unknown? (if we want to be really picky, I also addressed this in my report... and based on its pharmacology, this is not *unknown*. We know that it is a KOR agonist and by virtue of that should be a low abuse liability), ~~t hat the mechanism of action by which *Salvia divinorum* works is still not fully understood,~~ and that more controlled systematic research in this area is needed.

~~The mechanism of action by which *Salvia divinorum* works is not fully understood.~~ (It was in this context that I felt there was some play... because people have very different experiences on the drug which have led to the idea that there might be more than just KOR at play.. or salviorin... But yes, just take it out). While some users have reported that the psychotropic effects of *Salvia divinorum* resemble those induced by other hallucinogens such as LSD and phencyclidine, the overall experience is quite unique.

Cheryl Tremblay/HC-SC/GC/CA



Cheryl  
Tremblay/HC-SC/GC/CA  
05/02/2009 02:03 PM

To Brittany Sauvé/HC-SC/GC/CA@HWC  
cc  
Subject Fw: Top 5 Recreational Drug Experiments-Salvia

Hi Brittany,

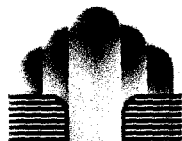
I just wanted to get your opinion on whether you think the following article warrants us changing our line in media lines re: "the mechanism of action by which *Salvia divinorum* works is still not fully understood"?

Willmore et al\_2007.pdf

Thanks,

Cheryl Tremblay  
Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Drug Strategy and Controlled Substances Directorate  
Health Canada  
Tel: (613) 954-6527  
Fax: (613) 946-4224

----- Forwarded by Cheryl Tremblay/HC-SC/GC/CA on 2009-02-05 01:56 PM -----



Jocelyn Kula/HC-SC/GC/CA

2009-01-02 09:28 AM

To Cheryl Tremblay/HC-SC/GC/CA@HWC

cc

Subject Fw: Top 5 Recreational Drug Experiments-Salvia

Ronald sent me this, and I wonder if you can confirm that the Neuropharmacology paper mentioned below is one we have in our files; just means we perhaps have to be less equivocal with respect to mechanism of action now, i.e., not sure what our media lines say but I thought we had something in there about not being sure how salvia works??

pls follow up and change lines if necessary- now is the time given that they are still in approvals.....

will also be important for IAS

JK

---

Jocelyn Kula  
Manager, Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Healthy Environments and Consumer Safety Branch  
Health Canada  
Tel: (613) 946-0125 Fax: (613) 946-4224

----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2009-01-02 09:26 AM -----



Ronald  
Denault/HC-SC/GC/CA

2008-12-31 01:34 PM

To Jocelyn Kula/HC-SC/GC/CA

cc

Subject Top 5 Recreational Drug Experiments-Salvia

<http://blog.wired.com/wiredscience/2008/04/top-5-recreatio.html#previouspost>

Check #3

Ronald

# Salvia Divinorum - Draft One

## The Issue

Certain websites are also promoting the use of *Salvia divinorum* (*S. divinorum*) as a "legal" alternative to street drugs. Health Canada recommends that you avoid using this substance because very little is known about how it acts on the brain, and there is no way to predict how it will affect you.

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## Background

Note: We feel that the Background section would flow better if some of the information was moved to other sections in the document. Please see suggestions in comments on right-hand side.

*S. divinorum* is a species of sage that belongs to the mint family. It is known to have psychotropic effects, which means it is capable of acting on the mind.

The leaves of this plant have been used traditionally by the Mazatec Indians in Mexico for medicinal and spiritual purposes. Traditional use involves chewing the leaves or using them to make a tea to treat such conditions as headache or stomach upset, or to induce a "mystical" or hallucinogenic experience.

Products that claim to contain *S. divinorum* – or its main active ingredient, salvinorin A – are widely available on the Internet and are sold in various "head shops" and natural food stores, etc. These products are sold in a number of formats, including seeds, and plant cuttings for propagation purposes. Fresh or dried leaves are intended to be either chewed, swallowed or smoked; liquid preparations are also available for consumption. Street names for *S. divinorum* include: diviner's sage, Magic mint, Maria pastra, puff encens special, ska pastora, ska Maria pastora, Sally D, Lady Sally and Salvia.

Recently, there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* specifically for its ability to produce hallucinations (i.e. "seeing" object that are not there).

Health Canada has not approved any *S. divinorum* products for sale in Canada. However, neither *S. divinorum* nor salvinorin A are controlled in Canada under the *Controlled Drugs and Substances Act*.

Several countries (e.g., Australia, Belgium, Denmark, Sweden, Italy, Spain, Finland and South Korea) have placed controls on the import and/or sale of *S. divinorum*. In the United States, *S. divinorum* is not regulated under the *Controlled Substances Act*, although a number of individual states have placed restrictions on its sale and/or import. For example, several states have placed *S. divinorum* and/or salvinorin A into Schedule I of state law, thereby making it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have enacted other forms of legislation restricting distribution of the plant.

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### Risks Associated With Using *Salvia Divinorum*

*S.* acts as a hallucinogen, which means that it distorts reality. The effects, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations
- out-of-body experiences
- loss of consciousness
- short-term memory loss
- uncontrollable laughter
- impaired ability to speak

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product
- how much is used
- how it is taken (e.g. ingested or smoked)
- the user's mood and expectations.

*S. divinorum* does not appear to cause the euphoria often associated with other psychoactive drugs, so many people who try it do not repeat the experience.

A major concern about *S. divinorum* is the fact that there have been so few scientific studies about the way it affects the body and the brain. For example, very little is known about the following:

- how it affects the brain and if it causes permanent damage
- whether it causes physical dependence or addiction
- how it interacts with other substances (including other drugs and alcohol)

Also, since no *S. divinorum* products have been approved for sale in Canada, products that claim to contain this substance have not been reviewed by Health Canada. As such, they may be counterfeit or may contain other ingredients that pose risks to health. In cases like this, it is always a matter of "buyer beware."

### The Legal Status of *Salvia Divinorum*

Note: Would start with a clear statement about the fact that *Salvia divinorum* is not regulated as a controlled substance in Canada at the present time and then would move to status in other countries. We also need to explain the fact that *Salvia divinorum* meets the definition of a natural health product under the *Natural Health Product Regulations*, but no NHPs containing *Salvia divinorum* have been approved.

From time to time, Health Canada is asked why *S. divinorum* and salvinorin A are not prohibited under the *Controlled Drugs and Substances Act* (CDSA). When assessing whether to regulate a

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substance under the *Controlled Drugs and Substances Act* (CDSA), Health Canada considers the following factors:

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- international requirements and trends in controlling the substance
- similarity to other substances already regulated under the CDSA
- whether there may be legitimate uses of the substance (e.g., potential health benefits)
- the potential for addiction and abuse/misuse of the substance
- the extent of actual abuse and misuse of the substance in Canada and elsewhere
- overall risk to public health and safety posed by the substance

In the case of *S. divinorum*, there is simply not enough information available to determine whether prohibition is the best option to manage the potential risks associated with its use. To date, no law enforcement agencies have advised Health Canada that the use of *Salvia divinorum* poses any particular threat to public safety. However, as noted earlier, very little is known about the potential for addiction or the extent of actual use.

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Questions about the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. The survey results will help fill some of the information gaps, but the data will not likely be available until 2010.

Comment: Suggest moving to HC's Role section.

### Minimizing Your Risk

Health Canada recommends that you avoid using *S. divinorum*. Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs and other substances that distort reality. (See the "Need More Info?" section below for links to resources that can help you with this.)

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Also, remember that just because a drug is plant-based or "natural," does not mean it is safe. Natural health products that have been approved by Health Canada will be labelled with one of the following:

- a Drug Identification Number - Homeopathic Medicine (DIN-HM) or
- a Natural Product Number (NPN)

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These numbers let you know that a product has undergone a rigorous review of formulation, labelling and instructions for use. In fact, no products containing *S. divinorum* have been approved by Health Canada.

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### Health Canada's Role

Health Canada continues to collect and consider information regarding *S. divinorum* and continues to consult with key stakeholders, including health officials in other countries, and law enforcement officials here at home. This will assist in determining the most appropriate strategy to manage the risks associated with the use of *S. divinorum*.

**Need More Info?**

For information about Health Canada's Drug Strategy and Controlled Substances Directorate, go to: <http://www.hc-sc.gc.ca/ahc-asc/branch-dirigen/hecs-dgsesc/dscsp-psasc/index-eng.php>

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Also, see the section on Prevention on the Government of Canada's National Anti-Drug Strategy Web site at: <http://www.nationalantidrugstrategy.gc.ca/>. This site has a number of helpful resources for parents, including "Tips on Talking to Your Teenager" and "What to do if Your Teen is using Drugs."

For more on the surveys that are collecting information about *S. divinorum* use in Canada, see:

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The Ontario Student Drug Use and Health Survey, at: <http://www.camh.net/Research/osdus.html>  
The 2008-2009 Youth Smoking Survey, at: [http://www.yss.uwaterloo.ca/ysssite\\_app/controller/index.cfm](http://www.yss.uwaterloo.ca/ysssite_app/controller/index.cfm)

Comment: Suggest reversing order to match order they appear in document.

Additional Resources:

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U.S. Drug Enforcement Administration: Drugs and Chemicals of Concern: *Salvia divinorum* and Salvinorin A at: [http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)  
U.S. Department of Health & Human Services, National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006 at: <http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf>

For additional articles on health and safety issues go to the *It's Your Health* Web site at: <http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/index-eng.php>  
<http://www.hc-sc.gc.ca/english/iyh/index.html>

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

Comment: Is this standard to all IYH Articles?

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Contacts: Jocelyn Kula, Cheryl Tremblay, Brittany Sauvé (HECSB)  
Valerie Hurry (NHPD - HPFB)  
No input from MHPD, but draft is being sent to Scott Jordan for review

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Britanny Sauvé - Comments

## Salvia Divinorum

### The Issue

Certain Web sites are promoting the use of *Salvia divinorum* (*S. divinorum*) as a “legal” alternative to street drugs. Health Canada recommends that you avoid using this substance because very little is known about the extent of adverse effects, and there is no way to predict how it will affect you.

### Background

*Salvia divinorum* is a species of sage that belongs to the mint family. It is known to have psychotropic effects, these are effects on the mind. ~~which means it is capable of acting on the mind.~~

The leaves of this plant are used traditionally by the Mazatec Indians in Mexico for medicinal and spiritual purposes. Traditional use involves chewing the leaves or using them to make a tea to treat such conditions as headache or stomach upset, or to produce a “mystical” experience.

Products that claim to contain *S. ~~alvia~~ divinorum* – or its main active ingredient, ~~s~~Salvinorin A – are widely available on the Internet and are sold in various “head shops” and corner stores (?-I am not sure that this is appropriate? Mainly herbal shops I think... right?). These products are sold in a number of formats, including seeds, plant cuttings, fresh or dried leaves and liquid extracts, and are intended to be either chewed, swallowed or smoked. Street names for *S. ~~alvia~~ divinorum* include: diviner’s sage, ~~m~~Magic mint, ~~m~~Maria pastra, puff encens special, ska pastora, ska ~~m~~Maria pastora, ~~s~~Sally D, ~~H~~ady ~~s~~Sally and ~~s~~Salvia.

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Recently, there have been reports suggesting that Canadian teens and young adults are using *S. ~~alvia~~ divinorum* to get “high,” but so far, there has been no solid research in Canada on its actual use.

Health Canada has not approved any *S. divinorum*~~Salvia~~ products for sale in Canada. However, neither *S. ~~alvia~~ divinorum* nor ~~s~~Salvinorin A is controlled in Canada under the *Controlled Drugs and Substances Act*.

Several countries (e.g., Australia, Belgium, Denmark, Sweden, Italy, Spain, Finland and South Korea) have placed controls on the import and/or sale of *S. ~~alvia~~ divinorum*. A number of individual ~~Ss~~(?)tates have done this as well, but *S. ~~alvia~~ divinorum* is not regulated under the *Controlled Substances Act* in the United States.

### Risks associated with using *Salvia Divinorum*

The use of *S. ~~alvia~~ divinorum* distorts reality. The effects vary from person to person, and may



## Brittany Sauvé - Comments

include the following:

- hallucinations (“seeing” objects that are not there)
- out-of-body experiences
- loss of consciousness
- short-term memory loss
- uncontrollable laughter
- loss of ability to speak

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use experience to the next, depending on such factors such as:

- ~~the~~ potency of the product,
- how much was used
- how it is taken (e.g. ingested or smoked), ~~whether it was ingested or smoked, and~~
- the person ~~user~~'s mood and expectations:

A major concern about *Salvia divinorum* is the fact that there have been so few scientific studies about the way it affects the body and the brain. For example, very little is known about the following issues:

- ~~whether it is toxic~~ (everything is toxic)
- ~~precisely how it affects~~ acts on the brain and if it causes permanent damage ~~how long it acts on the brain and whether there are permanent effects~~
- whether it causes physical or ~~psychological~~ dependence or addiction
- how it interacts with other substances (including drugs and alcohol)

Also, since no *S. alvia divinorum* products have been approved for sale in Canada, products that claim to contain this substance have not been reviewed by Health Canada. As such, they may be ~~counterfeit or may contain other ingredients that pose risks to health. In cases like this, it is~~ always a matter of “buyer beware.”<sup>22</sup>

## The Legal Status of *Salvia Divinorum*

From time to time, Health Canada is asked why *S. alvia divinorum* and ~~s~~Salvinorin A are not prohibited under the *Controlled Drugs and Substances Act* (CDSA). When assessing whether to regulate a substance under the CDSA, Health Canada considers many factors, including the following:

- international requirements and trends in controlling the substance
- similarity to other substances already regulated under the CDSA
- whether there may be legitimate uses of the substance (e.g., potential health benefits)
- the potential for addiction and abuse/misuse of the substance
- the extent of actual abuse and misuse of the substance in Canada and elsewhere
- overall risk to public health and safety posed by the substance

## Britanny Sauvé - Comments

In the case of *Salvia divinorum*, there is simply not enough information available to determine whether prohibition is the best option to manage the risks. To date, no law enforcement agencies have advised Health Canada that the use of *Salvia divinorum* poses any particular threat to public safety. (This sentence sounds odd a bit because its not just law enforcement that can judge public safety) However, as noted earlier, very little is known about the potential for addiction or the extent of actual use.

Questions about the use of *S. atvia divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. The survey results will help fill some of the information gaps, but the data will not likely be available until 2010.

### **Minimizing Your Risk**

Health Canada recommends that you avoid using *S. atvia divinorum*. Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs and other substances that distort reality. (See the "Need More Info?" section below for links to resources that can help you with this.)

Also, remember that just because a product is "natural;" this does not mean it is safe. Natural Health Products that have been approved by Health Canada will have one of the following:

- a Drug Identification Number - Homeopathic Medicine (DIN-HM) or
- a Natural Product Number (NPN)

These numbers let you know that the products have undergone and passed a review of their formulation, labelling and instructions for use. As stated earlier, no *S. divinorum* *Salvia* products have been approved by Health Canada.

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### **Health Canada's Role**

Health Canada continues to collect and consider information regarding *Salvia divinorum* and continues to consult with key stakeholders, including health officials in other countries, and law enforcement officials here at home. This will assist in determining the most appropriate strategy to manage the risks associated with the use of *S. atvia divinorum* and to control the availability of this substance.

### **Need More Info?**

For information about Health Canada's Drug Strategy and Controlled Substances Programme, go to: <http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hecs-dgsesc/dscsp-psasc/index-eng.php>

Also, see the section on Prevention on the Government of Canada's National Anti-Drug Strategy Web site at: <http://www.nationalantidrugstrategy.gc.ca/>. This site has a number of helpful resources for parents, including "Tips on Talking to Your Teenager" and "What to do if Your Teen is using Drugs."

Britanny Sauvé - Comments

For more on the surveys that are collecting information about *Salvia divinorum* use in Canada,  
see:

The Ontario Student Drug Use and Health Survey, at: <http://www.camh.net/Research/osdus.html>  
The 2008-2009 Youth Smoking Survey, at:  
[http://www.yss.uwaterloo.ca/ysssite\\_app/controller/index.cfm](http://www.yss.uwaterloo.ca/ysssite_app/controller/index.cfm)

Also, see the following Web sites:

U.S. Drug Enforcement Administration: Drugs and Chemicals of Concern: *Salvia divinorum* and  
Salvinorin A at: [http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)

U.S. Department of Health & Human Services, National Survey on Drug Use and Health: Use of  
Specific Hallucinogens: 2006 at:  
<http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf>

For additional articles on health and safety issues go to the *It's Your Health* Web site at:  
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No input from MHPD, but draft is being sent to Scott Jordan for review

Original

## **Salvia Divinorum**

### **The Issue**

Certain Web sites are promoting the use of *Salvia divinorum* as a “legal” alternative to street drugs. Health Canada recommends that you avoid using this substance because very little is known about the extent of adverse effects, and there is no way to predict how it will affect you.

### **Background**

*Salvia divinorum* is a species of sage that belongs to the mint family. It is known to have psychotropic effects, which means it is capable of acting on the mind.

The leaves of this plant are used traditionally by the Mazatec Indians in Mexico for medicinal and spiritual purposes. Traditional use involves chewing the leaves or using them to make tea to treat such conditions as headache or stomach upset, or to produce a “mystical” experience.

Products that claim to contain *Salvia divinorum* – or its main active ingredient, Salvinorin A – are widely available on the Internet and are sold in various “head shops” and corner stores. These products are sold in a number of formats, including seeds, plant cuttings, fresh or dried leaves and liquid extracts, and are intended to be either chewed, swallowed or smoked. Street names for *Salvia divinorum* include: diviner’s sage, Magic mint, Maria pastra, puff encens special, ska pastora, ska Maria pastora, Sally D, Lady Sally and Salvia.

Recently, there have been reports suggesting that Canadian teens and young adults are using *Salvia divinorum* to get “high,” but so far, there has been no solid research in Canada on actual use.

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Health Canada has not approved any *Salvia* products for sale in Canada. However, neither *Salvia divinorum* nor Salvinorin A is controlled in Canada under the *Controlled Drugs and Substances Act*.

Several countries (e.g., Australia, Belgium, Denmark, Sweden, Italy, Spain, Finland and South Korea) have placed controls on the import and/or sale of *Salvia divinorum*. A number of individual states have done this as well, but *Salvia divinorum* is not regulated under the *Controlled Substances Act* in the United States.

### **Risks associated with using *Salvia Divinorum***

The use of *Salvia divinorum* distorts reality. The effects vary from person to person, and may include the following:

- hallucinations (“seeing” objects that are not there)
- out-of-body experiences
- loss of consciousness
- short-term memory loss

- uncontrollable laughter
- loss of ability to speak

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one experience to the next, depending on such factors as the potency of the product, how much was used, whether it was ingested or smoked, and the user's mood and expectations.

A major concern about *Salvia divinorum* is the fact that there have been so few scientific studies about the way it affects the body and the brain. For example, very little is known about the following issues:

- whether it is toxic
- precisely how it acts on the brain
- how long it acts on the brain and whether there are permanent effects
- whether it causes physical or psychological dependence
- how it interacts with other substances (including drugs and alcohol)

Also, since no *Salvia divinorum* products have been approved for sale in Canada, products that claim to contain this substance have not been reviewed by Health Canada. As such, they may be counterfeit or may contain other ingredients that pose risks to health. In cases like this, it is always a matter of "buyer beware."

### **The Legal Status of *Salvia Divinorum***

From time to time, Health Canada is asked why *Salvia divinorum* and Salvinorin A are not prohibited under the *Controlled Drugs and Substances Act* (CDSA). When assessing whether to regulate a substance under the CDSA, Health Canada considers many factors, including the following:

- 
- international requirements and trends in controlling the substance
  - similarity to other substances already regulated under the CDSA
  - whether there may be legitimate uses of the substance (e.g., potential health benefits)
  - the potential for addiction and abuse/misuse of the substance
  - the extent of actual abuse and misuse of the substance in Canada and elsewhere
  - overall risk to public health and safety posed by the substance

In the case of *Salvia divinorum*, there is simply not enough information available to determine whether prohibition is the best option to manage risks. To date, no law enforcement agencies have advised Health Canada that the use of *Salvia divinorum* poses any particular threat to public safety. However, as noted earlier, very little is known about the potential for addiction or the extent of actual use.

Questions about the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. The survey results will help fill some of the information gaps, but the data will not likely be available until 2010.

## Minimizing Your Risk

Health Canada recommends that you avoid using *Salvia divinorum*. Also, if you have children, talk to them about peer pressure and the risks of using drugs and other substances that distort reality. (See the "Need More Info?" section below for links to resources that can help you with this.)

Also, remember that just because a product is "natural," this does not mean it is safe. Natural Health Products that have been approved by Health Canada will have one of the following:

- a Drug Identification Number - Homeopathic Medicine (DIN-HM) or
- a Natural Product Number (NPN)

These numbers let you know that the products have undergone and passed a review of their formulation, labelling and instructions for use. As stated earlier, no *Salvia* products have been approved by Health Canada.

## Health Canada's Role

Health Canada continues to collect and consider information regarding *Salvia divinorum* and continues to consult with key stakeholders, including health officials in other countries, and law enforcement officials here at home. This will assist in determining the most appropriate strategy to manage the risks associated with the use of *Salvia divinorum* and to control the availability of this substance.

## Need More Info?

For information about Health Canada's Drug Strategy and Controlled Substances Programme, go to: <http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hecs-dgsesc/dscsp-psasc/index-eng.php>

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U.S. Department of Health & Human Services, National Survey on Drug Use and Health: Use of  
Specific Hallucinogens: 2006 at:

<http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf>

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Cheryl Tremblay - Comments

## **Salvia Divinorum**

### **The Issue**

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### **Background**

*Salvia divinorum* is a species of sage that belongs to the mint family. It is known to have psychotropic effects, which means it is capable of acting having an influence on the mind.

The leaves of this plant are used traditionally by the Mazatec Indians in Mexico for medicinal and spiritual purposes. Traditional use involves chewing the leaves or using them to make tea to treat such conditions as headache or stomach upset, or to produce a "mystical" experience.

Products that claim to contain *Salvia divinorum* – or its main active ingredient, Salvinorin A – are widely available on the Internet and are sold in various "head shops" and corner stores. These products are sold in a number of formats, including seeds, plant cuttings, fresh or dried leaves and liquid extracts, and are intended to be either chewed, swallowed or smoked. Street names for *Salvia divinorum* include: diviner's sage, Magic mint, Maria pastra, puff encens special, ska pastora, ska Maria pastora, Sally D, Lady Sally and Salvia.

Recently, there have been reports suggesting that Canadian teens and young adults are using *Salvia divinorum* specifically for its ability to produce hallucinations (i.e. "seeing" objects that are not there), to get "high," but so far, there has been no solid research in Canada on actual use.

Questions about the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. These survey results will help fill some of the information gaps, but the data will not likely be available until 2010. (2008 Canadian Alcohol and Drug Use Monitoring Survey too? - only general open-ended question - not specific to Salvia)

~~Health Canada has not approved any Salvia products for sale in Canada. However~~ In Canada, neither *Salvia divinorum* nor Salvinorin A is are controlled in Canada under the *Controlled Drugs and Substances Act*. *Salvia divinorum* does meet the definition of a natural health product under the *Natural Health Product Regulations*, which means that a product that contains *Salvia divinorum* must be approved by Health Canada prior to being sold in Canada. Health Canada has, however, not approved any Salvia products for sale in Canada.

Several countries (e.g., Australia, Belgium, Denmark, Sweden, Italy, Spain, Finland and South Korea) have placed controls on the import and/or sale of *Salvia divinorum*. A number of



Cheryl Tremblay - Comments

individual U.S. states have done this as well, but *Salvia divinorum* is not federally regulated under the *Controlled Substances Act* in the United States.

### **Risks associated with using *Salvia Divinorum***

The use of *Salvia divinorum* distorts reality. The effects vary from person to person, and may include the following:

- hallucinations (~~“seeing” objects that are not there~~)
- out-of-body experiences
- loss of consciousness
- short-term memory loss
- uncontrollable laughter
- loss of ability to speak

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one experience to the next, depending on such factors as the potency of the product, how much was used, whether it was ingested or smoked, and the user's mood and expectations.

A major concern about *Salvia divinorum* is the fact that there have been so few scientific studies about the way it affects the body and the brain. For example, very little is known about the following issues:

- whether it is toxic
- precisely how it acts on the brain
- how long it acts on the brain and whether there are permanent effects
- whether it causes physical or psychological dependence
- ~~how it interacts with other substances (including drugs and alcohol)~~

Also, since no *Salvia divinorum* products have been approved for sale in Canada, ~~products that claim to contain this substance~~ and thus have not been reviewed by Health Canada. ~~As such, they may be counterfeit or may contain other ingredients that pose risks to health.~~ In cases like this, it is always a matter of “buyer beware.”

### **The Legal Status of *Salvia Divinorum***

From time to time, Health Canada is asked why *Salvia divinorum* and Salvinorin A are not prohibited under the *Controlled Drugs and Substances Act* (CDSA). When assessing whether to regulate a substance under the CDSA, Health Canada considers many factors, including the following:

- international requirements and trends in controlling the substance
- similarity to other substances already regulated under the CDSA
- whether there may be legitimate uses of the substance (e.g., potential health benefits)

Cheryl Tremblay - Comments

- the potential for addiction and abuse/misuse of the substance
- the extent of actual abuse and misuse of the substance in Canada and elsewhere
- overall risk to public health and safety posed by the substance

In the case of *Salvia divinorum*, there is simply not enough information available to determine whether prohibition is the best option to manage risks. To date, no law enforcement agencies have advised Health Canada that the use of *Salvia divinorum* poses any particular threat to public safety. However, as noted earlier, very little is known about the potential for addiction or the extent of actual use.

~~Questions about the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. The survey results will help fill some of the information gaps, but the data will not likely be available until 2010.~~

### **Minimizing Your Risk**

Health Canada recommends that you avoid using *Salvia divinorum*. Also, if you have children, talk to them about peer pressure and the risks of using drugs and other substances that distort reality. (See the "Need More Info?" section below for links to resources that can help you with this.)

Also, remember that just because a product is "natural," this does not mean it is safe. Natural Health Products that have been approved by Health Canada will have one of the following:

- a Drug Identification Number - Homeopathic Medicine (DIN-HM) or
- a Natural Product Number (NPN)

~~These numbers let you know that the products have undergone and passed a review of their formulation, labelling and instructions for use. As stated earlier, no *Salvia divinorum* products have been approved by Health Canada.~~

### **Health Canada's Role**

Health Canada continues to collect and consider information regarding *Salvia divinorum* and continues to consult with key stakeholders, including health officials in other countries, and law enforcement officials here at home. This will assist in determining the most appropriate strategy to manage the risks associated with the use of *Salvia divinorum* and to control the availability of this substance.

### **Need More Info?**

For information about Health Canada's Drug Strategy and Controlled Substances Programme Directorate (however, still says Programme on HC website), go to:

<http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hecs-dgsesc/dscsp-psasc/index-eng.php>

Cheryl Tremblay - Comments

Also, see the section on Prevention on the Government of Canada's National Anti-Drug Strategy Web site at: <http://www.nationalantidrugstrategy.gc.ca/>. This site has a number of helpful resources for parents, including "Tips on Talking to Your Teenager" and "What to do if Your Teen is using Drugs."

For more on the surveys that are collecting information about *Salvia divinorum* use in Canada, see:

The Ontario Student Drug Use and Health Survey, at: <http://www.camh.net/Research/osdus.html>  
The 2008-2009 Youth Smoking Survey, at:  
[http://www.yss.uwaterloo.ca/ysssite\\_app/controller/index.cfm](http://www.yss.uwaterloo.ca/ysssite_app/controller/index.cfm)

The order of the two surveys listed above should be reversed to reflect the order that they appear in the document.

Include reference to 2008 Canadian Alcohol and Drug Use Monitoring Survey if added above.

Also, see the following Web sites:

U.S. Drug Enforcement Administration: Drugs and Chemicals of Concern: *Salvia divinorum* and Salvinorin A at: [http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)

U.S. Department of Health & Human Services, National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006 at:  
<http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf>

~~For additional articles on health and safety issues go to the *It's Your Health* Web site at:  
<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/index-eng.php>~~

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

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**Contacts:** Jocelyn Kula, Cheryl Tremblay, Brittany Sauvé (HECSB)  
Valery Hurry (NHPD - HPFB)  
No input from MHPD, but draft is being sent to Scott Jordan for review

Valerie Hurry - Comments

## **Salvia Divinorum**

### **The Issue**

Certain Web sites are promoting the use of *Salvia divinorum* as a “legal” alternative to street drugs. Health Canada recommends that you avoid using this substance because very little is known about the extent of adverse effects, and there is no way to predict how it will affect you.

### **Background**

*Salvia divinorum* is a species of sage that belongs to the mint family. It is known to have psychotropic effects, which means it is capable of acting on the mind.

The leaves of this plant are used traditionally by the Mazatec Indians in Mexico for medicinal and spiritual purposes. Traditional use involves chewing the leaves or using them to make tea to treat such conditions as headache or stomach upset, or to produce “mystical” or hallucinogenic experiences.

Products that claim to contain *Salvia divinorum* – or its main active ingredient, Salvinorin A – are widely available on the Internet and are sold in various “head shops” and corner stores. These products are sold in a number of formats, including seeds; and plant cuttings for propagation purposes. ~~†Fresh or dried leaves and liquid extracts;~~ are intended to be either chewed, swallowed or smoked; liquid preparations are also available for consumption. Street names for *Salvia divinorum* include: diviner’s sage, Magic mint, Maria pastra, puff encens special, ska pastora, ska Maria pastora, Sally D, Lady Sally and Salvia.

~~Recently, there have been reports suggesting that Canadian teens and young adults are using *Salvia divinorum* to get “high,” but so far, there has been no solid research in Canada on actual use.~~

Health Canada has not approved any ~~Salvia~~ *Salvia divinorum* products for sale in Canada.

Several countries (e.g., Australia, Belgium, Denmark, Sweden, Italy, Spain, Finland and South Korea) have placed controls on the import and/or sale of *Salvia divinorum*. ~~A number of individual states have done this as well, but~~ *Salvia divinorum* It is not regulated under the *Controlled Substances Act* in the United States but a number of individual states have placed restrictions on its sale.

### **Risks associated with using *Salvia Divinorum***

The use of *Salvia divinorum* distorts reality. The effects vary from person to person, are often described as unpleasant, and may include the following:

- hallucinations (“seeing” objects that are not there);

### Valerie Hurry - Comments

- out-of-body experiences;
- loss of consciousness;
- short-term memory loss;
- uncontrollable laughter;
- impaired ability to speak.

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one experience to the next, depending on such factors as the potency of the product, how much was used, whether it was ingested or smoked, and the user's mood and expectations. It does not appear to cause the euphoria often associated with other psychoactive drugs, so many people who try it do not repeat the experience.

A major concern about *Salvia divinorum* is the fact that there have been so few scientific studies about the way it affects the body and the brain. For example, very little is known about the following issues:

- whether it is toxic;
- precisely how it acts on the brain;
- how long it acts on the brain and whether there are permanent effects;
- whether it causes physical or psychological dependence (unlikely according to the evidence available so far);
- how it interacts with other substances (including drugs and alcohol).

Also, since no *Salvia divinorum* products have been approved for sale in Canada, products that claim to contain this substance have not been reviewed by Health Canada. As such, they may be counterfeit or may contain other ingredients that pose risks to health. In cases like this, it is always a matter of "buyer beware."

---

### The Legal Status of *Salvia divinorum*

From time to time, Health Canada is asked why *Salvia divinorum* and Salvinorin A are not prohibited under the *Controlled Drugs and Substances Act* (CDSA). When assessing whether to regulate a substance under the CDSA, Health Canada considers many factors, including the following:

- international requirements and trends in controlling the substance;
- similarity to other substances already regulated under the CDSA;
- whether there may be legitimate uses of the substance (e.g., potential health benefits);
- the potential for addiction and abuse/misuse of the substance;
- the extent of actual abuse and misuse of the substance in Canada and elsewhere;
- overall risk to public health and safety posed by the substance.

In the case of *Salvia divinorum*, there is simply not enough information available to determine whether prohibition is the best option to manage risks. ~~To date, no law enforcement agencies have advised Health Canada that the use of *Salvia divinorum* poses any particular threat to public~~

## Valerie Hurry - Comments

~~safety. However, as noted earlier, very little is known about the potential for addiction or the extent of actual use.~~

Questions about the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. The survey results will help fill some of the information gaps, but the data will not likely be available until 2010.

### **Minimizing Your Risk**

Health Canada recommends that you avoid using *Salvia divinorum*. Also, if you have children, talk to them about peer pressure and the risks of using drugs and other substances that distort reality. (See the "Need More Info?" section below for links to resources that can help you with this.)

Also, remember that just because a product is "natural," this does not mean it is safe. Natural Health Products that have been approved by Health Canada will have one of the following:

- a Natural Product Number (NPN) or
- a Drug Identification Number - Homeopathic Medicine (DIN-HM)

reversed order of NPN and DIN-HM

These numbers indicate that the product's quality, safety and efficacy, including labelling and instructions for use, have been reviewed. As stated earlier, no *Salvia divinorum* products have been approved by Health Canada.

---

### **Health Canada's Role**

Health Canada continues to collect and consider information regarding *Salvia divinorum* and continues to consult with key stakeholders, including health officials in other countries, and law enforcement officials here at home. This will assist in determining the most appropriate strategy to manage the risks associated with the use of *Salvia divinorum* and to control the availability of this substance.

### **Need More Info?**

For information about Health Canada's Drug Strategy and Controlled Substances Programme, go to: <http://www.hc-sc.gc.ca/ahc-asc/branch-dirigen/hecs-dgsesc/dscsp-psasc/index-eng.php>

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Valerie Hurry - Comments

For more on the surveys that are collecting information about *Salvia divinorum* use in Canada, see:

The Ontario Student Drug Use and Health Survey, at: <http://www.camh.net/Research/osdus.html>  
The 2008-2009 Youth Smoking Survey, at:  
[http://www.yss.uwaterloo.ca/ysssite\\_app/controller/index.cfm](http://www.yss.uwaterloo.ca/ysssite_app/controller/index.cfm)

Also, see the following Web sites:

U.S. Drug Enforcement Administration: Drugs and Chemicals of Concern: *Salvia divinorum* and Salvinorin A at: [http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)

U.S. Department of Health & Human Services, National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006 at:  
<http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf>

For additional articles on health and safety issues go to the *It's Your Health* Web site at:  
<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/index-eng.php>

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Version/date: Draft One, February 5, 2009

Contacts: Jocelyn Kula, Cheryl Tremblay, Brittany Sauvé (HECSB)  
Valery Hurry (NHPD - HPFB)  
No input from MHPD, but draft is being sent to Scott Jordan for review



Some reports indicate that the consumption of salvia can ~~cause~~ adverse effects like

Q: What network about some comment like "A street" names Salvia Ann, Diviner's Sage, Nir

### Salvia Divinorum

#### The Issue

① Add websites (alone word)   
 ② Certain websites are promoting the use of *Salvia divinorum* (*S. divinorum*) as a "legal" alternative to street drugs. Health Canada recommends that you avoid using this substance because very little is known about ~~the extent of adverse effects~~, and there is no way to predict how it will affect you.   
 how it acts on the brain,

#### Background

*Salvia divinorum* is a species of sage that belongs to the mint family. ~~It is known to have psychotropic effects, these are effects on the mind.~~

Wait bring water

The leaves of this plant ~~are~~ used traditionally by the Mazatec Indians in Mexico for medicinal and spiritual purposes. Traditional use involves chewing the leaves or using them to make a tea to treat such conditions as headache or stomach upset, or to produce a "mystical" or hallucinogenic experiences.   
 induce what about natural stores etc?

① Products that claim to contain *S. divinorum* – or its main active ingredient, salvinorin A – are widely available on the Internet and are sold in various "head shops". These products are sold in a number of formats, including seeds, plant cuttings for propagation purposes. Fresh or dried leaves are intended to be either chewed, swallowed or smoked; liquid preparations are also available for consumption. Street names for *S. divinorum* include: diviner's sage, magic mint, maria pastra, puff encens special, ska pastora, ska maria pastora, sally D, lady sally and salvia.

this could not be a statement in place of other line

Recently, there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* specifically for its ability to produce hallucinations (i.e. "seeing" objects that are not there), but so far, there has been no solid research in Canada on its actual use.

Questions about the use of *S. divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. The survey results will help fill some of the information gaps, but the data will not be available until 2010. (2008 Canadian Alcohol and Drug Use Monitoring Survey too?)   
 to HC role

see note below

Health Canada has not approved any *Salvia divinorum* products for sale in Canada. In Canada, neither *S. divinorum* nor salvinorin A are controlled, under the *Controlled Drugs and Substances Act*. *Salvia divinorum* does meet the definition of a natural health product under the *Natural Health Product Regulations*, which means that a product that contains *Salvia divinorum* must be approved by Health Canada prior to being sold in Canada. Health Canada has, however, not approved any *Salvia* products for sale in Canada.

para is repetitive and quite frankly confusing also goes better with the legal status   
 Several countries (e.g., Australia, Belgium, Denmark, Sweden, Italy, Spain, Finland and South Korea) have placed controls on the import and/or sale of *S. divinorum*. A number of individual

- Comment: Comments are ... [1]
- Comment: BS - All com ... [2]
- Comment: BS ... [3]
- Deleted: which means it ... [4]
- Comment: VH
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- Comment: BS - I am not ... [5]
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- Comment: VH, CT - Dis ... [6]
- Deleted: ,
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- Deleted: and liquid extracts, and
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- Comment: CT - Moved ... [7]
- Comment: CT - only gen ... [8]
- Comment: CT - Remove
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- Deleted: in Canada
- Comment: CT
- Deleted: alvia

Note: Order of background is very confusing and has no "flow" to it ... would suggest starting with eliminating some info that is really not background but more about HC's role etc/ legal status   
 (can't see SWEL questions like this!!)

Move 1 and 2 to Legal Status

1  
2

U.S. States have done this as well, but *S. divinorum* is not federally regulated under the *Controlled Substances Act* in the United States.

In the United States, salvia is ~~not regulated under the *Controlled Substances Act* in the United States~~ although a number of individual states have placed restrictions on its sale and/or import, e.g. add

**Risks Associated with Using *Salvia Divinorum***

*Salvia divinorum* acts as a hallucinogen which means that it distorts reality. The effects vary from person to person, are often described as unpleasant and may include the following:

- hallucinations
- out-of-body experiences
- loss of consciousness
- short-term memory loss
- uncontrollable laughter
- impaired ability to speak

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product
- how much is used
- how it is taken (e.g. ingested or smoked)
- the person's mood and expectations

It does not appear to cause the euphoria often associated with other psychoactive drugs, so many people who try it do not repeat the experience.

A major concern about *S. divinorum* is the fact that there have been so few scientific studies about the way it affects the body and the brain. For example, very little is known about the following issues:

- how it affects the brain and if it causes permanent damage
- whether it causes physical dependence or addiction (unlikely according to the evidence available so far)
- how it interacts with other substances (including drugs and alcohol)

Also, since no *S. divinorum* products have been approved for sale in Canada, and thus have not been reviewed by Health Canada, they may be counterfeit or may contain other ingredients that pose risks to health.

**The Legal Status of *Salvia Divinorum***

From time to time, Health Canada is asked why *S. divinorum* and salvinorin A are not prohibited under the *Controlled Drugs and Substances Act* (CDSA). When assessing whether to regulate a substance under the CDSA, Health Canada considers many factors, including the following:

Comment: CT
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Comment: VH, CT - Valerie has suggested revising above sentence as follows. Agree with re-order, but not with reference only to restrictions on sale as some U.S. states have placed import restrictions as well.
Deleted: alvia
Comment: VH, CT - Agree
Comment: CT - placed ... [14]
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Deleted: f... [24]
Comment: BS
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Comment: CT
Deleted: alvia... product... [25]
Comment: CT
Deleted: . As such
Deleted: In cases like th... [26]
Deleted: alvia... S ... [27]

Salvia

too complicated for this doc

would start with clear statement about fact that not regulated as uncontrolled substance at the present time. States in other countries then move to

Also need to explain whole meets a

factors:

- international requirements and trends in controlling the substance
- similarity to other substances already regulated under the CDSA
- whether there may be legitimate uses of the substance (e.g., potential health benefits)
- the potential for addiction and abuse/misuse of the substance
- the extent of actual abuse and misuse of the substance in Canada and elsewhere
- overall risk to public health and safety posed by the substance

In the case of *S. divinorum*, there is simply not enough information available to determine whether prohibition is the best option to manage the potential risks associated with its use. Questions about the use of *S. divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. The survey results will help fill some of the information gaps, but the data will not be available until 2010.

### Minimizing Your Risk

Health Canada recommends that you avoid using *S. divinorum*. Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs and other substances that distort reality. (See the "Need More Info?" section below for links to resources that can help you with this.)

Also, remember that just because a product is "natural," this does not mean it is safe. Natural Health Products that have been approved by Health Canada will have one of the following:

- a Natural Product Number (NPN) or
- a Drug Identification Number - Homeopathic Medicine (DIN-HM)

These numbers let you know that the products have undergone and passed a review of their formulation, labelling and instructions for use. As stated earlier, no *S. divinorum* products have been approved by Health Canada.

### Health Canada's Role

Health Canada continues to collect and consider information regarding *Salvia divinorum* and continues to consult with key stakeholders, including health officials in other countries, and law enforcement officials here at home. This will assist in determining the most appropriate strategy to manage the risks associated with the use of *S. divinorum* and to control the availability of this substance.

### Need More Info?

For information about Health Canada's Drug Strategy and Controlled Substances Directorate, go to: <http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hecs-dgsesc/dscsp-psasc/index-eng.php>

Also, see the section on Prevention on the Government of Canada's National Anti-Drug Strategy Web site at: <http://www.nationalantidrugstrategy.gc.ca/>. This site has a number of helpful

repeats  
at more  
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drug plant-based or

be labelled with

a product has a rigorous  
infacts

containing  
*S. divinorum*

Add sentence re. surveys...

<b>Deleted:</b> <i>alvia</i>
<b>Comment:</b> CT
<b>Comment:</b> VH - Suggested removing this sentence all together.
<b>Comment:</b> BS - This sentence sounds odd a bit because its not just law enforcement that can judge public safety
<b>Deleted:</b> To date, no law enforcement agencies have advised Health C
<b>Deleted:</b> anada that the use of <i>Salvia divinorum</i> poses any particular threat to public safety. However, as noted earlier, very little is known about the potential for addiction or the extent of actual use.
<b>Deleted:</b> <i>alvia</i>
<b>Comment:</b> CT - Suggest moving this to Background section after sentence, "there has been no solid research in Canada on its actual use."
<b>Deleted:</b> likely
<b>Deleted:</b> <i>alvia</i>
<b>Comment:</b> BS CT - Disagree - <i>Salvia</i> is legal.
<b>Deleted:</b> <#>a Drug Identification Number - Homeopathic Medicine (DIN-HM) or¶
<b>Comment:</b> VH - Reversed order
<b>Formatted:</b> Indent: Left: 0 cm, Hanging: 1.27 cm, Bulleted + Level: 1 + Aligned at: 0 cm + Tab after: 0 cm + Indent at: 0 cm
<b>Deleted:</b> <i>Salvia</i>
<b>Formatted:</b> Font: Italic
<b>Formatted:</b> Font: Italic
<b>Deleted:</b> <i>alvia</i>
<b>Comment:</b> CT - However, still says Programme on HC website.
<b>Deleted:</b> Programme

resources for parents, including “Tips on Talking to Your Teenager” and “What to do if Your Teen is using Drugs.”

For more on the surveys that are collecting information about *Salvia divinorum* use in Canada, see:

The Ontario Student Drug Use and Health Survey, at: <http://www.camh.net/Research/osdus.html>  
The 2008-2009 Youth Smoking Survey, at:  
[http://www.yss.uwaterloo.ca/ysss/site\\_app/controller/index.cfm](http://www.yss.uwaterloo.ca/ysss/site_app/controller/index.cfm)

**Comment:** Reverse order - Should be listed in order that they appear in text.

2008 Canadian Alcohol and Drug Use Monitoring Survey

**Comment:** CT - Add reference if included above.

Also, see the following Web sites:

U.S. Drug Enforcement Administration: Drugs and Chemicals of Concern: *Salvia divinorum* and Salvinorin A at: [http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)  
U.S. Department of Health & Human Services, National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006 at:  
<http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf>

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<http://www.hc-sc.gc.ca/english/iyh/index.html>

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

← do we need this?

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**Comment:** CT

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<b>Page 1: [1] Comment</b>	<b>CTREMBLA</b>	<b>2009-02-17 8:59 AM</b>
Comments are identified by colour as follows: Brittany Sauvé (DSCSD), Cheryl Tremblay (DSCSD), Valerie Hurry (NHPD)		
<b>Page 1: [2] Comment</b>	<b>CTREMBLA</b>	<b>2009-02-17 8:59 AM</b>
BS – All comments on <i>S. divinorum</i> . CT – I think that we should use full name throughout document.		
<b>Page 1: [3] Comment</b>	<b>CTREMBLA</b>	<b>2009-02-17 8:59 AM</b>
BS CT - or “which means it is capable of having an influence on the mind”?		
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which means it is capable of acting on the mind.		
<b>Page 1: [5] Comment</b>	<b>CTREMBLA</b>	<b>2009-02-17 8:59 AM</b>
BS - I am not sure that this is appropriate? Mainly herbal shops I think... right? CT - Agree		
<b>Page 1: [6] Comment</b>	<b>CTREMBLA</b>	<b>2009-02-17 8:59 AM</b>
VH, CT – Disagree - too technical for laymans terms.		
<b>Page 1: [7] Comment</b>	<b>CTREMBLA</b>	<b>2009-02-17 8:59 AM</b>
CT – Moved from Legal Status of Salvia section.		
<b>Page 1: [8] Comment</b>	<b>CTREMBLA</b>	<b>2009-02-17 8:59 AM</b>
CT- only general open-ended question not specific to Salvia.		
<b>Page 1: [9] Comment</b>	<b>CTREMBLA</b>	<b>2009-02-17 8:59 AM</b>
CT- Reversed order, sounded a little confusing to me.		
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Health Canada has not approved any Sa		
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lvia products for sale in Canada. However		
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s		
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<i>alvia</i>		
<b>Page 2: [14] Comment</b>	<b>CTREMBLA</b>	<b>2009-02-17 8:59 AM</b>
CT – placed above instead		
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("seeing" objects that are not there)		
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experience		
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such		
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<b>Page 2: [20] Deleted</b> .	<b>CTREMBLA</b>	<b>2009-02-06 2:05 PM</b>
<b>Page 2: [21] Comment</b> BS - Every thing is toxic	<b>CTREMBLA</b>	<b>2009-02-17 8:59 AM</b>
<b>Page 2: [22] Formatted</b> Indent: Left: 0 cm, Hanging: 1.27 cm, Bulleted + Level: 1 + Aligned at: 0 cm + Tab after: 0 cm + Indent at: 0 cm	<b>CTREMBLA</b>	<b>2009-02-06 2:09 PM</b>
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<b>Page 2: [23] Deleted</b> acts on	<b>CTREMBLA</b>	<b>2009-02-06 2:08 PM</b>
<b>Page 2: [24] Deleted</b>  how long it acts on the brain and whether there are permanent effects	<b>CTREMBLA</b>	<b>2009-02-06 2:09 PM</b>
<b>Page 2: [25] Deleted</b> <i>alvia</i>	<b>CTREMBLA</b>	<b>2009-02-06 2:11 PM</b>
<b>Page 2: [25] Deleted</b> products that claim to contain this substance	<b>CTREMBLA</b>	<b>2009-02-13 8:38 AM</b>
<b>Page 2: [26] Deleted</b> In cases like this, it is always a matter of "buyer beware."	<b>CTREMBLA</b>	<b>2009-02-06 2:11 PM</b>
<b>Page 2: [27] Deleted</b> <i>alvia</i>	<b>CTREMBLA</b>	<b>2009-02-06 2:12 PM</b>
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Cheryl,

This is interesting and I  
have to be honest and  
say I have a lot of  
comments - mostly on  
organization and flow.

Let's discuss how to relay  
to Sue L. b/c you should  
not have to write the  
doc for her

JK.



## Salvia Divinorum

### The Issue

Certain websites are also promoting the use of *Salvia divinorum* (*S. divinorum*) as a "legal" alternative to street drugs. Health Canada recommends that you avoid using this substance because very little is known about how it acts on the brain, and there is no way to predict how it will affect you.

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### Background

Note: <sup>We feel that</sup> the Background section would flow better if some of the information <sup>was moved</sup> that is better suited to other sections in the document, <sup>was moved</sup>. Please see suggestions <sup>in comments on</sup> <sup>RT side.</sup>

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- Comment: Suggest moving to Risks section.
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*S. divinorum* is a species of sage that belongs to the mint family. It is known to have psychotropic effects, which means it is capable of acting on the mind. (Risks)

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The leaves of this plant have been used traditionally by the Mazatec Indians in Mexico for medicinal and spiritual purposes. Traditional use involves chewing the leaves or using them to make a tea to treat such conditions as headache or stomach upset, or to induce a "mystical" or hallucinogenic experience.

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Products that claim to contain *S. divinorum* – or its main active ingredient, salvinorin A – are widely available on the Internet and are sold in various "head shops" and natural food stores, etc. These products are sold in a number of formats, including seeds, and plant cuttings for propagation purposes. Fresh or dried leaves are intended to be either chewed, swallowed or smoked; liquid preparations are also available for consumption. Street names for *S. divinorum* include: diviner's sage, Magic mint, Maria pastra, puff encens special, ska pastora, ska Maria pastora, Sally D, Lady Sally and Salvia. (Issue)

Recently, there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* specifically for its ability to produce hallucinations (i.e. "seeing" object that are not there). (Issue)

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- Comment: Suggest moving to The Issue section.

Health Canada has not approved any *S. divinorum* products for sale in Canada. However, neither *S. divinorum* nor salvinorin A are controlled in Canada under the *Controlled Drugs and Substances Act*. (Legal)

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Several countries (e.g., Australia, Belgium, Denmark, Sweden, Italy, Spain, Finland and South Korea) have placed controls on the import and/or sale of *S. divinorum*. In the United States, *S. divinorum* is not regulated under the *Controlled Substances Act*, although a number of individual states have placed restrictions on its sale and/or import. For example, several states have placed *S. divinorum* and/or salvinorin A into Schedule I of state law, thereby making it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have enacted other forms of legislation restricting distribution of the plant. (Legal)

- Comment: Suggest moving to Legal Status section.
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Issue

### Risks Associated With Using *Salvia Divinorum*

*S.* acts as a hallucinogen, which means that it distorts reality. The effects, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations
- out-of-body experiences
- loss of consciousness
- short-term memory loss
- uncontrollable laughter
- impaired ability to speak

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product
- how much is used
- how it is taken (e.g. ingested or smoked)
- the user's mood and expectations.

*S. divinorum* does not appear to cause the euphoria often associated with other psychoactive drugs, so many people who try it do not repeat the experience.

A major concern about *S. divinorum* is the fact that there have been so few scientific studies about the way it affects the body and the brain. For example, very little is known about the following:

- how it affects the brain and if it causes permanent damage
- whether it causes physical dependence or addiction
- how it interacts with other substances (including other drugs and alcohol)

Also, since no *S. divinorum* products have been approved for sale in Canada, products that claim to contain this substance have not been reviewed by Health Canada. As such, they may be counterfeit or may contain other ingredients that pose risks to health. In cases like this, it is always a matter of "buyer beware." (Remove)

### The Legal Status of *Salvia Divinorum*

Note: Would start with a clear statement about the fact that *Salvia divinorum* is not regulated as a controlled substance in Canada at the present time and then would move to status in other countries. We also need to explain the fact that *Salvia divinorum* meets the definition of a natural health product under the *Natural Health Product Regulations*, but no NHPs containing *Salvia divinorum* have been approved.

From time to time, Health Canada is asked why *S. divinorum* and salvinorin A are not prohibited under the *Controlled Drugs and Substances Act* (CDSA). When assessing whether to regulate a

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Comment: Suggest removing sentence all together.

substance under the *Controlled Drugs and Substances Act* (CDSA), Health Canada considers the following factors:

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- international requirements and trends in controlling the substance
- similarity to other substances already regulated under the CDSA
- whether there may be legitimate uses of the substance (e.g., potential health benefits)
- the potential for addiction and abuse/misuse of the substance
- the extent of actual abuse and misuse of the substance in Canada and elsewhere
- overall risk to public health and safety posed by the substance

In the case of *S. divinorum*, there is simply not enough information available to determine whether prohibition is the best option to manage the potential risks associated with its use. To date, no law enforcement agencies have advised Health Canada that the use of *Salvia divinorum* poses any particular threat to public safety. However, as noted earlier, very little is known about the potential for addiction or the extent of actual use. (Remove)

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Comment: Suggest removing this sentence as it is not just law enforcement that is responsible for judging public safety.

Questions about the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. The survey results will help fill some of the information gaps, but the data will not likely be available until 2010. (HC's Role)

Comment: Suggest moving to HC's Role section.

### Minimizing Your Risk

Health Canada recommends that you avoid using *S. divinorum*. Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs and other substances that distort reality. (See the "Need More Info?" section below for links to resources that can help you with this.)

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Also, remember that just because a drug is plant-based or "natural," does not mean it is safe. Natural health products that have been approved by Health Canada will be labelled with one of the following:

- a Drug Identification Number - Homeopathic Medicine (DIN-HM) or
- a Natural Product Number (NPN)

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Comment: Suggest reversing order of DIN-HM and NPN.

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These numbers let you know that a product has undergone a rigorous review of formulation, labelling and instructions for use. In fact, no products containing *S. divinorum* have been approved by Health Canada.

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### Health Canada's Role

Health Canada continues to collect and consider information regarding *S. divinorum* and continues to consult with key stakeholders, including health officials in other countries, and law enforcement officials here at home. This will assist in determining the most appropriate strategy to manage the risks associated with the use of *S. divinorum*.

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**Need More Info?**

For information about Health Canada's Drug Strategy and Controlled Substances Directorate, go to: <http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hecs-dgsesc/dscsp-psasc/index-eng.php>

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Also, see the section on Prevention on the Government of Canada's National Anti-Drug Strategy Web site at: <http://www.nationalantidrugstrategy.gc.ca/>. This site has a number of helpful resources for parents, including "Tips on Talking to Your Teenager" and "What to do if Your Teen is using Drugs."

For more on the surveys that are collecting information about *S. divinorum* use in Canada, see:

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The Ontario Student Drug Use and Health Survey, at: <http://www.camh.net/Research/osdus.html>  
The 2008-2009 Youth Smoking Survey, at: [http://www.yss.uwaterloo.ca/ysssite\\_app/controller/index.cfm](http://www.yss.uwaterloo.ca/ysssite_app/controller/index.cfm)

Comment: Suggest reversing order to match order they appear in document.

**Additional Resources:**

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U.S. Drug Enforcement Administration: Drugs and Chemicals of Concern: *Salvia divinorum* and Salvinorin A at: [http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)  
U.S. Department of Health & Human Services, National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006 at: <http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf>

For additional articles on health and safety issues go to the *It's Your Health* Web site at: <http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/index-eng.php>  
<http://www.hc-sc.gc.ca/english/iyh/index.html>

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

Comment: Is this standard to all IYH Articles?

Original:

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Catalogue#  
ISBN#

Writer: Sue Lumsden [redacted]

Version/date: Draft One, February 5, 2009

Contacts: Jocelyn Kula, Cheryl Tremblay, Brittany Sauvé (HECSB)  
Valerie Hurry (NHPD - HPFB)  
No input from MHPD, but draft is being sent to Scott Jordan for review

Deleted: y




Brittany  
Sauvé/HC-SC/GC/CA  
2009-02-05 02:48 PM

To Cheryl Tremblay/HC-SC/GC/CA@HWC  
cc  
bcc

Subject Re: Fw: Top 5 Recreational Drug Experiments-Salvia 

History:

 This message has been forwarded.

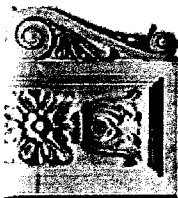
Yeah, I remember going over that in my head the last chance we got before these were finalized and what I should do in regards to that... But in hindsight, I would take it out. See my comments below.

**Q1 – If Health Canada is aware of *Salvia divinorum* 's ill-effects, why isn't it illegal?**

A - Human studies that demonstrate reliable, systematic and controlled observations on the physical and psychotropic effects of *Salvia divinorum* are sparse, and using these studies to predict its potential for addiction and abuse is difficult . The information currently available to Health Canada indicates that the likelihood of abuse/misuse of *Salvia divinorum* is unknown? (if we want to be really picky, I also addressed this in my report... and based on its pharmacology, this is not *unknown*. We know that it is a KOR agonist and by virtue of that should be a low abuse liability), ~~t hat the mechanism of action by which *Salvia divinorum* works is still not fully understood~~, and that more controlled systematic research in this area is needed.

~~The mechanism of action by which *Salvia divinorum* works is not fully understood.~~ (It was in this context that I felt there was some play... because people have very different experiences on the drug which have led to the idea that there might be more than just KOR at play.. .or salviorin... But yes, just take it out). While some users have reported that the psychotropic effects of *Salvia divinorum* resemble those induced by other hallucinogens such as LSD and phencyclidine, the overall experience is quite unique.

Cheryl Tremblay/HC-SC/GC/CA



Cheryl  
Tremblay/HC-SC/GC/CA  
05/02/2009 02:03 PM

To Brittany Sauvé/HC-SC/GC/CA@HWC  
cc

Subject Fw: Top 5 Recreational Drug Experiments-Salvia

Hi Brittany,

I just wanted to get your opinion on whether you think the following article warrants us changing our line in media lines re: "the mechanism of action by which *Salvia divinorum* works is still not fully understood"?

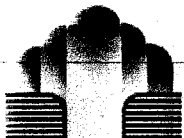


Willmore et al\_2007.pdf

Thanks,

Cheryl Tremblay  
Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Drug Strategy and Controlled Substances Directorate  
Health Canada  
Tel: (613) 954-6527  
Fax: (613) 946-4224

----- Forwarded by Cheryl Tremblay/HC-SC/GC/CA on 2009-02-05 01:56 PM -----



Jocelyn Kula/HC-SC/GC/CA

2009-01-02 09:28 AM

To Cheryl Tremblay/HC-SC/GC/CA@HWC

cc

Subject Fw: Top 5 Recreational Drug Experiments-Salvia

Ronald sent me this, and I wonder if you can confirm that the Neuropharmacology paper mentioned below is one we have in our files; just means we perhaps have to be less equivocal with respect to mechanism of action now, i.e., not sure what our media lines say but I thought we had something in there about not being sure how salvia works??

pls follow up and change lines if necessary- now is the time given that they are still in approvals.....

will also be important for IAS

JK

---

Jocelyn Kula  
Manager, Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Healthy Environments and Consumer Safety Branch  
Health Canada  
Tel: (613) 946-0125 Fax: (613) 946-4224

----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2009-01-02 09:26 AM -----



Ronald  
Denault/HC-SC/GC/CA

2008-12-31 01:34 PM

To Jocelyn Kula/HC-SC/GC/CA

cc

Subject Top 5 Recreational Drug Experiments-Salvia

<http://blog.wired.com/wiredscience/2008/04/top-5-recreatio.html#previouspost>

Check #3

Ronald



Brittany  
Sauvé/HC-SC/GC/CA  
2009-02-05 02:31 PM

To Cheryl Tremblay/HC-SC/GC/CA@HWC  
cc  
bcc

Subject Re: Fw: Top 5 Recreational Drug Experiments-Salvia

History: This message has been forwarded.

Yes, I know where you are coming from. This is something that I have struggled with too as it's an oversimplification of the information. In my report you will see that I say that the mechanism of action of salvinorin A is as a potent KOR agonist. This is not really new information... the paper you send reinforces its action as an agonist on that receptor. What is unknown is if this exactly how it exerts its action as a psychomimetic... that is still up in the air... given people's individual responses/experiences on the drug.

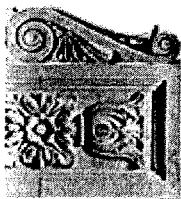
I will have a look at this... I know that it was in the media lines and I questioned whether or not it should stay that way. I don't believe I took it out... Upon looking at it again, I think that you might be right... it might be an oversimplification that leads people to think that there is no information around this that exists... when for salvinorin A the information is clear.

When i review the document I will decide how to present that...

Thank you for the question... it's definitely an issue... and plain language is never kind to our scientific documents!

Brittany

Cheryl Tremblay/HC-SC/GC/CA



Cheryl  
Tremblay/HC-SC/GC/CA  
05/02/2009 02:03 PM

To Brittany Sauvé/HC-SC/GC/CA@HWC  
cc

Subject Fw: Top 5 Recreational Drug Experiments-Salvia

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Willmore et al\_2007.pdf

Thanks,  
Cheryl Tremblay  
Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Drug Strategy and Controlled Substances Directorate  
Health Canada  
Tel: (613) 954-6527  
Fax: (613) 946-4224

----- Forwarded by Cheryl Tremblay/HC-SC/GC/CA on 2009-02-05 01:56 PM -----



Jocelyn Kula/HC-SC/GC/CA

2009-01-02 09:28 AM

To Cheryl Tremblay/HC-SC/GC/CA@HWC

cc

Subject Fw: Top 5 Recreational Drug Experiments-Salvia

Ronald sent me this, and I wonder if you can confirm that the Neuropharmacology paper mentioned below is one we have in our files; just means we perhaps have to be less equivocal with respect to mechanism of action now, i.e., not sure what our media lines say but I thought we had something in there about not being sure how salvia works??

pls follow up and change lines if necessary- now is the time given that they are still in approvals.....

will also be important for IAS

JK

---

Jocelyn Kula  
Manager, Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Healthy Environments and Consumer Safety Branch  
Health Canada

Tel: (613) 946-0125 Fax: (613) 946-4224

----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2009-01-02 09:26 AM -----



Ronald  
Denault/HC-SC/GC/CA

2008-12-31 01:34 PM

To Jocelyn Kula/HC-SC/GC/CA

cc

Subject Top 5 Recreational Drug Experiments-Salvia

<http://blog.wired.com/wiredscience/2008/04/top-5-recreatio.html#previouspost>

Check #3

Ronald





Available online at [www.sciencedirect.com](http://www.sciencedirect.com)

 ScienceDirect

Neuropharmacology 53 (2007) 481–486

**NEURO**  
PHARMACOLOGY

[www.elsevier.com/locate/neuropharm](http://www.elsevier.com/locate/neuropharm)

## The hallucinogen derived from *Salvia divinorum*, salvinorin A, has $\kappa$ -opioid agonist discriminative stimulus effects in rats

Catherine B. Willmore-Fordham<sup>a,\*</sup>, Daniel M. Krall<sup>a</sup>, Christopher R. McCurdy<sup>b</sup>,  
David H. Kinder<sup>a</sup>

<sup>a</sup> Ohio Northern University, Department of Pharmaceutical and Biomedical Sciences, Raabe College of Pharmacy,  
525 S. Main Street, Ada, OH 45810, USA

<sup>b</sup> University of Mississippi, Department of Medicinal Chemistry, School of Pharmacy, P.O. Box 1848, University, MS 38677, USA

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### Abstract

Data from clinical and preclinical studies converge implicating the plant-derived hallucinogen salvinorin A as an important pharmacologic tool; this psychoactive compound may expand scientific understandings on mammalian  $\kappa$ -opioid receptor systems. Human salvinorin A effects, consistent with  $\kappa$ -opioid receptor agonism, include antinociception, sedation, dysphoria and distorted perceptions. The experiments reported here measured salvinorin A (1–3 mg/kg, i.p.) discriminative stimulus properties in male Sprague–Dawley rats conditioned to recognize the discriminative stimulus cue generated by the well characterized  $\kappa$ -opioid agonist U-69593 (0.56 mg/kg, i.p.). At three distinct active doses, salvinorin A fully substituted for U-69593 without altering response rates. The lever choice pattern in U-69593 trained animals reverted to vehicle lever responding when a kappa selective antagonist compound, nor-BNI (4.5 nM, i.c.v.) was administered 1 h prior to salvinorin A, yet nor-BNI alone failed to impact the rate or pattern of subject responses. These findings confirm and extend results published after similar drug discrimination tests were performed in rhesus monkeys. The discussion section of this article highlights public concern over salvinorin A misuse and emphasizes several potential pharmacotherapeutic applications for salvinorin A or analogue compounds.

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**Keywords:** Salvinorin A; *Salvia divinorum*; Kappa opioid; Drug discrimination; Operant conditioning

### 1. Introduction

Salvinorin A is a structurally unique furanolactone neoclerodane diterpene and is the main active drug in *Salvia divinorum*, a ‘Mexican-mint’ sage plant belonging to the Lamiaceae family. Salvinorin A is both pharmacologically and chemically unique in that it represents the first non-nitrogenous, naturally occurring  $\kappa$ -opioid receptor selective agonist and the only known non-alkaloidal hallucinogen (Roth et al., 2002). *Salvia divinorum* has a long history of use for traditional spiritual purposes by Mazatec shamans of Oaxaca, Mexico (Valdés, 1994). More recently, the leaves and extracts of *S. divinorum*

have been misused for hallucinatory and mind-expanding effects (Bucheler et al., 2005). Cultivation and purchase of *Salvia divinorum* first appeared in young people from Mexican cities and has since spread through Europe, showing that global abuse of the drug is increasing. The use or possession of *Salvia divinorum* is not banned by most countries, which draws appeal from drug users. Attraction to the drug among recreational users can be attributed to hallucinogenic effects, which in doses above 200  $\mu$ g rival the synthetic hallucinogen lysergic acid diethylamide (LSD) in doses of 50–250  $\mu$ g (Bucheler et al., 2005). *Salvia* product abusers experience a psychic depersonalization condition, a unique sensation of being disconnected from one’s body.

Currently, few studies with salvinorin A have been performed in vivo. In mice, antinociceptive effects of the drug

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were shown using tail-flick and hot plate thermal nociceptive assays (McCurdy et al., 2006). Sedation and motor incoordinating effects of the drug were also shown in mice as disrupting climbing strategies in an inverted screen task (Fantegrossi et al., 2005). A forced swim test (Carlezon et al., 2006) revealed increased immobility accompanied by decreased swimming behaviors in rats, opposite to that seen by SSRIs, suggesting that salvinorin A produces pro-depressant like effects; however, salvinorin A elicits a complex spectrum of effects on mood-related variables. Indeed, clinic data suggest salvinorin A abuse is growing *because* of the complex mindset and mood changes invoked (Bucheler et al., 2005; National Drug Intelligence Center, 2007; Halpern, 2004). When leaves of *Salvia divinorum* are chewed or smoked, exposed individuals describe an intensely positive hallucinogenic experience (e.g., altered depth perception, heightened sensual and aesthetic appreciation, creative dream-like state). At least one case report secures mood-elevating effects from salvinorin A. This case documented a 26-year-old woman, depressed according to HAM-D scores, who remitted the symptoms of her depression with *Salvia divinorum* bought through a mail-order herbalist (Hanes, 2001). In line with the clinic report of a *Salvia* derivative's mood-elevating effects, Braida et al. (2007) showed reinforcing effects in a conditioned place preference test after injecting zebra fish with salvinorin.

Drug discrimination has long proven to be a reliable, robust, and selective model to discover the behavioral effects of various compounds. Drug discrimination is also endorsed as a test to infer neurological underlays and/or receptor mediation pathways for psychoactive drugs. Drug discriminating animals are rewarded for responding appropriately (i.e., correct lever-press sequence) after either a 'training' drug or its vehicle is administered. The discriminative stimulus properties of salvinorin A were studied in rhesus monkeys by Butelman et al. (2004). The Butelman study used a well characterized  $\kappa$ -opioid agonist, U-69593, to train responses under distinguishable stimulus conditions (i.e., training drug versus vehicle sessions). Butelman et al. (2004) reported  $\kappa$ -opioid receptor mediation of salvinorin A's psychotropic effects when subcutaneous injections of salvinorin A cross generalized to U-69593. Our search of the published literature revealed no rodent drug discrimination studies to verify  $\kappa$ -opioid receptor mediation of salvinorin A's effects. To fill this research gap, a group of ten Sprague–Dawley rats were trained to recognize the discriminative stimulus effects of U-69593, and generalization tests followed to discover whether or not rats would respond similarly to the interoceptive cue generated by salvinorin A (1–3 mg/kg, i.p.). In a second series of experiments, a subgroup of the U-69593 discriminating rats received pre-session injections (i.c.v.) with the  $\kappa$ -opioid antagonist nor-BNI, before being injected with salvinorin A, to verify the proposed pharmacologic mode of action. Our expectation, as this experimental series started, was to note salvinorin A substitution for U-69593. While most in vivo and in vitro research data have supported  $\kappa$ -opioid receptor mediation of salvinorin A's central nervous system effects (Chavkin et al., 2004; Fantegrossi et al., 2005; McCurdy et al., 2006; Roth et al., 2002),

pause is taken while interpreting the findings in two non-human primate experiments where an incomplete reversal of salvinorin A effects was reported for monkeys pretreated with a  $\kappa$ -opioid receptor selective antagonist (Butelman et al., 2004, 2007).

## 2. Materials and methods

### 2.1. Subjects

Ten male Sprague–Dawley rats (Harlan Laboratories, Indianapolis, IN), weighing 280–340 g at the beginning of the experiments were subjects for this study. The rats were housed individually in plexiglass cages with free access to water in a temperature controlled room ( $23 \pm 1^\circ\text{C}$ , with humidity  $50 \pm 10\%$ ) scheduled for 12 h light/dark exposure cycles. Subjects for these experiments were drug naive and were maintained in facilities accredited by the Institutional Animal Care and Use Committee at Ohio Northern University. Rats were maintained at  $\sim 80\%$  of their free feeding body weight in order to motivate operant responding for food rewards. Effort was expended to minimize animal suffering over the course of these experiments.

### 2.2. Apparatus

Operant conditioning chambers (Lafayette Instruments) constructed with left- and right-mounted response levers and a central food cup were used. Research Diet<sup>®</sup> (Natick, MA) 45-mg rat pellets rewarded conditioned behaviors. A 15-W white house light above the chamber's transparent ceiling was lit for all sessions. Chambers were set in sound-attenuating wooden cubicles with a fan motor to provide ventilation and mask noise. ABET<sup>™</sup> software controlled the experimental environment. Repeat conditioning induced a pairing of right chamber levers (red cue-light) to drug (U-69593) injection and left chamber levers (amber cue-light) to vehicle injection.

### 2.3. Drugs

U-69593 ((5 $\alpha$ ,7 $\alpha$ ,8 $\beta$ )-(–)-N-methyl-N-[7-(pyrrolidinyl)-1-oxaspiro[4,5]-dec-8-yl]-benzeneacetamide; Sigma-Aldrich, St. Louis, MO) was dissolved in isotonic saline with 10  $\mu\text{l}$  of glacial acetic acid. Salvinorin A (isolated and purified from *Salvia divinorum* in Oxford, Mississippi (McCurdy laboratory)) was first dissolved in dimethylsulfoxide and then dissolved in isotonic saline for injection. Norbinaltorphimine dihydrochloride (nor-BNI) (Sigma-Aldrich, St. Louis, MO) was dissolved in isotonic saline. All drugs except nor-BNI were administered in a volume of 1 ml/kg. Doses were calculated as those of the bases. The doses and pre-injection intervals for U-69593, salvinorin A, and nor-BNI were selected from pilot studies or from previously published reports (McCurdy et al., 2006).

### 2.4. Administration of norbinaltorphimine into the right lateral ventricle

Six rats were anesthetized with a mixture of ketamine plus xylazine (80 mg/kg plus 12 mg/kg, i.p.; Sigma-Aldrich, St. Louis, MO) and given diazepam (10 mg/kg, i.m.). Guide cannulae were then implanted using a Stoelting (model 51400) stereotaxic frame, but coordinate measurements were taken manually with a plastic ruler. The skull was exposed, and a small hole was drilled unilaterally. The cannula was lowered to 1 mm above the target site (coordinates relative to bregma: A, –1.3; L, 1.0; V, 4.0), and, together with two additional screws, was embedded in dental cement.

The tips of the guide cannulae (25 gauge, Plastics One, VA, USA) extended beyond the skull by 1 mm. Microinjection of nor-BNI was done manually, with a Hamilton syringe, in a volume of 3  $\mu\text{l}$ . Intracerebroventricular injection (i.c.v.) doses were instilled over a 60 s period, and followed by a 2  $\mu\text{l}$  of saline flush. The injection cannula was left in place for 60 additional seconds. Although six of the ten U-69593 discriminating animals underwent surgery to implant intracerebroventricular cannulae, a nor-BNI-blocked dose effect curve for

salvinorin A was only determined in five subjects because the i.c.v. cannula dislodged from supportive dental cement in one surgically prepared animal.

## 2.5. Experimental procedure

### 2.5.1. Training with U69,593 as a discriminative stimulus

Training sessions occurred from Monday to Saturday, between 1100 and 1800 h. Early training was arranged on a double alternation schedule—daily sessions exposed all subjects three times per week to U-69593 (0.56 mg/kg) injections and three times per week to saline injections. As the right lever was arbitrarily paired with training drug, consecutive responses at the right lever (FR-10) were reinforced by the delivery of a food pellet on the days designated for U-69593 injection. Responses emitted on the opposite lever (FR-10) produced food pellet rewards on the days designated for saline injection. Injections of U-69593 or saline were given i.p. 10 min before subjects were placed into operant chambers. Responses on the incorrect lever reset the response count on the correct lever. All training sessions ended after 20 min, when animals were returned to home cages and given a sufficient quantity of Purina Laboratory Chow to sustain ~80% of their expected free-fed weight.

Drug-induced stimulus control was assumed to be present when the animals consistently selected the appropriate lever (U-69593 or vehicle) first in three vehicle plus three training-drug consecutive sessions. Our training procedure also stipulates rats must emit 80% of all lever press responses at the correct lever and a minimum of 80 lever presses must be emitted for a training session to be counted. Once this level of performance was achieved, testing with various doses of salvinorin A was initiated.

### 2.5.2. Pilot tests to resolve salvinorin A dose range

The sparse literature describing salvinorin A effects in rats made it difficult to specify an appropriate salvinorin A dosage range for substitution tests. Therefore, pilot tests were conducted to scrutinize salvinorin A effects on spontaneous locomotion and to detect dose-dependent influences on treated subjects' responsiveness to stimuli. The pilot test series consisted of six open-field observing sessions, 30 min in duration, to assess salvinorin A influences in a separate group of naive female rats with no operant conditioning history. Pilot test rats were watched in an open field environment—an exploratory environment wherein experimenters introduced cues to elicit a variety of spontaneous reactive behaviors (e.g., righting reflex, response to pencil-pokes, reaction to food stimuli). Six discrete doses of salvinorin A were assessed during pilot tests: (i) 0.1 mg/kg, (ii) 0.3 mg/kg, (iii) 1.0 mg/kg, (iv) 3.0 mg/kg, (v) 5.6 mg/kg, (vii) 10 mg/kg. Data from pilot tests suggested 0.1 mg/kg and 0.3 mg/kg as “no-effect” doses, and all doses above the 1.0 mg/kg dose produced motor incoordination during the last 15 min of observation plus dose-dependent catalepsy at times proximal to i.p. drug administration. The 5.6 mg/kg and 10 mg/kg doses also produced salivation/drooling and forelimb tremor. After completing the pilot tests and consulting the relevant literature, the 1.0–3.0 mg/kg range was considered optimal to reflect salvinorin A discriminative stimulus effects.

### 2.5.3. Discrimination tests with salvinorin A

When a rat met testing criteria for consistent U-69593 discrimination performance, test sessions were planned to present salvinorin A doses in an irregular order. Ultimately, all subjects received the range of salvinorin A doses (1.0 mg/kg, 1.9 mg/kg, and 3.0 mg/kg), but the order of dose presentations varied among subjects. Test sessions were identical to training sessions with the exception that 10 consecutive responses on either lever produced food delivery. When salvinorin A substitution tests commenced, a single alternation schedule between training drug, saline vehicle, and salvinorin A was followed. Rats were considered eligible for substitution testing only after completing two prior training sessions (U-69593 plus vehicle) at an accuracy level of at least 80% and after emitting their first response (FR10) at the correct lever. If the accuracy of trained animals deteriorated relative to stated criteria, further training sessions were given before testing was reinstated.

### 2.5.4. Discrimination tests with nor-BNI pretreatment

Following the discrimination tests with salvinorin A, similar tests were done with a pretreatment of the  $\kappa$ -opioid antagonist nor-BNI. Rats were given

nor-BNI (10 mg/ml solution, 3  $\mu$ l, i.c.v.) 60 min before the administration of salvinorin A. The discrimination tests then preceded as described above. To demonstrate stimulus control from the same training dose of U-69593, probe tests (2 min at the start of each training session) were performed with U-69593 or saline. In order to rule out the possibility that behavioral changes were due to nor-BNI during sessions of  $\kappa$ -opioid antagonist and salvinorin A co-administration, extra control sessions were scheduled for each test animal. Thus, a preliminary control session measured nor-BNI (10 mg/ml solution, 3  $\mu$ l, i.c.v.) against nor-BNI's vehicle (saline, i.c.v.). After noting that nor-BNI failed to alter behavior relative to its vehicle, a second i.p. saline control session was scheduled. Data from the i.p. saline control session was statistically analyzed against data collected in sessions of nor-BNI and salvinorin A co-administration.

## 2.6. Data analysis

Data from salvinorin A test sessions were analyzed for similarity to U-69593 by determining the mean percentage of responses on the U-69593-associated lever. An a priori decision was made to deem 80% or more U-69593-lever responding, during salvinorin A test sessions, as full generalization. In addition to monitoring U-69593 appropriate responding, the total number of lever presses in each session was recorded and response rates were tabulated to reflect non-specific effects on behavior. The response rate data were graphed after conversion to a percentage of the average saline session response rate (mean in 5 saline injection sessions). Finally, reinforcement pellets earned in each 20 min testing session was recorded and caloric equivalent tabulated to adjust post-session feedings.

The data of primary interest are the proportion of responses made on the drug-state appropriate lever during salvinorin A test sessions. Because the drug-lever selection data is difficult to interpret when the subject is severely impaired, data from sessions in which responding was less than 0.06 responses/min were excluded from determination of the mean percentage of U-69593-lever responding. Data from sessions exceeding the 0.06 responses/min threshold were used in a General Linear Model (GLM) analysis to distinguish any significant effects related to salvinorin A dose. This GLM statistical analysis was applied for salvinorin A testing sessions both with and without prior nor-BNI injection. The variance of GLM mean measures was further examined in Dunnett's *t* posteriori comparison tests where appropriate. Calculations were performed using SPSS, version 10 software. A similar GLM analysis was undertaken to discover whether or not salvinorin A significantly affected rats' responding rates.

## 3. Results

Drug discriminative stimulus control was shown unequivocally for U-69593, and the mean number of training periods to establish discrimination was 85 ( $\pm$ 3) sessions. At all three active doses, salvinorin A displayed a rapid onset of action (i.e., 10 min for visible effects). Results from substitution tests with salvinorin A are shown in Fig. 1. Salvinorin A fully substituted for the U-69593 interoceptive cue. Salvinorin A, administered at either the 1 mg/kg or 3 mg/kg dosage resulted in 96% subject responding at the drug appropriate lever, while the middle dose of salvinorin A, 1.9 mg/kg, yielded 88% drug appropriate responding in U-69593-trained rats. A GLM statistical analysis confirmed cross generalization of salvinorin A to U-69593 [ $F(3,18) = 8.37$ ,  $p < 0.01$ ], and post hoc tests proved all salvinorin A doses were statistically different from vehicle ( $p < 0.05$ ).

The effects of salvinorin A on response rates are shown in Fig. 2. While specific doses of salvinorin A had influence over bar press rates, no statistically significant change in rats' responding rates was revealed [ $F(3,18) = 0.23$ ,  $p > 0.98$ ].

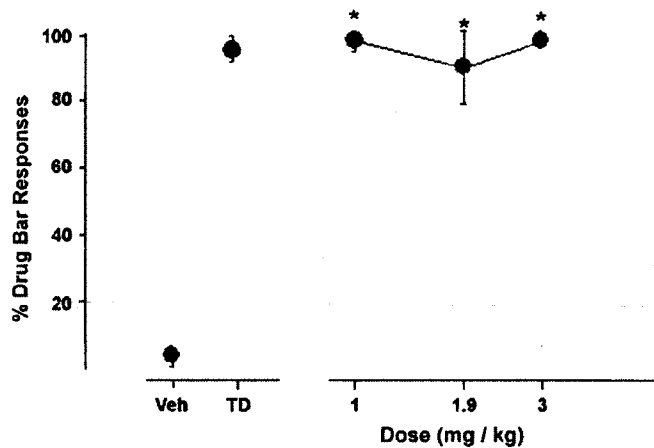


Fig. 1. Stimulus generalization (% DBR) following three doses of salvinorin A (1.0–3.0 mg/kg, i.p.) in male rats ( $n = 10$ ) trained to discriminate U-69593 (0.56 mg/kg, i.p.) from saline. Lever selection data are plotted as group mean; error bars show standard error of the mean. Data points above Veh and TD represent the results of control tests with saline and training drug (U-69593). Significant differences from vehicle session choice patterns are designated by an asterisk.

Visual inspection of graphed means for rats' percent control response rate shows salvinorin A provoked a slight decrease in the rate of bar pressing at the 1 mg/kg and the 3 mg/kg dose levels, but no rate change was apparent in sessions testing the middle dose (1.9 mg/kg).

The discriminative effects of salvinorin A were blocked by nor-BNI (4.5 nM, i.c.v.) in all subjects. In support of this, pre-session injections of nor-BNI completely reverted the lever selections of rats that later received salvinorin A (1 mg/kg, 1.9 mg/kg, 3 mg/kg, i.p.). As shown in the upper panel of Fig. 3, during the sessions of nor-BNI and salvinorin A co-

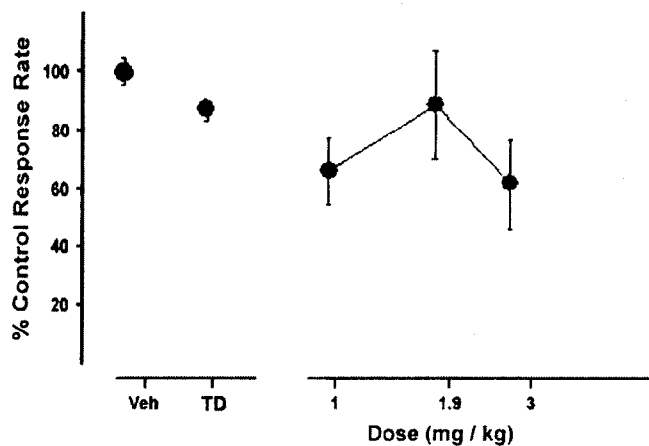


Fig. 2. Mean response rates, expressed as a percentage of vehicle control response rates (% CRR) in male rats ( $n = 10$ ) trained to discriminate U-69593 (0.56 mg/kg, i.p.) from saline during salvinorin A substitution tests. The total number of responses emitted on both levers during salvinorin A test sessions was divided by the session duration (1200 s) for each rat, and data from individual rats were averaged for each test condition. Data points above Veh and TD represent the results of control tests with saline and training drug (U-69593; 1.0 mg/kg). Data points show group mean; error bars show standard error of the mean.

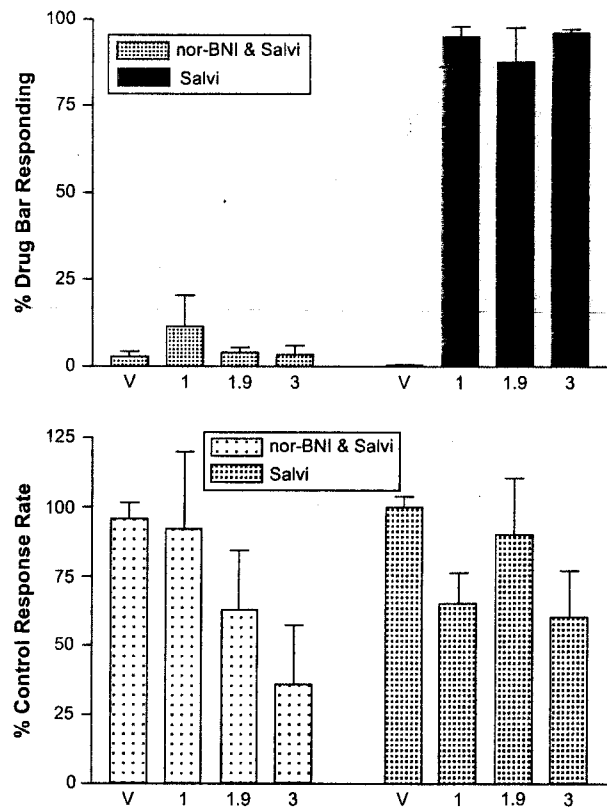


Fig. 3. Upper panel: the left series of bars plots antagonism of the discriminative stimulus effects of salvinorin A (1.0–3.0 mg/kg, i.p.; expressed as % DBR), and salvinorin A vehicle, during nor-BNI (4.5 nM, i.c.v.) co-administration sessions. The right side plots % DBR data during sessions without nor-BNI pre-administration. Salvinorin A cross generalization tests used male rats trained to discriminate U-69593 (0.56 mg/kg, i.p.) from saline. Lever selection data are plotted as group mean; error bars show standard error of the mean. Lower panel: the left series of bars shows response rates tabulated during salvinorin A generalization tests (1.0–3.0 mg/kg, i.p.; expressed as % CRR) and indicates a salvinorin A vehicle session rate, while nor-BNI (10 mg/kg, i.c.v.) co-administration was stipulated. The right side plots % CRR data during sessions without nor-BNI pre-administration. Salvinorin A cross generalization tests used male rats trained to discriminate U-69593 (0.56 mg/kg, i.p.) from saline. % CRR is plotted to show group mean; error bars show standard error of the mean.

administration, subjects overwhelmingly emitted vehicle lever responses. However, data collected while concomitantly dosing antagonist and agonist do not indicate differences in bar press rates (Fig. 3, lower panel). In other words, pre-treatment with the  $\kappa$ -opioid selective antagonist compound revoked drug appropriate responding but had no impact on the rate of lever pressing.

#### 4. Discussion

The present study targets a broader general awareness of the sage plant-derived hallucinogen, salvinorin A. The illicit use of easy access hallucinogenic compounds, like salvinorin A, is a reemerging health problem, particularly among well-educated young adults and teenagers (Hunt, 1997; Schuster et al., 1998). Salvinorin A is misused because intake of this

herb, by smoking or leaf-chewing, produces a short-lived inebriant state with intense, bizarre feelings of depersonalization (Halpern and Pope, 2001). Readers may view it odd that any 'out-of-body' or depersonalized state would be desired; on the other hand, the cohort groups sanctioning use of this drug defend it vigorously. Supporters of recreational *Salvia divinorum* use claim, while certain elements in the drug trip may cause discomfort, bad trip experiences are likely to be trumped by positive experiences (Giroud et al., 2000; Sheffler and Roth, 2003). Since *Salvia divinorum* extracts are hallucinogenic and act principally through opioid receptors, experts in this field of study view *Salvia* products as 'narcotic'.

Behavior analysts define a narcotic 'cue' as, "the discriminative stimulus complex which is exclusively associated with the specific central actions of a narcotic drug" (Colpaert et al., 1975). Results from the present study show salvinorin A produces a discriminative stimulus complex in rats similar to that of the  $\kappa$ -opioid agonist U-69593. This finding, together with salvinorin A's high and selective affinity at  $\kappa$ -opioid receptors in vitro (Roth et al., 2002) and replicate demonstrations of salvinorin A's  $\kappa$ -opioid like signal transduction cascade (Vortherms et al., 2007; Wang et al., 2005) support  $\kappa$ -opioid receptor mediation of the subjective effects of salvinorin A. In this experimental series, we showed salvinorin A induction of drug appropriate lever selections in U-69593 trained rats, but lever selections reverted to the vehicle designated lever when the kappa selective antagonist compound nor-BNI was administered by intracerebroventricular injection. The possibility that non-specific effects of nor-BNI were responsible for its surmounting salvinorin A substitution for U-69593 can be ruled out, since nor-BNI alone provoked responses at the vehicle designated lever. The antagonist reversal of conditioned responses reported here is consistent with results published by Zhang et al. (2005), showing nor-BNI blockade of salvinorin A-induced place aversion and a decrease in dopamine levels in the nucleus accumbens. Likewise, reversal of conditioned responses in this experimental series falls in line with a report describing zebra fish swim pattern changes after intramuscular injection of salvinorin A in a conditioned place preference test when paired with nor-BNI (Braidia et al., 2007). More data to bolster the scientific claim that salvinorin A's effects are  $\kappa$  opioid receptor mediated were published from a series of experiments that used  $\kappa$  opioid receptor knockout mice as subjects. Ansonoff et al. (2006) showed  $\kappa$  opioid receptor knockout mice do not respond to salvinorin A when analgesia and temperature are used as readouts. On the other hand, a partial (~66%) block of salvinorin A substitution for U-69593 in drug discriminating monkeys was reported by Butelman et al. (2004). A different antagonist was used in the Butelman study, namely GNTI. GNTI resembles nor-BNI pharmacologically by virtue of its  $\kappa$ -opioid selectivity (Jones and Portoghese, 2000). However, Butelman and colleagues injected GNTI peripherally before measuring cross generalization between salvinorin A and U-69593. Even while granting GNTI likeness to nor-BNI, differences in the species used and routes of administration distinguish our experiments from the discrimination tests in Butelman et al. (2004), which rationalizes an outcome disparity.

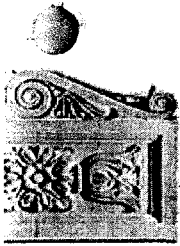
Salvinorin A did not systematically decrement rats' response rates as dose increased. Visual inspection of the graphed response rate data (Fig. 2) shows an inverted U shaped dose effect curve. Our search of the drug discrimination literature revealed precedence for this type of response rate curve, exemplified when the  $\kappa$ -opioid agonist probes E-2078 and R-84760 were administered to ascertain cross substitution in U 50488-trained and TRK-820-trained animals, respectively (Mori et al., 2004). Another aspect of the salvinorin A precipitated changes to bar press rates warrants mention because, in the pilot segment of our investigations, non-specific motor impairment (e.g., motor incoordination, motor depression, catalepsy) was specified for naïve rats that received salvinorin A injections in the 3–10 mg/kg dosing range. Since a systematic response rate decrement was not concluded during salvinorin A drug discriminating sessions, the possibility remains open that discordant motor effects, in discriminating relative to naïve rats, are reflecting cross-tolerance (Colpaert, 1978). If acceptance is granted for this interpretation, then the analyst asserts that animals receiving daily doses of U-69593 may manifest tolerance to the motor sedative effects of many  $\kappa$ -opioid receptor agonists. Further, tolerance to the motor effects of *Salvia* products seem to manifest in dosing ranges lower than that required for tolerance to narcotic cuing. Finally, the slow and uncoordinated motor performance we detected after administering 3–10 mg/kg salvinorin A to naïve animals is consistent with the test outcomes reported for salvinorin A when mice were examined (Fantegrossi et al., 2005; Zhang et al., 2005).

Together, these data provide empirical verification that the salvinorin A discriminative stimulus cue is  $\kappa$ -opioid receptor mediated in rats. These findings corroborate conclusions about the central origin of salvinorin A's narcotic cue in monkeys (Butelman et al., 2004). An important question arises when  $\kappa$ -opioid receptor mediation of salvinorin A effects is contemplated: how can research teams, focused on medicinal product development, harness a therapeutic effect from *Salvia* plant extracts or related synthetic analogues? It is instructive to recall the ubiquity of  $\kappa$ -opioid receptor expression in central and peripheral neural circuits (Barry and Zuo, 2005). Moreover, recent data critically implicate distinct  $\kappa$ -opioid receptor isotypes (e.g.,  $\kappa_1$ ,  $\kappa_2$ ,  $\kappa_3$  opioid receptors) in pain signaling (McCurdy et al., 2006; Przewlocki et al., 1983), food intake (Morley and Levine, 1983), mood (Carlezon et al., 2006; Pfeiffer et al., 1986) and drug seeking behaviors (Glick et al., 1995; Kuzmin et al., 1997; Schenk et al., 1999; Walsh et al., 2001). Therefore, a proliferation of interest in *Salvia divinorum* should soon emerge to identify  $\kappa$ -opioid agonist and/or antagonist compounds as antinociceptive, antidepressant, and addiction therapies.

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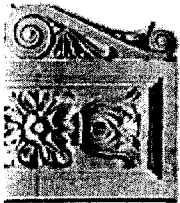
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Cheryl  
Tremblay/HC-SC/GC/CA  
2009-02-11 11:34 AM

To Cheryl Tremblay/HC-SC/GC/CA@HWC  
cc  
bcc  
Subject Fw: Media Lines for Salvia Divinorum

----- Forwarded by Cheryl Tremblay/HC-SC/GC/CA on 2009-02-11 11:34 AM -----



Cheryl  
Tremblay/HC-SC/GC/CA  
2009-02-11 11:06 AM

To Jocelyn Kula/HC-SC/GC/CA  
cc  
Subject Re: Fw: Media Lines for Salvia Divinorum 

Hi Jocelyn,

Here are the HPFB comments on the media lines for *Salvia divinorum* and my suggestions to each of the comments.

**HPFB - Comments only**



HPFB Coms Comments Feb 3 2009.doc

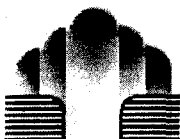
**HPFB - Comments and my Suggestions**



HPFB Coms Comments Feb 3 2009\_CT Suggestions.doc

I have placed a hard copy in your inbox as well.

Thanks,  
Cheryl Tremblay  
Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Drug Strategy and Controlled Substances Directorate  
Health Canada  
Tel: (613) 954-6527  
Fax: (613) 946-4224  
Jocelyn Kula/HC-SC/GC/CA



Jocelyn Kula/HC-SC/GC/CA  
2009-02-09 01:09 PM

To Cheryl Tremblay/HC-SC/GC/CA@HWC  
cc  
Subject Fw: Media Lines for Salvia Divinorum

pls review carefully- I see that we may need to talk to HPFB again as they still have that content in there

about being an NHP under certain conditions of use, which goes against the legal opinion from Simon Carvalho.....

---

Jocelyn Kula  
Manager, Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Healthy Environments and Consumer Safety Branch  
Health Canada  
Tel: (613) 946-0125 Fax: (613) 946-4224

----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2009-02-09 01:08 PM -----

Stephanie  
Mitchell/HC-SC/GC/CA  
2009-02-09 11:49 AM

To Cheryl Tremblay/HC-SC/GC/CA@HWC, Jocelyn  
Kula/HC-SC/GC/CA@HWC  
cc Andrew Adams/HC-SC/GC/CA@HWC, Gary  
Condran/HC-SC/GC/CA@HWC, Carmen  
Berube/HC-SC/GC/CA@HWC  
Subject Fw: Media Lines for Salvia Divinorum

Hi Cheryl and Jocelyn,

HPFB has finally sent the salvia media lines back with their additions. Could you look at it and make sure you're OK with them? Then, I'll get Andrew's approval again.



Salvia ML Feb. 9, 2009 v.3.doc

Thanks,

Stephanie Mitchell

Communications Advisor  
Conseillère des communications  
Health Canada | Santé Canada  
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stephanie\_mitchell@hc-sc.gc.ca

----- Forwarded by Stephanie Mitchell/HC-SC/GC/CA on 2009-02-09 11:47 AM -----



Darrin Denne/HC-SC/GC/CA  
2009-02-05 10:29 AM

To Stephanie Mitchell/HC-SC/GC/CA@HWC  
cc Lisa Holmes/HC-SC/GC/CA@HWC  
Subject Re: Fw: Media Lines for Salvia Divinorum

Hi Stephanie,

Here are the lines, revised with input from HPFB program areas. Sorry it has taken so long. Lots of



competing priorities these days, and one of my program areas in particular was being difficult. I have noted a concern about the answer in the first Q&A for your consideration.

Do you want to run these by your program areas for a look at the changes before we send them for DG approval?



ML - Salvia - January 2009 - draft v03.doc

Cheers,  
Darrin

---

Darrin Denne  
Senior Communications Advisor - HPFB / Conseiller principal en communications - DGPSA  
Strategic Communications Directorate / Direction des communications stratégique  
Public Affairs, Consultation and Communications Branch (PACCB) /  
Direction générale des affaires publiques, de la consultation et des communications (DGAPCC)  
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Stephanie Mitchell/HC-SC/GC/CA

Stephanie  
Mitchell/HC-SC/GC/CA  
2009-01-20 03:02 PM

To Darrin Denne/HC-SC/GC/CA@HWC  
cc Lisa Holmes/HC-SC/GC/CA@HWC  
Subject Fw: Media Lines for Salvia Divinorum

Hi Darrin,

Have you had a chance to work on these salvia lines? It would be good to get them going.

Thanks,

Stephanie Mitchell

Communications Advisor  
Conseillère des communications  
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stephanie\_mitchell@hc-sc.gc.ca

----- Forwarded by Stephanie Mitchell/HC-SC/GC/CA on 2009-01-20 03:00 PM -----

Stephanie  
Mitchell/HC-SC/GC/CA  
2008-12-12 11:25 AM

To Darrin Denne/HC-SC/GC/CA  
cc Chantal Trepanier/HC-SC/GC/CA@HWC

Subject Re: Fw: Media Lines for Salvia Divinorum

What you say makes a lot of sense. Since they are mainly HPFB issues, could you and your clients take a stab and updating/adding to the lines before we get legal approval? I hadn't realized so many changes were still necessary.

Thanks,

Stephanie Mitchell

Communications Advisor  
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stephanie\_mitchell@hc-sc.gc.ca

Darrin Denne/HC-SC/GC/CA



Darrin Denne/HC-SC/GC/CA

2008-12-12 11:21 AM

To Stephanie Mitchell/HC-SC/GC/CA@HWC

cc Chantal Trepanier/HC-SC/GC/CA@HWC

Subject Re: Fw: Media Lines for Salvia Divinorum

Hi Stephanie

I have no problem sharing it with Legal now, but I think from a communications point of view there are also things I would change about the lines. The language is very bureaucratic. We don't address the adverse reaction reports we've got on file (reporters always ask), or why we've never acted on the the MHPD report that recommended the substance be scheduled under the CDSA (which media keeps bringing up). We don't really explain how it is that we would regulate a product made from salvia, but not salvia itself. I hope we'll be able to address some of these issues in the approvals process as well before it goes to DGs.


Cheers,  
Darrin

---

Darrin Denne  
Senior Communications Advisor - HPFB / Conseiller principal en communications - DGPSA  
Strategic Communications Directorate / Direction des communications stratégique  
Public Affairs, Consultation and Communications Branch (PACCB) /  
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Stephanie Mitchell/HC-SC/GC/CA

Stephanie  
Mitchell/HC-SC/GC/CA  
2008-12-12 10:50 AM

To Darrin Denne/HC-SC/GC/CA@HWC  
cc Chantal Trepanier/HC-SC/GC/CA@HWC  
Subject Re: Fw: Media Lines for Salvia Divinorum 

Thanks, Darrin. I'd like to get legal approval at this stage because I have a feeling legal might want to make quite a few changes, and I'd like the DGs and ADMs to see those changes. Does that work for you?

Cheers,


Stephanie Mitchell

Communications Advisor  
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Health Canada | Santé Canada  
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stephanie\_mitchell@hc-sc.gc.ca

Darrin Denne/HC-SC/GC/CA



Darrin Denne/HC-SC/GC/CA  
2008-12-12 10:45 AM

To Chantal Trepanier/HC-SC/GC/CA@HWC  
cc Stephanie Mitchell/HC-SC/GC/CA@HWC  
Subject Re: Fw: Media Lines for Salvia Divinorum 

This is the first time I have seen the media lines, so I don't think so. In HPFB's normal approval process, Legal reviews Comms products right before ADM approval.

Cheers,  
Darrin

---

Darrin Denne  
Senior Communications Advisor - HPFB / Conseiller principal en communications - DGPSA  
Strategic Communications Directorate / Direction des communications stratégique  
Public Affairs, Consultation and Communications Branch (PACCB) /  
Direction générale des affaires publiques, de la consultation et des communications (DGAPCC)  
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Chantal Trepanier/HC-SC/GC/CA



Chantal  
Trepanier/HC-SC/GC/CA  
2008-12-12 10:42 AM

To Darrin Denne/HC-SC/GC/CA@HWC  
cc Stephanie Mitchell/HC-SC/GC/CA@HWC  
Subject Re: Fw: Media Lines for Salvia Divinorum

Thank you,

Was the media lines sent to Angela?

Chantal  
Tél/Tel: 613 946-5682  
Télé/Fax: 613 954-9485

Darrin Denne/HC-SC/GC/CA



Darrin Denne/HC-SC/GC/CA  
12/12/2008 10:40 AM

To Stephanie Mitchell/HC-SC/GC/CA@HWC  
cc Chantal Trepanier/HC-SC/GC/CA@HWC  
Subject Re: Fw: Media Lines for Salvia Divinorum

I don't deal with NHP legal issues that often, but I believe it is Angela Lin.

Cheers,  
Darrin

---

Darrin Denne  
Senior Communications Advisor - HPFB / Conseiller principal en communications - DGPSA  
Strategic Communications Directorate / Direction des communications stratégique  
Public Affairs, Consultation and Communications Branch (PACCB) /  
Direction générale des affaires publiques, de la consultation et des communications (DGAPCC)  
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Fax: (613) 957-8805

Stephanie Mitchell/HC-SC/GC/CA

Stephanie  
Mitchell/HC-SC/GC/CA  
2008-12-12 10:15 AM

To Chantal Trepanier/HC-SC/GC/CA@HWC, Darrin  
Denne/HC-SC/GC/CA@HWC  
cc  
Subject Re: Fw: Media Lines for Salvia Divinorum

Hi, Chantal and Darrin,

Chantal, I didn't send the media lines to the counsel in NHP. Darrin (my colleague in HPFB), could you tell Chantal who you usually deal with in legal for NHP issues?

Thank you both,

Stephanie Mitchell

Communications Advisor  
Conseillère des communications  
Health Canada | Santé Canada  
Government of Canada | Gouvernement du Canada  
269 Laurier Ave | 269 ave Laurier Ottawa ON K1A 0K9  
613 941-3107 | telephone / téléphone  
613-948-8085 | facsimile / télécopieur  
stephanie\_mitchell@hc-sc.gc.ca

Chantal Trepanier/HC-SC/GC/CA



Chantal  
Trepanier/HC-SC/GC/CA  
2008-12-12 10:09 AM

To Stephanie Mitchell/HC-SC/GC/CA@HWC  
cc

Subject Fw: Media Lines for Salvia Divinorum

Hello Stephanie,

Did you also sent the media lines to a legal counsel for NHP? If so, can you tell me who?

Thanks!

Chantal  
Tél/Tel: 613 946-5682  
Télé/Fax: 613 954-9485

----- Forwarded by Chantal Trepanier/HC-SC/GC/CA on 12/12/2008 09:57 AM -----

Diane  
Labelle/HC-SC/GC/CA  
11/12/2008 03:42 PM

To Stephanie Mitchell/HC-SC/GC/CA@HWC  
cc Chantal Trepanier/HC-SC/GC/CA@HWC, Jason  
Brannen/HC-SC/GC/CA@HWC  
Subject Re: Fw: Media Lines for Salvia Divinorum

Hi Stephanie,

Chantal Trépanier will review the media lines. The Controlled Drugs and Substances legal team is made up of four lawyers: Chantal Trépanier, Caroline Mercier, Mélanie Poirier and Christine Evans. FYI, Jason Brannen does litigation related work, and we call on his help (or Mary Ormerod's) when a matter is being litigated, which is not the case here.

As head of the team you can always contact me.

Cheers,  
Diane

Stephanie Mitchell/HC-SC/GC/CA

**Stephanie  
Mitchell/HC-SC/GC/CA**  
11/12/2008 03:19 PM

To Diane Labelle/HC-SC/GC/CA@HWC, Jason  
Brannen/HC-SC/GC/CA@HWC, Chantal  
Trepanier/HC-SC/GC/CA@HWC

cc

Subject Fw: Media Lines for Salvia Divinorum

Hi Diane, Jason and Chantal,

We're working on media lines for salvia. Could you please tell me who I should send them to in legal for approval?



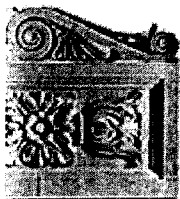
Salvia ML Dec. 11, 2008.doc

Thanks so much,

Stephanie Mitchell

Communications Advisor  
Conseillère des communications  
Health Canada | Santé Canada  
Government of Canada | Gouvernement du Canada  
269 Laurier Ave | 269 ave Laurier Ottawa ON K1A 0K9  
613 941-3107 | telephone / téléphone  
613-948-8085 | facsimile / télécopieur  
stephanie\_mitchell@hc-sc.gc.ca

----- Forwarded by Stephanie Mitchell/HC-SC/GC/CA on 2008-12-11 03:16 PM -----



**Cheryl  
Tremblay/HC-SC/GC/CA**  
2008-12-11 02:10 PM

To Stephanie Mitchell/HC-SC/GC/CA@HWC

cc Jocelyn Kula/HC-SC/GC/CA@HWC, Andrew  
Adams/HC-SC/GC/CA@HWC, Suzanne  
Desjardins/HC-SC/GC/CA@HWC

Subject Media Lines for Salvia Divinorum

Hi Stephanie,

Further to inter-branch meetings between HPFB (NHPD, MHPD, HPFBI) and HECSB (DSCSD) in September, 2007, which were held to discuss *Salvia divinorum* and reach a consensus on next steps, and recent discussions concerning Salvia among the Director Generals of the above

mentioned Directorates in September 2008, DSCSD is working to finalize the latest version of the media lines on *Salvia divinorum* . These lines have been distributed to the HPFB Directorates for comment at the working level and have been approved by:

Andrew Adams, Director, Office of Controlled Substances, DSCSD, and  
Suzanne Desjardins, Director, Office of Research and Surveillance, DSCSD

Please find attached, a copy of the media lines for *Salvia divinorum* for your coordination of senior management approvals with HPFB communications.



Media Lines Salvia Divinorum Dec 11 2008.wpd

Thank you,

Cheryl Tremblay  
Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Drug Strategy and Controlled Substances Directorate  
Health Canada  
Tel: (613) 954-6527  
Fax: (613) 946-4224

DRAFT – HPFB Communications Comments  
February 3, 2009

**Media Lines**  
**Regulatory Control of Salvia Divinorum**

Issue

Since 2006, Health Canada has observed a steady increase in the amount of media interest regarding the availability of *Salvia divinorum* on the Canadian market. Health Canada has also received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum*, particularly given reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties.

Key Messages:

- Health Canada continues to collect relevant information about *Salvia divinorum* and its active ingredient, Salvinorin A, from both national and international sources in order to determine what, if any, regulatory controls are needed.
- While the media has reported that the use of *Salvia divinorum* is on the rise in certain parts of the country, Health Canada does not currently have statistics on its use across the Canadian population.
- Health Canada is taking steps to address this lack of data. Questions regarding the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. A general open-ended question about the use of other substances has also been included in the 2008 Canadian Alcohol and Drug Use Monitoring Survey.

**Comment:** This bullet was moved to supplementary messages.

**Deleted:** <#>In Canada, neither the herb, *Salvia divinorum*, nor its main active ingredient, Salvinorin A, is controlled under the *Controlled Drugs and Substances Act* (CDSA). ¶

**Deleted:** support decision-making regarding appropriate

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**Deleted:** the actual population

**Deleted:** of *Salvia divinorum*

**Deleted:** , but data from these surveys likely will not be available until 2010.

**Deleted:** Results from that survey will be available summer 2009.

Supplementary Messages:

- In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, Salvinorin A, is controlled under the *Controlled Drugs and Substances Act* (CDSA).
- *Salvia divinorum* is not listed under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these conventions.
- Several countries (Australia, Belgium, Denmark, Sweden, Italy, Spain,

**Comment:** Moved from key messages.

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**Deleted:** <#>Health Canada has not approved any *Salvia divinorum* products for sale in Canada. ¶

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Finland and South Korea) have placed controls on the import and/or sale of *Salvia divinorum*. Although some individual U.S. states have implemented laws restricting its use, sale and/or distribution, *Salvia divinorum* is not federally regulated under the *Controlled Substances Act* in the United States.

- In Canada, *Salvia divinorum* under some conditions of use meets the definition of a natural health product under the *Natural Health Product Regulations*. This means that a product making health claims that contains *Salvia divinorum* must be approved by Health Canada prior to being sold in Canada. Products that don't comply with the regulations may be subject to compliance and enforcement actions.
- As of January 2009, Health Canada had not approved any *Salvia divinorum* products for sale in Canada.

**If asked for specifics on when the survey data will be available:**

- Data from the Canadian Alcohol and Drug Use Monitoring Survey will be available in summer 2009, while the results of the Youth Smoking Survey and the Ontario Student Drug Use and Health Survey likely will not be available until 2010.

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- Deleted: and, therefore, *Salvia divinorum*
- Deleted: s
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- Deleted: in accordance with the Health Products and Food Branch's Compliance and Enforcement Policy (POL-0001)
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**Questions and Answers**

**Q1 – If Health Canada is aware of *Salvia divinorum*'s ill-effects, why isn't it illegal?**

A1 - There are very few controlled scientific studies of the physical and psychotropic effects of *Salvia divinorum* on humans, and using these studies to predict its potential for addiction and abuse is difficult. The mechanism of action by which *Salvia divinorum* works is still not fully understood from the existing information, and more controlled systematic research in this area is needed.

Health Canada has only received a limited number of communications regarding *Salvia divinorum* from law enforcement agencies, and none has advised that the use of *Salvia divinorum* poses any particular threat to public safety.

**Q2 - How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?**

A2 – The *Natural Health Products Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *Salvia divinorum*.

**Q3 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum*. What does that involve and what stage is it at?**

- Deleted: Human studies that demonstrate reliable, systematic and
- Deleted: observations
- Deleted: n
- Deleted: are sparse
- Deleted: The information currently available to Health Canada indicates that the likelihood of abuse/misuse of *Salvia divinorum* is unknown, that t
- Deleted: that
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A3 - Health Canada considers several factors in determining whether scheduling a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

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- International requirements and trends in control and scheduling;
- Chemical and pharmacological similarity to other substances already scheduled under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Addiction liability and potential for abuse/misuse of the substance;
- Extent of actual abuse and misuse of the substance in Canada and internationally;
- and
- Overall risk to public health and safety posed by the substance.

Health Canada has only anecdotal information about the last three of the above-mentioned factors.

Health Canada will continue to collect and consider information regarding *Salvia divinorum* as it becomes available, in order to determine whether the controls imposed by the CDSA are an appropriate strategy for managing the risks associated with *Salvia divinorum*'s use and controlling its availability.

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**Q4 – Didn't an internal report from Health Canada's Marketed Health Products Directorate recommend that *Salvia divinorum* be scheduled under the CDSA? Why has that recommendation not been acted upon?**

A4 – Health Canada maintains an active file on this topic. Health Canada will continue to collect and consider information regarding *Salvia divinorum* as it becomes available, in order to determine whether the controls imposed by the CDSA are an appropriate strategy for managing the risks associated with *Salvia divinorum*'s use and controlling its availability.

**Q5 – Has Health Canada received any reports of adverse reactions related to the use of *Salvia divinorum*?**

A5 -- Since 2005, Health Canada has received four reports of adverse reactions associated with the use of *Salvia divinorum* as a hallucinogen, with three being considered non-serious (requiring no medical attention) and the fourth being considered serious (medical intervention was required).

Where did these reports come from?

**Background**

*Salvia divinorum* is a species of sage belonging to the mint family that is chewed or smoked in order to induce its psychotropic effects. These effects are short-acting in nature and include hallucinations, out-of-body experiences, unconsciousness and short-term memory loss.

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The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. While no validated data exist regarding usage in Canada, data from a 2006 National Survey on Drug Use and Health Report, published by the U.S. Substance Abuse and Mental Health Services Administration has estimated that:

- 1.8 million persons aged 12 or older used *Salvia divinorum* at least once in their lifetime, and approximately 750,000 did so in the past year.
- Use was more common among young adults (18 to 25 years old) as opposed to older adults (>26 years of age).
- Young adults were 3 times more likely than youths aged 12 to 17 to have used *Salvia divinorum* in the past year.
- Use was more common in males than females.

*Salvia divinorum* is widely touted on the Internet as a "legal" alternative to street drugs.

The mechanism of action by which *Salvia divinorum* works is not fully understood. While some users have reported that the psychotropic effects of *Salvia divinorum* resemble those induced by other hallucinogens, such as LSD and phencyclidine, the overall experience is quite unique.

Prepared by Cheryl Tremblay, Policy and Regulatory Affairs Division, DSCSD  
Stephanie Mitchell, Communications Officer (HECSB)  
Darrin Denne, Communications Officer (HPFB)

Approved by

Approved	Andrew Adams, Director, OCS, DSCSD
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Pending	HPFB programme APPROVALS (NHPD)
Pending	HPFB programme APPROVALS (MHPD)
Pending	HPFB programme APPROVALS (HPFBI)
Pending	Kathleen Malone, Senior Communications Executive, HECSB
Pending	Peter Yendall, A/Director, Public Affairs, PACR
Pending	Paul Glover, ADM, HECSB
Pending	Meena Ballantyne, ADM, HPFB
Pending	DMO
Pending	MO
Pending	PCO

DRAFT – HPFB Communications Comments  
February 3, 2009

**Media Lines**  
**Regulatory Control of Salvia Divinorum**

Issue

Since 2006, Health Canada has observed a steady increase in the amount of media interest regarding the availability of *Salvia divinorum* on the Canadian market. Health Canada has also received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum*, particularly given reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties.

Key Messages:

- Health Canada continues to collect relevant information about *Salvia divinorum* and its active ingredient, Salvinorin A, from both national and international sources in order to determine what, if any, regulatory controls are needed.
- While the media has reported that the use of *Salvia divinorum* is on the rise in certain parts of the country, Health Canada does not currently have statistics on its use across the Canadian population.
- Health Canada is taking steps to address this lack of data. Questions regarding the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. A general open-ended question about the use of other substances has also been included in the 2008 Canadian Alcohol and Drug Use Monitoring Survey.

Supplementary Messages:

- In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, Salvinorin A, is controlled under the *Controlled Drugs and Substances Act* (CDSA).
- *Salvia divinorum* is not listed under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these conventions.
- Several countries (Australia, Belgium, Denmark, Sweden, Italy, Spain,

**Comment:** My response to HPFB comments in blue – Cheryl.

**Comment:** Moved to supplementary messages.  
CT - ✓ Agree.

**Deleted:** <#>In Canada, neither the herb, *Salvia divinorum*, nor its main active ingredient, Salvinorin A, is controlled under the *Controlled Drugs and Substances Act* (CDSA). ¶

**Comment:** CT - ✓ Agree.

**Comment:** CT - ✓ Agree.

**Deleted:** support decision-making regarding appropriate

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**Comment:** CT - ✓ Agree.

**Deleted:** the actual population

**Comment:** CT - ✓ Agree.

**Deleted:** of *Salvia divinorum*

**Comment:** CT - ✓ Agree.

**Comment:** CT - ✓ Agree.  
Moved to last bullet in supplementary messages.

**Deleted:** , but data from these surveys likely will not be available until 2010.

**Comment:** CT - ✓ Agree.  
Moved to last bullet in supplementary messages.

**Deleted:** Results from that survey will be available summer 2009.

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**Comment:** CT - Should be "are"?

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**Comment:** Moved from key messages. CT - ✓ Agree.

**Comment:** CT - ✓ Agree.  
Moved to 2<sup>nd</sup> last bullet under supplementary messages.

**Deleted:** <#>Health Canada has not approved any *Salvia divinorum* products for sale in Canada. ¶

**Comment:** CT - ✗ Disagree.  
Makes it unclear that count ... [1]

**Deleted:** is, therefore, not required

**Comment:** CT - ✓ Agree.

Finland and South Korea) have placed controls on the import and/or sale of *Salvia divinorum*. Although some individual U.S. states have implemented laws restricting its use, sale and/or distribution, *Salvia divinorum* is not federally regulated under the *Controlled Substances Act* in the United States.

- In Canada, *Salvia divinorum* under some conditions of use meets the definition of a natural health product under the *Natural Health Product Regulations*. This means that a product making health claims that contains *Salvia divinorum* must be approved by Health Canada prior to being sold in Canada. Products that don't comply with the regulations may be subject to compliance and enforcement actions.
- As of January 2009, Health Canada has not approved any *Salvia divinorum* products for sale in Canada.

**If asked for specifics on when the survey data will be available:**

- Data from the Canadian Alcohol and Drug Use Monitoring Survey will be available in summer 2009, while the results of the Youth Smoking Survey and the Ontario Student Drug Use and Health Survey likely will not be available until 2010.

**Questions and Answers**

**Q1 – If Health Canada is aware of *Salvia divinorum*'s ill-effects, why isn't it illegal?**

A1 - There are very few controlled scientific studies of the physical and psychotropic effects of *Salvia divinorum* on humans, and using these studies to predict its potential for addiction and abuse is difficult. The mechanism of action by which *Salvia divinorum* works is still not fully understood from the existing information, and more controlled systematic research in this area is needed.

Health Canada has only received a limited number of communications regarding *Salvia divinorum* from law enforcement agencies, and none has advised that the use of *Salvia divinorum* poses any particular threat to public safety.

**Q2 - How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?**

A2 - The *Natural Health Products Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *Salvia divinorum*.

**Q3 - Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum*. What does that involve and what stage is it at?**

- Comment: CT - ✓ Agree.
- Comment: CT - ✓ Agree.
- Comment: CT - ✓ Agree.
- Comment: CT - X Disagree. Legal opinion by Simon Carvalho.
- Formatted: Font: Not Italic
- Comment: CT - ✓ Agree.
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- Comment: CT - X Disagree. Legal opinion by Simon Carvalho.
- Deleted: and, therefore, *Salvia divinorum*
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- Formatted: Font: Italic
- Comment: CT - ✓ Agree.
- Deleted: sale
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- Comment: CT - ✓ Agree.
- Deleted: in accordance with the Health Products and Food Branch's Compliance and Enforcement Policy (POL-0001)
- Comment: CT - ✓ Agree.
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- Comment: CT - ✓ Agree ... [2]
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- Comment: CT - ✓ Agree.
- Deleted: are sparse
- Comment: Brittany has a ... [6]
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- Comment: CT - This lin ... [8]
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- Comment: CT - ✓ Agree ... [9]
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A3 - Health Canada considers several factors in determining whether scheduling a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

**Comment:** CT - ✓ Agree.

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- International requirements and trends in control and scheduling;
- Chemical and pharmacological similarity to other substances already scheduled under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Addiction liability and potential for abuse/misuse of the substance;
- Extent of actual abuse and misuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada has only anecdotal information about the last three of the above-mentioned factors.

Health Canada will continue to collect and consider information regarding *Salvia divinorum* as it becomes available, in order to determine whether the controls imposed by the CDSA are an appropriate strategy for managing the risks associated with *Salvia divinorum*'s use and controlling its availability.

**Comment:** CT - ✓ Agree, however, this line is included under A4 as well. Suggest removing from A3.

**Deleted:** or not

**Q4 – Didn't an internal report from Health Canada's Marketed Health Products Directorate recommend that *Salvia divinorum* be scheduled under the CDSA? Why has that recommendation not been acted upon?**

A4 – Health Canada maintains an active file on this topic. Health Canada will continue to collect and consider information regarding *Salvia divinorum* as it becomes available, in order to determine whether the controls imposed by the CDSA are an appropriate strategy for managing the risks associated with *Salvia divinorum*'s use and controlling its availability.

**Comment:** CT - This line is under A3 as well suggest removing from A3.

**Comment:** CT - ✗ Disagree. Counterintuitive to emphasize importance of ADR's when HRA states "it is important to note that accumulated case reports cannot be used to determine the incidence of a reaction, nor the risk associated with the use of a product, because of the unknown number of individuals exposed to the product and because of the significant under-reporting of ADR's. The CADRMP is not an appropriate tool to obtain information concerning adverse reactions associated with the use of *Salvia divinorum* as a street drug." and non-serious nature of 3 of the events and concomitant use of alcohol and ADD in 4<sup>th</sup> case.

**Q5 – Has Health Canada received any reports of adverse reactions related to the use of *Salvia divinorum*?**

A5 -- Since 2005, Health Canada has received four reports of adverse reactions associated with the use of *Salvia divinorum* as a hallucinogen, with three being considered non-serious (requiring no medical attention) and the fourth being considered serious (medical intervention was required).

Where did these reports come from?

**Background**

*Salvia divinorum* is a species of sage belonging to the mint family that is chewed or smoked in order to induce its psychotropic effects. These effects are short-acting in nature and include hallucinations, out-of-body experiences, unconsciousness and short-term memory loss.

**Comment:** CT - ✓ Agree.

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**Comment:** CT - ✓ Agree,

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The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. While no validated data exist regarding usage in Canada, data from a 2006 National Survey on Drug Use and Health Report, published by the U.S. Substance Abuse and Mental Health Services Administration has estimated that:

- 1.8 million persons aged 12 or older used *Salvia divinorum* at least once in their lifetime, and approximately 750,000 did so in the past year.
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*Salvia divinorum* is widely touted on the Internet as a "legal" alternative to street drugs.

The mechanism of action by which *Salvia divinorum* works is not fully understood. While some users have reported that the psychotropic effects of *Salvia divinorum* resemble those induced by other hallucinogens, such as LSD and phencyclidine, the overall experience is quite unique.

**Comment:** CT - This line appears under background as well and Brittany has suggested that we remove this line after reading the Willmore et al. article. "It was in this context that I felt there was some play...because people have very different experiences on the drug which have led to the idea that there might be more than just KOR at play....or salvinorin...but yes, just take it out" - Brittany

Prepared by Cheryl Tremblay, Policy and Regulatory Affairs Division, DSCSD  
Stephanie Mitchell, Communications Officer (HECSB)  
Darrin Denne, Communications Officer (HPFB)

Approved by

Approved	Andrew Adams, Director, OCS, DSCSD
Pending	Ray Edwards, A/DG, DSCSD
Pending	HPFB programme APPROVALS (NHPD)
Pending	HPFB programme APPROVALS (MHPD)
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Pending	Peter Yendall, A/Director, Public Affairs, PACR
Pending	Paul Glover, ADM, HECSB
Pending	Meena Ballantyne, ADM, HPFB
Pending	DMO
Pending	MO
Pending	PCO


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<b>Page 1: [1] Comment</b>	<b>CTREMBLA</b>	<b>2009-02-11 10:52 AM</b>
CT - X Disagree. Makes it unclear that countries can still regulate on their own accord. Prefer "and, therefore, is not required to be regulated"		
<b>Page 2: [2] Comment</b>	<b>CTREMBLA</b>	<b>2009-02-11 10:52 AM</b>
CT - ✓ Agree. Moved from 1 <sup>st</sup> to last bullet under supplementary messages.		
<b>Page 2: [3] Change</b>	<b>CTREMBLA</b>	<b>2009-02-11 9:17 AM</b>
Formatted Bullets and Numbering		
<b>Page 2: [4] Comment</b>	<b>CTREMBLA</b>	<b>2009-02-11 10:52 AM</b>
CT - ✓ Agree. Moved from 3 <sup>rd</sup> bullet under key messages.		
<b>Page 2: [5] Deleted</b>	<b>CTREMBLA</b>	<b>2009-02-10 1:29 PM</b>
Human studies that demonstrate reliable, systematic and		
<b>Page 2: [6] Comment</b>	<b>CTREMBLA</b>	<b>2009-02-11 10:52 AM</b>
Brittany has also suggested that we removed this line after reading the Willmore et al. article. " if we want to be really picky, I also addressed this in my report...and based on its pharmacology, this is not <i>unknown</i> . We know that it is a KOR agonist and by virtue of that should be a low abuse liability."		
<b>Page 2: [7] Deleted</b>	<b>CTREMBLA</b>	<b>2009-02-10 1:30 PM</b>
The information currently available to Health Canada indicates that the likelihood of abuse/misuse of <i>Salvia divinorum</i> is unknown, that t		
<b>Page 2: [8] Comment</b>	<b>CTREMBLA</b>	<b>2009-02-11 10:52 AM</b>
CT - This line appears under Q1 as well and again Brittany has suggested that we remove this line after reading the Willmore et al. article. "It was in this context that I felt there was some play...because people have very different experiences on the drug which have led to the idea that there might be more than just KOR at play....or salvinorin...but yes, just take it out" - Brittany		
<b>Page 2: [9] Comment</b>	<b>CTREMBLA</b>	<b>2009-02-11 10:52 AM</b>
CT - ✓ Agree.		

Valerie Hurry/HC-SC/GC/CA  
2009-02-17 08:11 AM

To Cheryl Tremblay/HC-SC/GC/CA@HWC  
cc Stephanie Lessard/HC-SC/GC/CA@HWC  
bcc  
Subject Re: Fw: It's Your Health - Salvia divinorum - Draft One 

History:  This message has been replied to.

With apologies for the delay

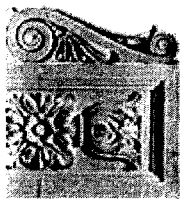


IYH - Salvia Divinorum - Draft Only\_NHPD ed by RJM.wpd


Valerie

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Valerie Hurry, M.Sc.  
Assessment Officer  
Natural Health Products Directorate  
Health Products and Food Branch  
Health Canada  
2936 Baseline Road  
A.L. 3302D  
Ottawa, Ontario K1A 0K9  
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Email: Valerie\_Hurry@hc-sc.gc.ca  
Cheryl Tremblay/HC-SC/GC/CA



Cheryl  
Tremblay/HC-SC/GC/CA  
2009-02-13 08:43 AM

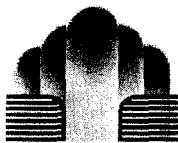
To Valerie Hurry/HC-SC/GC/CA@HWC  
cc  
Subject Re: Fw: It's Your Health - Salvia divinorum - Draft One 

Hi Valerie,

Just wondering if you've had an opportunity to review the It's Your Health Article on *Salvia divinorum*? I don't think that Sue Lumsden gave us a particular deadline, but we're hoping to have our comments to her mid-week next week.

Thanks,  
Cheryl Tremblay  
Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Drug Strategy and Controlled Substances Directorate  
Health Canada  
Tel: (613) 954-6527  
Fax: (613) 946-4224  
Jocelyn Kula/HC-SC/GC/CA

 Jocelyn Kula/HC-SC/GC/CA



2009-02-05 12:38 PM

To Cheryl Tremblay/HC-SC/GC/CA@HWC, Brittany Sauvé/HC-SC/GC/CA@HWC, Valerie Hurry/HC-SC/GC/CA@HWC

cc

Subject Fw: It's Your Health - Salvia divinorum - Draft One

May I suggest that we try and provide one set of comments for Sue to work from? Perhaps if everyone could provide comments to Cheryl, she can collate and then circulate for all to agree on before we pass on to Sue. Just might be easier for Sue to work from.

Let me know.

Jocelyn

---

Jocelyn Kula  
Manager, Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Healthy Environments and Consumer Safety Branch  
Health Canada

Tel: (613) 946-0125 Fax: (613) 946-4224

--- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2009-02-05 12:36 PM ---

s.19(1)



"Sue Lumsden"

2009-02-05 12:34 PM

To "Jocelyn Kula" <jocelyn\_kula@hc-sc.gc.ca>, "Cheryl Tremblay" <Cheryl\_Tremblay@hc-sc.gc.ca>, Brittany Sauvé <brittany\_sauve@hc-sc.gc.ca>, "Valerie Hurry" <Valerie\_Hurry@hc-sc.gc.ca>

cc <Scott\_Jordan@hc-sc.gc.ca>

Subject It's Your Health - Salvia divinorum - Draft One

Good afternoon,

With apologies for the delay since we spoke about this issue, I'm forwarding a first draft of the It's Your Health (IYH) article on Salvia Divinorum.

When reviewing this document, please keep in mind that IYH is geared towards an audience with grade 10-12 literacy skills. We try to use plain language and a conversational tone. I realize this draft is quite simplistic in content, especially when compared to Brittany's research paper.

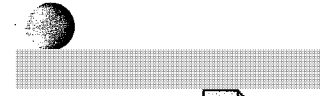
The usual process with IYH is for the draft to go back and forth between the writer and the Program contacts until you are satisfied with the content and tone of the article, at which point it is forwarded to the IYH Manager (Lisa Mackay) to begin the formal approvals process.

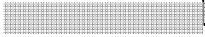

I'll be happy to work with you on revisions via e-mail or telephone, whichever you prefer.

Thank you. I look forward to seeing or hearing your comments on this first draft.

Sue

**s.19(1)**



  - IYH - Salvia Divinorum - Draft One.wpd



Valerie Hurry - Comments

## **Salvia Divinorum**

### **The Issue**

Certain Web sites are promoting the use of *Salvia divinorum* as a “legal” alternative to street drugs. Health Canada recommends that you avoid using this substance because very little is known about the extent of adverse effects, and there is no way to predict how it will affect you.

### **Background**

*Salvia divinorum* is a species of sage that belongs to the mint family. It is known to have psychotropic effects, which means it is capable of acting on the mind.

The leaves of this plant are used traditionally by the Mazatec Indians in Mexico for medicinal and spiritual purposes. Traditional use involves chewing the leaves or using them to make tea to treat such conditions as headache or stomach upset, or to produce “mystical” or hallucinogenic experiences.

Products that claim to contain *Salvia divinorum* – or its main active ingredient, Salvinorin A – are widely available on the Internet and are sold in various “head shops” and corner stores. These products are sold in a number of formats, including seeds; and plant cuttings for propagation purposes. Fresh or dried leaves and liquid extracts; are intended to be either chewed, swallowed or smoked; liquid preparations are also available for consumption. Street names for *Salvia divinorum* include: diviner’s sage, Magic mint, Maria pastra, puff encens special, ska pastora, ska Maria pastora, Sally D, Lady Sally and Salvia.

Recently, there have been reports suggesting that Canadian teens and young adults are using *Salvia divinorum* to get “high,” but so far, there has been no solid research in Canada on actual use.

Health Canada has not approved any ~~Salvia~~ *Salvia divinorum* products for sale in Canada.

Several countries (e.g., Australia, Belgium, Denmark, Sweden, Italy, Spain, Finland and South Korea) have placed controls on the import and/or sale of *Salvia divinorum*. ~~A number of individual states have done this as well, but~~ *Salvia divinorum* It is not regulated under the *Controlled Substances Act* in the United States but a number of individual states have placed restrictions on its sale.

### **Risks associated with using *Salvia Divinorum***

The use of *Salvia divinorum* distorts reality. The effects vary from person to person, are often described as unpleasant, and may include the following:

- hallucinations (“seeing” objects that are not there);

## Valerie Hurry - Comments

- out-of-body experiences;
- loss of consciousness;
- short-term memory loss;
- uncontrollable laughter;
- impaired ability to speak.

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one experience to the next, depending on such factors as the potency of the product, how much was used, whether it was ingested or smoked, and the user's mood and expectations. It does not appear to cause the euphoria often associated with other psychoactive drugs, so many people who try it do not repeat the experience.

A major concern about *Salvia divinorum* is the fact that there have been so few scientific studies about the way it affects the body and the brain. For example, very little is known about the following issues:

- whether it is toxic;
- precisely how it acts on the brain;
- how long it acts on the brain and whether there are permanent effects;
- whether it causes physical or psychological dependence (unlikely according to the evidence available so far);
- how it interacts with other substances (including drugs and alcohol).


Also, since no *Salvia divinorum* products have been approved for sale in Canada, products that claim to contain this substance have not been reviewed by Health Canada. As such, they may be counterfeit or may contain other ingredients that pose risks to health. In cases like this, it is always a matter of "buyer beware."

## The Legal Status of *Salvia divinorum*

From time to time, Health Canada is asked why *Salvia divinorum* and Salvinorin A are not prohibited under the *Controlled Drugs and Substances Act* (CDSA). When assessing whether to regulate a substance under the CDSA, Health Canada considers many factors, including the following:

- international requirements and trends in controlling the substance;
- similarity to other substances already regulated under the CDSA;
- whether there may be legitimate uses of the substance (e.g., potential health benefits);
- the potential for addiction and abuse/misuse of the substance;
- the extent of actual abuse and misuse of the substance in Canada and elsewhere;
- overall risk to public health and safety posed by the substance.

In the case of *Salvia divinorum*, there is simply not enough information available to determine whether prohibition is the best option to manage risks. ~~To date, no law enforcement agencies have advised Health Canada that the use of *Salvia divinorum* poses any particular threat to public~~



## Valerie Hurry - Comments

~~safety. However, as noted earlier, very little is known about the potential for addiction or the extent of actual use.~~

Questions about the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. The survey results will help fill some of the information gaps, but the data will not likely be available until 2010.

### Minimizing Your Risk

Health Canada recommends that you avoid using *Salvia divinorum*. Also, if you have children, talk to them about peer pressure and the risks of using drugs and other substances that distort reality. (See the "Need More Info?" section below for links to resources that can help you with this.)

Also, remember that just because a product is "natural," this does not mean it is safe. Natural Health Products that have been approved by Health Canada will have one of the following:

- a Natural Product Number (NPN) or
- a Drug Identification Number - Homeopathic Medicine (DIN-HM)

reversed order of NPN and DIN-HM

These numbers indicate that the product's quality, safety and efficacy, including labelling and instructions for use, have been reviewed. As stated earlier, no *Salvia divinorum* products have been approved by Health Canada.

### Health Canada's Role

Health Canada continues to collect and consider information regarding *Salvia divinorum* and continues to consult with key stakeholders, including health officials in other countries, and law enforcement officials here at home. This will assist in determining the most appropriate strategy to manage the risks associated with the use of *Salvia divinorum* and to control the availability of this substance.

### Need More Info?

For information about Health Canada's Drug Strategy and Controlled Substances Programme, go to: <http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hecs-dgsesc/dscsp-psasc/index-eng.php>

Also, see the section on Prevention on the Government of Canada's National Anti-Drug Strategy Web site at: <http://www.nationalantidrugstrategy.gc.ca/>. This site has a number of helpful resources for parents, including "Tips on Talking to Your Teenager" and "What to do if Your Teen is using Drugs."

Valerie Hurry - Comments

For more on the surveys that are collecting information about *Salvia divinorum* use in Canada, see:

The Ontario Student Drug Use and Health Survey, at: <http://www.camh.net/Research/osdus.html>  
The 2008-2009 Youth Smoking Survey, at:  
[http://www.yss.uwaterloo.ca/ysss/site\\_app/controller/index.cfm](http://www.yss.uwaterloo.ca/ysss/site_app/controller/index.cfm)

Also, see the following Web sites:

U.S. Drug Enforcement Administration: Drugs and Chemicals of Concern: *Salvia divinorum* and Salvinorin A at: [http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)

U.S. Department of Health & Human Services, National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006 at:  
<http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf>

For additional articles on health and safety issues go to the *It's Your Health* Web site at:  
<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/index-eng.php>

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

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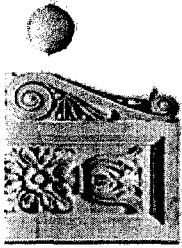
Writer: Sue Lumsden 

s.19(1)

Version/date: Draft One, February 5, 2009

Contacts: Jocelyn Kula, Cheryl Tremblay, Brittany Sauvé (HECSB)  
Valery Hurry (NHPD - HPFB)  
No input from MHPD, but draft is being sent to Scott Jordan for review





Cheryl  
Tremblay/HC-SC/GC/CA  
2009-02-17 09:51 AM

To Jocelyn Kula/HC-SC/GC/CA@HWC  
cc  
bcc Cheryl Tremblay/HC-SC/GC/CA  
Subject Re: Fw: It's Your Health - Salvia divinorum - Draft One

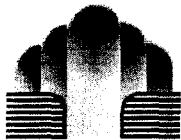
Hi Jocelyn,

I received Valerie's comments this am. Here is the draft with all of our comments included. I'll give Isabel a hard copy for you as well.



IYH - Salvia Divinorum - Draft One\_DSCSD\_NHPD Comments.doc

Thanks,  
Cheryl  
Jocelyn Kula/HC-SC/GC/CA



Jocelyn Kula/HC-SC/GC/CA  
2009-02-15 10:33 PM

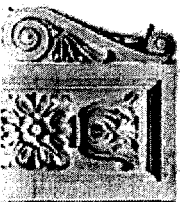
To Cheryl Tremblay/HC-SC/GC/CA@HWC  
cc  
Subject Re: Fw: It's Your Health - Salvia divinorum - Draft One

thanks but I think I would prefer to see all the comments together.....can you pls track down Valerie if you don't see anything when you are back on Tuesday.....I would like to honour the commitment to Sue Lumsden and we may need to meet with people, i.e., ORS before that.....

JK

---

Jocelyn Kula  
Manager/ Gestionnaire  
Policy and Regulatory Affairs Division/ Division des politiques et affaires réglementaires  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0125 Fax: (613) 946-4224  
Cheryl Tremblay/HC-SC/GC/CA



Cheryl  
Tremblay/HC-SC/GC/CA  
2009-02-13 08:47 AM

To Jocelyn Kula/HC-SC/GC/CA@HWC  
cc  
Subject Re: Fw: It's Your Health - Salvia divinorum - Draft One

Hi Jocelyn,

I'm not sure if you want to see this before we've received all comments (I sent a reminder to Valerie this am to let her know that we would like to send Sue our comments next week sometime) but here are Brittany and my comments thus far.

[attachment "IYH - Salvia Divinorum - Draft One\_DSCSD\_NHPD Comments.doc" deleted by Jocelyn Kula/HC-SC/GC/CA]

Thanks,  
Cheryl Tremblay  
Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Drug Strategy and Controlled Substances Directorate  
Health Canada  
Tel: (613) 954-6527  
Fax: (613) 946-4224  
Jocelyn Kula/HC-SC/GC/CA



Jocelyn Kula/HC-SC/GC/CA

2009-02-05 12:38 PM

To Cheryl Tremblay/HC-SC/GC/CA@HWC, Brittany Sauvé/HC-SC/GC/CA@HWC, Valerie Hurry/HC-SC/GC/CA@HWC

cc

Subject Fw: It's Your Health - Salvia divinorum - Draft One

May I suggest that we try and provide one set of comments for Sue to work from? Perhaps if everyone could provide comments to Cheryl, she can collate and then circulate for all to agree on before we pass on to Sue. Just might be easier for Sue to work from.

Let me know.

Jocelyn

s.19(1)

---

Jocelyn Kula  
Manager, Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Healthy Environments and Consumer Safety Branch  
Health Canada  
Tel: (613) 946-0125 Fax: (613) 946-4224

----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2009-02-05 12:36 PM -----



"Sue Lumsden"

2009-02-05 12:34 PM

To "Jocelyn Kula" <jocelyn\_kula@hc-sc.gc.ca>, "Cheryl Tremblay" <Cheryl\_Tremblay@hc-sc.gc.ca>, Brittany Sauvé <brittany\_sauve@hc-sc.gc.ca>, "Valerie Hurry" <Valerie\_Hurry@hc-sc.gc.ca>  
cc <Scott\_Jordan@hc-sc.gc.ca>

Subject It's Your Health - Salvia divinorum - Draft One

Good afternoon,

# Salvia Divinorum

## The Issue

Certain Web sites are promoting the use of *Salvia divinorum* (*S. divinorum*) as a "legal" alternative to street drugs. Health Canada recommends that you avoid using this substance because very little is known about the extent of adverse effects, and there is no way to predict how it will affect you.

## Background

*Salvia divinorum* is a species of sage that belongs to the mint family. It is known to have psychotropic effects, these are effects on the mind.

The leaves of this plant are used traditionally by the Mazatec Indians in Mexico for medicinal and spiritual purposes. Traditional use involves chewing the leaves or using them to make a tea to treat such conditions as headache or stomach upset, or to produce a "mystical" or hallucinogenic experiences.

Products that claim to contain *S. divinorum* – or its main active ingredient, salvinorin A – are widely available on the Internet and are sold in various "head shops". These products are sold in a number of formats, including seeds, plant cuttings for propagation purposes. Fresh or dried leaves are intended to be either chewed, swallowed or smoked; liquid preparations are also available for consumption. Street names for *S. divinorum* include: diviner's sage, magic mint, maria pastra, puff encens special, ska pastora, ska maria pastora, sally D, lady sally and salvia.

Recently, there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* specifically for its ability to produce hallucinations (i.e. "seeing" objects that are not there), but so far, there has been no solid research in Canada on its actual use.

Questions about the use of *S. divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. The survey results will help fill some of the information gaps, but the data will not be available until 2010. (2008 Canadian Alcohol and Drug Use Monitoring Survey too?)

Health Canada has not approved any *Salvia divinorum* products for sale in Canada. In Canada, neither *S. divinorum* nor salvinorin A are controlled, under the *Controlled Drugs and Substances Act*. *Salvia divinorum* does meet the definition of a natural health product under the *Natural Health Product Regulations*, which means that a product that contains *Salvia divinorum* must be approved by Health Canada prior to being sold in Canada. Health Canada has, however, not approved any Salvia products for sale in Canada.

Several countries (e.g., Australia, Belgium, Denmark, Sweden, Italy, Spain, Finland and South Korea) have placed controls on the import and/or sale of *S. divinorum*. A number of individual

- Comment: Comments ar (... [1])
- Comment: BS – All com (... [2])
- Comment: BS (... [3])
- Deleted: which means it (... [4])
- Comment: VH (... [5])
- Deleted: alvia
- Deleted: S
- Comment: BS - I am not (... [6])
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- Comment: VH, CT - Dis (... [7])
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- Comment: CT
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- Comment: CT - Moved (... [8])
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- Comment: CT - Remove
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U.S. States have done this as well, but *S. divinorum* is not federally regulated under the *Controlled Substances Act* in the United States.

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Comment: CT

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It is not regulated under the *Controlled Substances Act* in the United States but a number of individual states have placed restrictions on its sale.

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Comment: VH, CT - Valerie has suggested revising above sentence as follows. Agree with re-order, but not with reference only to restrictions on sale as some U.S. states have placed import restrictions as well.

**Risks associated with using *Salvia Divinorum***

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The use of *S. divinorum* distorts reality. The effects vary from person to person, are often described as unpleasant and may include the following:

Comment: VH, CT - Agree

- hallucinations
- out-of-body experiences
- loss of consciousness
- short-term memory loss
- uncontrollable laughter
- impaired ability to speak

Comment: CT - placed [14]

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Comment: VH

Deleted: loss of

Deleted:

Comment: BS

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

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- potency of the product
- how much is used
- how it is taken (e.g. ingested or smoked)
- the person's mood and expectations

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It does not appear to cause the euphoria often associated with other psychoactive drugs, so many people who try it do not repeat the experience.

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Comment: VH

A major concern about *S. divinorum* is the fact that there have been so few scientific studies about the way it affects the body and the brain. For example, very little is known about the following issues:

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- how it affects the brain and if it causes permanent damage
- whether it causes physical dependence or addiction (unlikely according to the evidence available so far);
- how it interacts with other substances (including drugs and alcohol)

Comment: BS - Every t [21]

Comment: BS

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Comment: BS

Also, since no *S. divinorum* products have been approved for sale in Canada, and thus have not been reviewed by Health Canada, they may be counterfeit or may contain other ingredients that pose risks to health.

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Comment: VH

Comment: CT

Comment: CT

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Comment: CT

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**The Legal Status of *Salvia Divinorum***

From time to time, Health Canada is asked why *S. divinorum* and salvinorin A are not prohibited under the *Controlled Drugs and Substances Act* (CDSA). When assessing whether to regulate a substance under the CDSA, Health Canada considers many factors, including the following:

Deleted: In cases like th [26]

Deleted: alvia... S [27]

- international requirements and trends in controlling the substance
- similarity to other substances already regulated under the CDSA
- whether there may be legitimate uses of the substance (e.g., potential health benefits)
- the potential for addiction and abuse/misuse of the substance
- the extent of actual abuse and misuse of the substance in Canada and elsewhere
- overall risk to public health and safety posed by the substance

In the case of *S. divinorum*, there is simply not enough information available to determine whether prohibition is the best option to manage the potential risks associated with its use. Questions about the use of *S. divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. The survey results will help fill some of the information gaps, but the data will not be available until 2010.

### Minimizing Your Risk

Health Canada recommends that you avoid using *S. divinorum*. Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs and other substances that distort reality. (See the "Need More Info?" section below for links to resources that can help you with this.)

Also, remember that just because a product is "natural," this does not mean it is safe. Natural Health Products that have been approved by Health Canada will have one of the following:

- a Natural Product Number (NPN) or
- a Drug Identification Number - Homeopathic Medicine (DIN-HM)

These numbers let you know that the products have undergone and passed a review of their formulation, labelling and instructions for use. As stated earlier, no *S. divinorum* products have been approved by Health Canada.

### Health Canada's Role

Health Canada continues to collect and consider information regarding *Salvia divinorum* and continues to consult with key stakeholders, including health officials in other countries, and law enforcement officials here at home. This will assist in determining the most appropriate strategy to manage the risks associated with the use of *S. divinorum* and to control the availability of this substance.

### Need More Info?

For information about Health Canada's Drug Strategy and Controlled Substances Directorate, go to: <http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hecs-dgsesc/dscsp-psasc/index-eng.php>

Also, see the section on Prevention on the Government of Canada's National Anti-Drug Strategy Web site at: <http://www.nationalantidrugstrategy.gc.ca/>. This site has a number of helpful

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**Comment:** VH - Suggested removing this sentence all together.

**Comment:** BS - This sentence sounds odd a bit because its not just law enforcement that can judge public safety

**Deleted:** To date, no law enforcement agencies have advised Health C

**Deleted:** anada that the use of *Salvia divinorum* poses any particular threat to public safety. However, as noted earlier, very little is known about the potential for addiction or the extent of actual use.

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**Comment:** CT - Suggest moving this to Background section after sentence, "there has been no solid research in Canada on its actual use."

**Deleted:** likely

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CT - Disagree - *Salvia* is legal.

**Deleted:** <#>a Drug Identification Number - Homeopathic Medicine (DIN-HM) or

**Comment:** VH - Reversed order

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**Comment:** CT - However, still says Programme on HC website.

**Deleted:** Programme

resources for parents, including "Tips on Talking to Your Teenager" and "What to do if Your Teen is using Drugs."

For more on the surveys that are collecting information about *Salvia divinorum* use in Canada, see:

Ontario Student Drug Use and Health Survey, at: <http://www.camh.net/Research/osdus.html>  
The 2008-2009 Youth Smoking Survey, at:  
[http://www.yss.uwaterloo.ca/ysssite\\_app/controller/index.cfm](http://www.yss.uwaterloo.ca/ysssite_app/controller/index.cfm)

**Comment:** Reverse order – Should be listed in order that they appear in text.  
**Comment:** CT – Add reference if included above.

2008 Canadian Alcohol and Drug Use Monitoring Survey

Also, see the following Web sites:

U.S. Drug Enforcement Administration: Drugs and Chemicals of Concern: *Salvia divinorum* and Salvinorin A at: [http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)  
U.S. Department of Health & Human Services, National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006 at:  
<http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf>

For additional articles on health and safety issues go to the *It's Your Health* Web site at:  
<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/index-eng.php>  
<http://www.hc-sc.gc.ca/english/iyh/index.html>  
You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

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s.19(1)

Writer: Sue Lumsden [REDACTED]

Version/date: Draft One, February 5, 2009

Contacts: Jocelyn Kula, Cheryl Tremblay, Brittany Sauvé (HECSB)  
Valerie Hurry (NHPD - HPFB)  
No input from MHPD, but draft is being sent to Scott Jordan for review

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<b>Page 1: [1] Comment</b>	<b>CTREMBLA</b>	<b>2009-02-17 8:59 AM</b>
Comments are identified by colour as follows: Brittany Sauvé (DSCSD), Cheryl Tremblay (DSCSD), Valerie Hurry (NHPD)		
<b>Page 1: [2] Comment</b>	<b>CTREMBLA</b>	<b>2009-02-17 8:59 AM</b>
BS – All comments on <i>S. divinorum</i> . CT – I think that we should use full name throughout document.		
<b>Page 1: [3] Comment</b>	<b>CTREMBLA</b>	<b>2009-02-17 8:59 AM</b>
BS CT - or “which means it is capable of having an influence on the mind”?		
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which means it is capable of acting on the mind.		
<b>Page 1: [5] Comment</b>	<b>CTREMBLA</b>	<b>2009-02-17 8:59 AM</b>
BS - I am not sure that this is appropriate? Mainly herbal shops I think... right? CT - Agree		
<b>Page 1: [6] Comment</b>	<b>CTREMBLA</b>	<b>2009-02-17 8:59 AM</b>
VH, CT – Disagree - too technical for laymans terms.		
<b>Page 1: [7] Comment</b>	<b>CTREMBLA</b>	<b>2009-02-17 8:59 AM</b>
CT – Moved from Legal Status of Salvia section.		
<b>Page 1: [8] Comment</b>	<b>CTREMBLA</b>	<b>2009-02-17 8:59 AM</b>
CT- only general open-ended question not specific to Salvia.		
<b>Page 1: [9] Comment</b>	<b>CTREMBLA</b>	<b>2009-02-17 8:59 AM</b>
CT- Reversed order, sounded a little confusing to me.		
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<i>alvia</i>		
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CT – placed above instead		
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("seeing" objects that are not there)		
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experience		
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<b>Page 2: [21] Comment</b> BS - Every thing is toxic	<b>CTREMBLA</b>	<b>2009-02-17 8:59 AM</b>
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<b>Page 2: [23] Deleted</b> acts on	<b>CTREMBLA</b>	<b>2009-02-06 2:08 PM</b>
<b>Page 2: [24] Deleted</b>  how long it acts on the brain and whether there are permanent effects	<b>CTREMBLA</b>	<b>2009-02-06 2:09 PM</b>
<b>Page 2: [25] Deleted</b> <i>alvia</i>	<b>CTREMBLA</b>	<b>2009-02-06 2:11 PM</b>
<b>Page 2: [25] Deleted</b> products that claim to contain this substance	<b>CTREMBLA</b>	<b>2009-02-13 8:38 AM</b>
<b>Page 2: [26] Deleted</b> In cases like this, it is always a matter of "buyer beware."	<b>CTREMBLA</b>	<b>2009-02-06 2:11 PM</b>
<b>Page 2: [27] Deleted</b> <i>alvia</i>	<b>CTREMBLA</b>	<b>2009-02-06 2:12 PM</b>
<b>Page 2: [27] Deleted</b> S	<b>CTREMBLA</b>	<b>2009-02-06 2:12 PM</b>

DRAFT  
February 24, 2009

## **Media Lines Regulatory Control of *Salvia Divinorum***

### **Issue**

Since 2006, Health Canada has observed a steady increase in the amount of media interest regarding the availability of *Salvia divinorum* on the Canadian market. Health Canada has also received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum*, particularly given reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties.

### **Key Messages:**

- Health Canada continues to collect relevant information about *Salvia divinorum* and its active ingredient, Salvinorin A, from both national and international sources in order to determine what, if any, regulatory controls are needed.
- While the media has reported that use of *Salvia divinorum* is on the rise in certain parts of the country, Health Canada does not currently have statistics on its use across the Canadian population.
- Health Canada is taking steps to address this lack of data. Questions regarding the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. A general open-ended question about the use of other substances has also been included in the 2008 Canadian Alcohol and Drug Use Monitoring Survey.

### **Supplementary Messages:**

#### ***On the classification of *Salvia divinorum*:***

- In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, Salvinorin A, are controlled under the *Controlled Drugs and Substances Act* (CDSA).
- *Salvia divinorum* is not listed under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these conventions.
- Several countries (Australia, Belgium, Denmark, Sweden, Italy, Spain, Finland and South Korea) have placed controls on the import and/or sale of *Salvia divinorum*. Although some individual U.S. states have implemented laws restricting its use,

sale and/or distribution, *Salvia divinorum* is not federally regulated under the *Controlled Substances Act* in the United States.

- *Salvia divinorum* does however meet the definition of a natural health product under the *Natural Health Product Regulations* (NHPR). This means that *Salvia* products that are not in compliance with the NHPR may be subject to compliance and enforcement actions.
- As of January 2009, Health Canada had not issued any Natural Product Number's (NPN) or Drug Identification Number's (DIN) - Homeopathic Medicine (DIN-HM) for *Salvia divinorum* products.

no apostrophes

***If asked for specifics on when the survey data will be available:***

- Data from the Canadian Alcohol and Drug Use Monitoring Survey will be available in summer 2009, while the results of the Youth Smoking Survey and the Ontario Student Drug Use and Health Survey likely will not be available until 2010.

## **Questions and Answers**

**Q1 – If Health Canada is aware of *Salvia divinorum*'s ill-effects, why isn't it illegal?**

A1 – Very few controlled scientific studies of the physical and psychotropic effects of *Salvia divinorum* on humans have been carried out, and using these studies to predict the potential for addiction and abuse associated with *Salvia divinorum* is difficult. The mechanism of action by which *Salvia divinorum* works is still not fully understood from the existing information, and more research is needed.

Health Canada has only received a limited number of communications regarding *Salvia divinorum* from law enforcement agencies, and none of these have advised that the use of *Salvia divinorum* poses any particular threat to public safety.

**Q2 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?**

A2 – The *Natural Health Product Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *Salvia divinorum*.

**Q3 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum*. What does that involve and what stage is it at?**

A3 - Health Canada considers several factors in determining whether scheduling a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in control and scheduling;

- Chemical and pharmacological similarity to other substances already scheduled under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- ~~Addiction liability and potential for abuse/misuse~~ <sup>Abuse</sup> of the substance;
- Extent of actual abuse and misuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada has only anecdotal information about the last three of the above-mentioned factors, and thus is not yet convinced that the controls imposed by the CDSA are an appropriate strategy for managing the risks associated with *Salvia divinorum* ~~use~~.

Health Canada will however continue to collect and consider information regarding <sup>the use of</sup> *Salvia divinorum* as it becomes available.

**Q4 – Didn't an internal report from Health Canada's Marketed Health Products Directorate recommend that *Salvia divinorum* be scheduled under the CDSA? Why has that recommendation not been acted upon?**

A4 – See A3

**Q5 – Has Health Canada received any reports of adverse reactions related to the use of *Salvia divinorum*?**

A5 – Since 2005, Health Canada has received four reports of adverse reactions associated with the use of *Salvia divinorum* as a hallucinogen, with three being considered non-serious (requiring no medical attention) and the fourth being considered serious (medical intervention was required).

Delete Q5&A5 OR...

~~① Health Canada has received reports related to~~  
 A5 - ~~Four adverse reactions associated with the use of *Salvia divinorum* as a hallucinogen have been reported to Health Canada through the Canadian Adverse Drug Reaction Monitoring Program (CADRMP). Three of these reports were considered non-serious (requiring no medical attention) and the fourth was considered serious (medical intervention was required). The CADRMP was, however, designed to receive reports concerning adverse drug reactions to marketed health products that have been reviewed and approved for sale in Canada, and not for adverse reactions associated with the use of *Salvia divinorum* as a street drug. As a result, some concerns regarding the significance of this information have been raised as it cannot be used to determine the incidence of a reaction, nor the risk associated with the use of *Salvia divinorum*, because of the unknown number of individuals exposed to this product and the significant under-reporting of adverse reactions.~~

~~② The number of reports and even the types of reactions, <sup>Health Canada does not have any information</sup> ~~reported e.g., XXX, not~~ is not significant however given that CADRMP is~~

I prefer my revised question what is the significance of ...  
 A: of which *Salvia* is not ...

*Salvia divinorum* is a species of sage belonging to the mint family that is chewed or smoked in order to induce its psychotropic effects. These effects are short-acting in nature and include hallucinations, out-of-body experiences, unconsciousness and short-term memory loss.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. While no validated data exist regarding usage in Canada, data from a 2006 National Survey on Drug Use and Health Report, published by the U.S. Substance Abuse and Mental Health Services Administration has estimated that:

- 1.8 million persons aged 12 or older used *Salvia divinorum* at least once in their lifetime, and approximately 750,000 did so in the past year.
- Use was more common among young adults (18 to 25 years old) as opposed to older adults (>26 years of age).
- Young adults were 3 times more likely than youths aged 12 to 17 to have used *Salvia divinorum* in the past year.
- Use was more common in males than females.

*Salvia divinorum* is widely touted on the Internet as a "legal" alternative to street drugs.

While some users have reported that the psychotropic effects of *Salvia divinorum* resemble those induced by other hallucinogens, such as LSD and phencyclidine, the overall experience appears to be quite unique.

**Prepared by:** Cheryl Tremblay, Policy and Regulatory Affairs Division, DSCSD  
Stephanie Mitchell, Communications Advisor (HECSB)  
Darrin Denne, Communications Officer (HPFB)

**Approved by :**

Approved	Andrew Adams, Director, OCS, DSCSD
	Nancy Richards, Director, Bureau of Policy and Regulatory Affairs, NHPD (January 23, 2009)
	Duc Vu, Director, Marketed Biologics, Biotechnology and Natural Health Products Bureau, MHPD (February 3, 2009)
Pending	Ray Edwards, A/DG, DSCSD
Pending	Chris Turner, DG, MHPD
Pending	Michelle Boudreau, DG, NHPD
Pending	Diana Dowthwaite, DG, HPFBI
Pending	Ken Polk, Communications Executive, HPFB
Pending	Kathleen Malone, Senior Communications Executive, HECSB
Pending	Peter Yendall, Director, Public Affairs, PACCB
Pending	Paul Glover, ADM, HECSB
Pending	Meena Ballantyne, ADM, HPFB
Pending	DMO

Pending  
Pending

MO  
PCO

Inspectate

Babara

Banning

Michelle

Gillespie

Jocelyn Kula/HC-SC/GC/CA  
2009-02-25 09:49 AM

To Cheryl Tremblay/HC-SC/GC/CA@HWC  
cc  
bcc

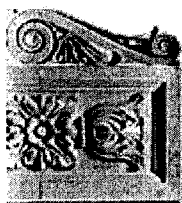
Subject Fw: Phone Enquiry - Salvia

Do you feel comfortable taking this one on? I think you should feel free to tell him that he is always welcome to keep us informed via the PRAD account.....and that we are always interested in reports of abuse/misuse/inappropriate sale etc. Specific info about retailers is also of interest.

In terms of regulating, I think you should be honest and say that at the moment, we have not yet made a decision as to whether prohibition under the CDSA is appropriate.....

JK

Jocelyn Kula  
Manager/ Gestionnaire  
Policy and Regulatory Affairs  
Office of Controlled Substances  
Healthy Environments and  
Consumer Safety  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0125 Fax:  
----- Forwarded by Jocelyn K



Carmen  
Berube/HC-SC/CA  
2009-02-25 09:1

Ecole Secondaire réglementaires  
le la santé environnementale et  
Sell Salvia to (200) kids in  
Belarus QC  
rcaruso@police-ns1.gc.ca  
(Medivian)  
dash  
A@HWC  
C/CA@HWC

Good morning Jocelyn,

Constable Richard Caruso (he is a police officer) called just now. He said that he is receiving a lot of complaints from people indicating that Salvia is readily available, advertised in some stores and sold to school kids in his community. He was told that HC is working on regulating this substance. He was wondering if there is a place where he can report these complaints here at OCS. He thinks that all the complaints should be recorded.

Constable Caruso can be reached today before 10:15 or from 4:00 PM on or tomorrow and Friday.

Please let me and Jennifer know once you have responded for our tracking purposes.

Thank you,  
Carmen

rcaruso@police-ns1.gc.ca

OCS-policy-and-regulatory-affairs@  
hc-sc.gc.ca

Richelieu Saint-Louis 000184  
Regional Police Service

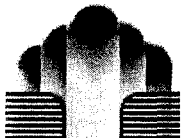
Inspectante

Babaa

Banning

Michelle

Gillespie



Jocelyn Kula/HC-SC/GC/CA  
2009-02-25 09:49 AM

To Cheryl Tremblay/HC-SC/GC/CA@HWC  
cc  
bcc

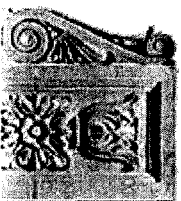
Subject Fw: Phone Enquiry - Salvia

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In terms of regulating, I think you should be honest and say that at the moment, we have not yet made a decision as to whether prohibition under the CDSA is appropriate.....

JK

Jocelyn Kula  
Manager/ Gestionnaire  
Policy and Regulatory Affairs Division/ Division des politiques et affaires réglementaires  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0125 Fax: (613) 946-4224  
---- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2009-02-25 09:46 AM ----



Carmen  
Berube/HC-SC/GC/CA  
2009-02-25 09:13 AM

To Jocelyn Kula/HC-SC/GC/CA@HWC  
cc Isabel Shanahan/HC-SC/GC/CA@HWC  
Subject Phone Enquiry - Salvia

Good morning Jocelyn,

Constable Richard Caruso (he is french speaking) called just now. He said that he is receiving a lot of complaints from people indicating that Salvia is readily available, advertized in some stores and sold to school kids in his community. He was told that HC is working on regulating this substance. He was wondering if there is a place where he can report these complaints here at OCS. He thinks that all the complaints should be recorded.

Constable Caruso can be reached today before 10:15 or from 4:00 PM on or tomorrow and Friday.

Please let me and Jennifer know once you have responded for our tracking purposes.

Thank you,  
Carmen

rcaruso@police-rs1.gc.ca

ocs-policy-and-regulatory-affairs@  
hc-sc.gc.ca

Richelieu Saint-Lau



Regional ~~Complex~~ <sup>Operational</sup> Center  
~~Office~~

(Merge) Francis Menead

Tel (450)-928-4015

FAX (450)-928-4184

Supervisor, Drug  
Investigations

Action Plan

- share internally
- cautions of distributing externally  
as they may identify loop holes.

DRAFT  
February 25, 2009

## **Media Lines Regulatory Control of *Salvia Divinorum***

### **Issue**

Since 2006, Health Canada has observed a steady increase in the amount of media interest regarding the availability of *Salvia divinorum* on the Canadian market. Health Canada has also received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum*, particularly given reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties.

### **Key Messages:**

- Health Canada continues to collect relevant information about *Salvia divinorum* and its active ingredient, Salvinorin A, from both national and international sources in order to determine what, if any, regulatory controls are needed.
- While the media has reported that use of *Salvia divinorum* is on the rise in certain parts of the country, Health Canada does not currently have statistics on its use across the Canadian population.
- Health Canada is taking steps to address this lack of data. Questions regarding the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. A general open-ended question about the use of other substances has also been included in the 2008 Canadian Alcohol and Drug Use Monitoring Survey.

### **Supplementary Messages:**

#### ***On the classification of *Salvia divinorum*:***

- In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, Salvinorin A, are controlled under the *Controlled Drugs and Substances Act* (CDSA).
- *Salvia divinorum* is not listed under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these conventions.
- Several countries (Australia, Belgium, Denmark, Sweden, Italy, Spain, Finland and South Korea) have placed controls on the import and/or sale of *Salvia divinorum*. Although some individual U.S. states have implemented laws restricting its use,

sale and/or distribution, *Salvia divinorum* is not federally regulated under the *Controlled Substances Act* in the United States.

- *Salvia divinorum* does however meet the definition of a natural health product under the *Natural Health Product Regulations* (NHPR). This means that *Salvia* products that are not in compliance with the NHPR may be subject to compliance and enforcement actions.
- As of January 2009, Health Canada had not issued any Natural Product Numbers (NPN) or Drug Identification Numbers – Homeopathic Medicine (DIN-HM) for *Salvia divinorum* products.

***If asked for specifics on when the survey data will be available:***

- Data from the Canadian Alcohol and Drug Use Monitoring Survey will be available in summer 2009, while the results of the Youth Smoking Survey and the Ontario Student Drug Use and Health Survey likely will not be available until 2010.

**Questions and Answers**

**Q1 – If Health Canada is aware of *Salvia divinorum*'s ill-effects, why isn't it illegal?**

A1 – Very few controlled scientific studies of the physical and psychotropic effects of *Salvia divinorum* on humans have been carried out, and using these studies to predict the potential for addiction and abuse associated with *Salvia divinorum* is difficult. More controlled systematic research in this area is needed.

Health Canada has only received a limited number of communications regarding *Salvia divinorum* from law enforcement agencies, and none of these have advised that the use of *Salvia divinorum* poses any particular threat to public safety.

**Q2 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?**

A2 – The *Natural Health Product Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *Salvia divinorum*.

**Q3 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum*. What does that involve and what stage is it at?**

A3 - Health Canada considers several factors in determining whether scheduling a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in control and scheduling;
- Chemical and pharmacological similarity to other substances already scheduled under the CDSA;

- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Abuse liability and addiction potential of the substance;
- Extent of actual abuse and misuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada has only anecdotal information about the last three of the above-mentioned factors, and thus is not yet convinced that the controls imposed by the CDSA are an appropriate strategy for managing the risks associated with the use of *Salvia divinorum*.

Health Canada will however continue to collect and consider information regarding *Salvia divinorum* as it becomes available.

**Q4 – Didn't an internal report from Health Canada's Marketed Health Products Directorate recommend that *Salvia divinorum* be scheduled under the CDSA? Why has that recommendation not been acted upon?**

A4 – See A3

**Q5 – What is the significance of the adverse reaction reports that Health Canada has received with respect to the use of *Salvia divinorum*?**

A5 – Health Canada has received four adverse reaction reports related to the use of *Salvia divinorum* as a hallucinogen through its Canadian Adverse Drug Reaction Monitoring Program (CADRMP). However, the number of reports and even the type of reactions reported (e.g. non serious – requiring no medical intervention or serious – medical intervention was required) is not significant given that the CADRMP is designed to receive adverse drug reaction reports related to health products that have been reviewed and approved for sale in Canada of which *Salvia divinorum* is not. [Health Canada ~~also~~ does not have any information about the number of individuals using or who have used *Salvia divinorum*.]

In this regard, and because [ ], these adverse ~~drug~~ reaction reports cannot be deemed to be significant.

As a result, some concerns regarding the significance of this information have been raised as it cannot be used to determine the incidence of a reaction, nor the risk associated with the use of *Salvia divinorum*, because of the unknown number of individuals exposed to this product and the significant under-reporting of adverse reactions.

### Background

*Salvia divinorum* is a species of sage belonging to the mint family that is chewed or smoked in order to induce its psychotropic effects. These effects are short-acting in nature and include hallucinations, out-of-body experiences, unconsciousness and short-term memory loss.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. While no validated data exist regarding usage in Canada, data

from a 2006 National Survey on Drug Use and Health Report, published by the U.S. Substance Abuse and Mental Health Services Administration has estimated that:

- 1.8 million persons aged 12 or older used *Salvia divinorum* at least once in their lifetime, and approximately 750,000 did so in the past year.
- Use was more common among young adults (18 to 25 years old) as opposed to older adults (>26 years of age).
- Young adults were 3 times more likely than youths aged 12 to 17 to have used *Salvia divinorum* in the past year.
- Use was more common in males than females.

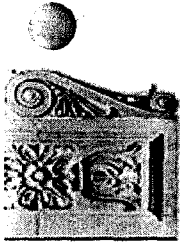
*Salvia divinorum* is widely touted on the Internet as a “legal” alternative to street drugs.

While some users have reported that the psychotropic effects of *Salvia divinorum* resemble those induced by other hallucinogens, such as LSD and phencyclidine, the overall experience appears to be quite unique.

**Prepared by:** Cheryl Tremblay, Policy and Regulatory Affairs Division, DSCSD  
Stephanie Mitchell, Communications Advisor (HECSB)  
Darrin Denne, Communications Officer (HPFB)

**Approved by :**

Approved	Andrew Adams, Director, OCS, DSCSD
	Nancy Richards, Director, Bureau of Policy and Regulatory Affairs, NHPD (January 23, 2009)
	Duc Vu, Director, Marketed Biologics, Biotechnology and Natural Health Products Bureau, MHPD (February 3, 2009)
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Pending	Paul Glover, ADM, HECSB
Pending	Meena Ballantyne, ADM, HPFB
Pending	DMO
Pending	MO
Pending	PCO



Carmen  
Berube/HC-SC/GC/CA  
2009-03-10 09:43 AM

To Cheryl Tremblay/HC-SC/GC/CA@HWC  
cc Jennifer Nicholson/HC-SC/GC/CA@HWC  
bcc  
Subject Phone Enquiry - Salvia w/phone number

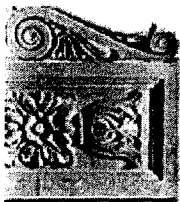
Cheryl,

Not that I'm aware of. Last week, I asked her and she said she would try, but I doubt she did because she was swamped and did not get back to him. He called back and was expecting a call last week.

Please let me and Jennifer know when you have contacted him.

Thanks,  
Carmen

Cheryl Tremblay/HC-SC/GC/CA



Cheryl  
Tremblay/HC-SC/GC/CA  
2009-03-10 07:49 AM

To Carmen Berube/HC-SC/GC/CA@HWC  
cc Isabel Shanahan/HC-SC/GC/CA@HWC, Jocelyn  
Kula/HC-SC/GC/CA@HWC, Jennifer  
Nicholson/HC-SC/GC/CA@HWC  
Subject Re: Phone Enquiry - Salvia w/phone number

s.19(1)

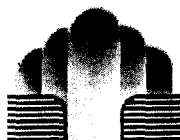
Hi Carmen,

I just got back into the office today.

Do you know whether or not Jocelyn had a chance to call Const. Caruso back last week? If not, I will call him today. I had tried him on Friday, February 27th with no luck.

Thanks,

Cheryl Tremblay  
Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Drug Strategy and Controlled Substances Directorate  
Health Canada  
Tel: (613) 954-6527  
Fax: (613) 946-4224  
Jocelyn Kula/HC-SC/GC/CA



Jocelyn Kula/HC-SC/GC/CA  
2009-03-03 05:49 PM

To Carmen Berube/HC-SC/GC/CA@HWC  
cc Isabel Shanahan/HC-SC/GC/CA@HWC, Jennifer  
Nicholson/HC-SC/GC/CA@HWC, Cheryl  
Tremblay/HC-SC/GC/CA@HWC  
Subject Re: Phone Enquiry - Salvia w/phone number

Constable Caruso can be reached today before 10:15 or from 4:00 PM on or tomorrow and Friday. He can be reached at 450-536-3334 x 232.

Please let me and Jennifer know once you have responded for our tracking purposes.

Thank you,  
Carmen

## PRAD Telephone Enquiry

Date of Call: Tuesday, March 10, 2009  
Subject: *Salvia Divinorum*  
Language of Correspondence: English/French

Caller Name: Constable Richard Caruso  
Caller Origin: Québec  
Caller Telephone Number: 450-536-3334 x 232  
Caller Email Address: rcaruso@police-rsl.qc.ca

### CALL SUMMARY:

I spoke to Constable Richard Caruso of the Richelieu Saint-Laurent Regional Police Service today. Constable Caruso had called to notify the Office of Controlled Substances (OCS) that he is receiving a lot of complaints from citizens indicating that *Salvia divinorum* is readily available, advertised in some stores, and sold to school-aged kids in his community. Const. Caruso had been told that Health Canada is working on regulating this substance and wanted to know whether he should report these complaints to OCS.

I confirmed with Const. Caruso that Health Canada is collecting relevant information about *Salvia divinorum* and its active ingredient, Salvinorin A, from both national and international sources in order to determine what, if any, regulatory controls are needed. I informed Const. Caruso that he is more than welcome to forward any information he has with respect to *Salvia divinorum* via [ocs\\_policy\\_and\\_regulatory\\_affairs@hc-sc.gc.ca](mailto:ocs_policy_and_regulatory_affairs@hc-sc.gc.ca) or fax at (613) 946-4224.

Upon the recommendation of Michelle Gillespie at the Health Products and Food Branch Inspectorate, I also sent Const. Caruso a follow-up email with contact information for Francine Menard, Supervisor of the Operational Centre for the Québec Region.

I told him to please not hesitate to contact us should he have any further questions.

Cheryl Tremblay  
Policy Analyst  
Policy and Regulatory Affairs Division



DRAFT  
March 10, 2009

### Media Lines Regulatory Control of Salvia Divinorum

**Issue**

Since 2006, Health Canada has observed a steady increase in the amount of media interest regarding the availability of *Salvia divinorum* on the Canadian market. Health Canada has also received a number of enquiries from various municipalities and members of the public regarding the availability of *Salvia divinorum* and media sources suggesting that *Salvia divinorum* is specifically for its hallucinogenic properties.

Cheryl

**Key Messages**

- ① Date of this version? (if includes MHPD changes)
- ② one small change Pg 3
- ③ Good job - so what next -> four ADM via Commes?
- ④ Where are we at with our IAS?

**Supplementary**

J/K

**On the**

- Is *Salvia divinorum* a psychoactive ingredient, as defined in the *Controlled Substances Act*?
- Is *Salvia divinorum* a controlled substance under the *Control Conventions* and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these conventions.
- Several countries (Australia, Belgium, Denmark, Sweden, Italy, Spain, Finland and South Korea) have placed controls on the import and/or sale of *Salvia divinorum*. Although some individual U.S. states have implemented laws restricting its use,

DRAFT  
March 10, 2009

## **Media Lines Regulatory Control of *Salvia Divinorum***

### **Issue**

Since 2006, Health Canada has observed a steady increase in the amount of media interest regarding the availability of *Salvia divinorum* on the Canadian market. Health Canada has also received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum*, particularly given reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties.

### **Key Messages:**

- Health Canada continues to collect relevant information about *Salvia divinorum* and its active ingredient, Salvinorin A, from both national and international sources in order to determine what, if any, regulatory controls are needed.
- While the media has reported that use of *Salvia divinorum* is on the rise in certain parts of the country, Health Canada does not currently have statistics on its use across the Canadian population.
- Health Canada is taking steps to address this lack of data. Questions regarding the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. A general open-ended question about the use of other substances was also included in the 2008 Canadian Alcohol and Drug Use Monitoring Survey.

### **Supplementary Messages:**

#### ***On the classification of *Salvia divinorum*:***

- In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, Salvinorin A, are controlled under the *Controlled Drugs and Substances Act* (CDSA).
- *Salvia divinorum* is not listed under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these conventions.
- Several countries (Australia, Belgium, Denmark, Sweden, Italy, Spain, Finland and South Korea) have placed controls on the import and/or sale of *Salvia divinorum*. Although some individual U.S. states have implemented laws restricting its use,

sale and/or distribution, *Salvia divinorum* is not federally regulated under the *Controlled Substances Act* in the United States.

- *Salvia divinorum* does, however, meet the definition of a natural health product under the *Natural Health Product Regulations* (NHPR). This means that *Salvia* products that are not in compliance with the NHPR may be subject to compliance and enforcement actions.
- As of January 2009, Health Canada had not issued any Natural Product Numbers (NPN) or Drug Identification Numbers – Homeopathic Medicine (DIN-HM) for *Salvia divinorum* products.

***If asked for specifics on when the survey data will be available:***

- Data from the Canadian Alcohol and Drug Use Monitoring Survey will be available in summer 2009, while the results of the Youth Smoking Survey and the Ontario Student Drug Use and Health Survey likely will not be available until 2010.

**Questions and Answers**

**Q1 – If Health Canada is aware of *Salvia divinorum*'s ill-effects, why isn't it illegal?**

A1 – Very few controlled scientific studies of the physical and psychotropic effects of *Salvia divinorum* on humans have been carried out, and using these studies to predict the potential for addiction and abuse associated with *Salvia divinorum* is difficult. More controlled systematic research in this area is needed.

Health Canada has only received a limited number of communications regarding *Salvia divinorum* from law enforcement agencies, and none of these has advised that the use of *Salvia divinorum* poses any particular threat to public safety.

**Q2 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?**

A2 – The *Natural Health Product Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *Salvia divinorum*.

**Q3 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum*. What does that involve and what stage is it at?**

A3 - Health Canada considers several factors in determining whether scheduling a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in control and scheduling;
- Chemical and pharmacological similarity to other substances already scheduled under the CDSA;

- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Abuse liability and addiction potential of the substance;
- Extent of actual abuse and misuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada has only anecdotal information about the last three of the above-mentioned factors, and thus is not yet convinced that the controls imposed by the CDSA are an appropriate strategy for managing the risks associated with the use of *Salvia divinorum*.

Health Canada will, however, continue to collect and consider information regarding *Salvia divinorum* as it becomes available.

**Q4 – Didn't an internal report from Health Canada's Marketed Health Products Directorate recommend that *Salvia divinorum* be scheduled under the CDSA? Why has that recommendation not been acted upon?**

A4 – See A3

**Q5 – What is the significance of the adverse reaction reports that Health Canada has received with respect to the use of *Salvia divinorum*?**

A5 – Health Canada has received four adverse reaction reports related to the use of *Salvia divinorum* as a hallucinogen through its Canadian Adverse Drug Reaction Monitoring Program (CADRMP). However, the number of reports and even the type of reactions reported (e.g., non serious – requiring no medical intervention or serious – medical intervention was required) is not significant given that the CADRMP is designed to receive adverse drug reaction reports related to health products that have been reviewed and approved for sale in Canada of which *Salvia divinorum* is not. In this regard, and because Health Canada does not have any information about the number of individuals using or who have used *Salvia divinorum*, these adverse reaction reports cannot be deemed to be significant.

### **Background**

*Salvia divinorum* is a species of sage belonging to the mint family that is chewed or smoked in order to induce its psychotropic effects. These effects are short-acting in nature and include hallucinations, out-of-body experiences, unconsciousness and short-term memory loss.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. While no validated data exist regarding usage in Canada, data from a 2006 National Survey on Drug Use and Health Report, published by the U.S. Substance Abuse and Mental Health Services Administration has estimated that:

- 1.8 million persons aged 12 or older used *Salvia divinorum* at least once in their lifetime, and approximately 750,000 did so in the past year.

have

- Use was more common among young adults (18 to 25 years old) as opposed to older adults (>26 years of age).
- Young adults were three times more likely than youths aged 12 to 17 to have used *Salvia divinorum* in the past year.
- Use was more common in males than females.

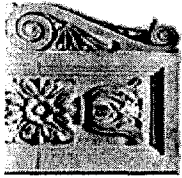
*Salvia divinorum* is widely touted on the Internet as a “legal” alternative to street drugs.

While some users have reported that the psychotropic effects of *Salvia divinorum* resemble those induced by other hallucinogens, such as LSD and phencyclidine, the overall experience appears to be quite unique.

**Prepared by:** Cheryl Tremblay, Policy and Regulatory Affairs Division, DSCSD  
Stephanie Mitchell, Communications Advisor (HECSB)  
Darrin Denne, Communications Officer (HPFB)

**Approved by :**

Approved	Andrew Adams, Director, OCS, DSCSD (March 1 <sup>st</sup> , 2009) Nancy Richards, Director, Bureau of Policy and Regulatory Affairs, NHPD Duc Vu, Director, Marketed Biologics, Biotechnology and Natural Health Products Bureau, MHPD
Pending	Ray Edwards, A/DG, DSCSD
Pending	Chris Turner, DG, MHPD
Pending	Michelle Boudreau, DG, NHPD
Pending	Diana Dowthwaite, DG, HPFBI
Pending	Ken Polk, Communications Executive, HPFB
Pending	Kathleen Malone, Senior Communications Executive, HECSB
Pending	Peter Yendall, Director, Public Affairs, PACCB
Pending	Paul Glover, ADM, HECSB
Pending	Meena Ballantyne, ADM, HPFB
Pending	DMO
Pending	MO
Pending	PCO



Cheryl  
Tremblay/HC-SC/GC/CA  
2009-03-11 12:09 PM

To rcaruso@police-rsl.qc.ca  
cc  
bcc Cheryl Tremblay/HC-SC/GC/CA  
Subject Salvia Divinorum

Bonjour Const. Caruso,

Further to the phone message that I left this morning, please find below the contact information for the Supervisor of the Regional Operational Centre for the Québec Region.

**Francine Menard**  
Surveillante, Enquêtes sur les médicaments  
Centre Opérationnel - Inspectorat  
Produits de Santé et Aiments  
Région du Québec  
Direction Générale des Régions et des Programmes  
Santé Canada  
Tél: (450) 928-4015  
Fax: (450) 928-4184

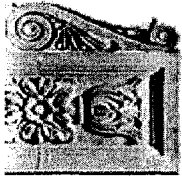
In addition, please feel free to send any information you have with respect to *Salvia divinorum* to the Office of Controlled Substances, Policy and Regulatory Affairs Division at:

Email: ocs\_policy\_and\_regulatory\_affairs@hc-sc.gc.ca  
Fax: (613) 946-4224

Please do not hesitate to contact me should you have any further questions.

Merci bien,

Cheryl Tremblay  
Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Drug Strategy and Controlled Substances Directorate  
Health Canada  
Tel: (613) 954-6527  
Fax: (613) 946-4224



Cheryl  
Tremblay/HC-SC/GC/CA  
2009-03-11 12:07 PM

To Francine Ménard/HC-SC/GC/CA@HWC  
cc  
bcc  
Subject Heads Up: Salvia Divinorum

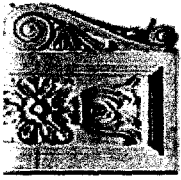
Good Afternoon Francine,

The Office of Controlled Substances recently received a phone call from a Constable Richard Caruso of the Richelieu Saint-Laurent Regional Police Service, to notify us that he is receiving a number of complaints from citizens indicating that *Salvia divinorum* is readily available, advertised in some stores, and sold to school-age children in his community, Beloeil, QC. Constable Caruso would like to know whether there is anything that can be done about this situation.

I just spoke with Michelle Gillespie at the Inspectorate and she suggested providing Constable Caruso with your contact information as this request should be handled at the regional level.

Thanks,

Cheryl Tremblay  
Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Drug Strategy and Controlled Substances Directorate  
Health Canada  
Tel: (613) 954-6527  
Fax: (613) 946-4224



Cheryl  
Tremblay/HC-SC/GC/CA  
2009-03-13 11:13 AM

To Jocelyn Kula/HC-SC/GC/CA@HWC  
cc  
bcc Cheryl Tremblay/HC-SC/GC/CA  
Subject Re: It's Your Health - Salvia divinorum - Draft One

Hi Jocelyn,

I spoke to Sue this am regarding our comments on the IYH for Salvia and she is in agreement with the majority of our suggestions, but would like us to consider the following:

(1) We had suggested removing the following paragraph from the Risks section as it was deemed too complicated for this document. We do address the fact that NHPs that have been approved by HC are labelled as (...) and have undergone a rigorous review, however, Sue still thinks that it is important that we capture the "buyer-beware" notion.

Also, since no *S. divinorum* products have been approved for sale in Canada, products that claim to contain this substance have not been reviewed by Health Canada. As such, they may be counterfeit or may contain other ingredients that pose risks to health. In cases like this, it is always a matter of "buyer beware".

(2) We had suggesting moving the following paragraph from the Legal Status section to the HC's Role section. Sue has suggested that we either (1) re-consider the move as the paragraphs before this one speak to the scheduling factors and the fact that we don't have enough information to determine whether scheduling is the best option, and thus beg the question, "well then what is being done to get more information." and flows nicely, OR (2) move to HC's Role section and elaborate on what exactly HC's Role is with respect to these surveys (i.e. funding, etc.) or how HC is going to use the information obtained from these surveys.

Questions about the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. The survey results will help fill some of the information gaps, but the data will not likely be available until 2010.

(3) We inserted the following sentence under the Risks section, however, the term psychoactive drugs has not been described elsewhere in the document and Sue has suggested that either (1) change the term to hallucinogens, which has been described previously in the document, or (2) provide some examples of psychoactive drugs (i.e. LSD and PCP perhaps)

*S. divinorum* does not appear to cause the euphoria often associated with other psychoactive drugs, so many people who try it do not repeat the experience.

Sue also wanted to let us know that her contract expires on March 31st and the RFP for the competition to refill the contract has not gone out yet. So....if we want to ensure that there is not a hiatus on the publication of this article she suggested that we request a rush to Lisa MacKay.

I have attached the comments that we had sent to Sue below for your reference.

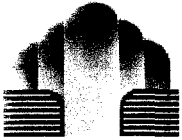


IYH - Salvia Divinorum - Draft One\_DSCSD\_NHPD Comments.doc

Thanks,  
Cheryl



Jocelyn Kula/HC-SC/GC/CA




Jocelyn Kula/HC-SC/GC/CA

2009-03-11 05:35 AM

To Cheryl Tremblay/HC-SC/GC/CA@HWC

cc


Subject Re: It's Your Health - Salvia divinorum - Draft One 

Hi there pls make sure I see next draft before it goes back to Sue  
Cheryl Tremblay

----- Original Message -----

**From:** Cheryl Tremblay


**Sent:** 2009-03-10 08:09 AM EDT

**To:** "Sue Lumsden" 

**Cc:** Cheryl Tremblay; Jocelyn Kula; Valerie Hurry; Brittany Sauvé

**Subject:** Re: It's Your Health - Salvia divinorum - Draft One

Hi Sue,


Sorry for the delay in getting back to you with our suggestions/revisions on the It's Your Health Article on *Salvia Divinorum*. I was out of the office all of last week and yesterday 

[attachment "IYH - Salvia Divinorum - Draft One\_DSCSD\_NHPD Comments.doc" deleted by Jocelyn Kula/HC-SC/GC/CA]

---


~~We are happy to discuss any of the changes we have suggested. Please do not hesitate to call me if you have any questions. Jocelyn will be away from March 5-15th.~~

---

Thanks,  
Cheryl Tremblay  
Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Drug Strategy and Controlled Substances Directorate  
Health Canada  
Tel: (613) 954-6527  
Fax: (613) 946-4224  
"Sue Lumsden" 



"Sue Lumsden"

  
2009-02-05 12:47 PM

To "Jocelyn Kula" <jocelyn\_kula@hc-sc.gc.ca>

cc "Cheryl Tremblay" <Cheryl\_Tremblay@hc-sc.gc.ca>

Subject Re: It's Your Health - Salvia divinorum - Draft One

s.19(1)

Hi Jocelyn and Cheryl,

Please do whatever works best for you. I'd be happy to deal with either a list of comments or direct edits to text. I do like your idea of streamlined feedback, however. That would be very helpful.

Sue

----- Original Message -----  
From: "Jocelyn Kula" <jocelyn\_kula@hc-sc.gc.ca>  
To: "Sue Lumsden" <[REDACTED]>  
Cc: "Cheryl Tremblay" <Cheryl\_Tremblay@hc-sc.gc.ca>  
Sent: Thursday, February 05, 2009 12:40 PM  
Subject: Re: It's Your Health - Salvia divinorum - Draft One

Hi Sue,

Thanks for this. Can I ask how you would like to receive feedback, i.e., a list of comments to be addressed or edits to the text directly? FYI, I have also suggested to the others that we try and collate comments so that the feedback is more streamlined.....

Jocelyn

---

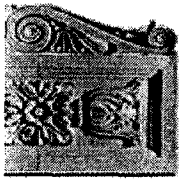
Jocelyn Kula  
Manager, Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Healthy Environments and Consumer Safety Branch  
Health Canada  
Tel: (613) 946-0125 Fax: (613) 946-4224

---

"Sue Lumsden"

[REDACTED]  
2009-02-05 12:34  
PM

To  
"Jocelyn Kula"  
<jocelyn\_kula@hc-sc.gc.ca>, "Cheryl  
Tremblay"  
<Cheryl\_Tremblay@hc-sc.gc.ca>,  
Brittany Sauvé  
<brittany\_sauve@hc-sc.gc.ca>,  
"Valerie Hurry"  
<Valerie\_Hurry@hc-sc.gc.ca>  
cc  
<Scott\_Jordan@hc-sc.gc.ca>  
Subject  
It's Your Health - Salvia divinorum  
- Draft One



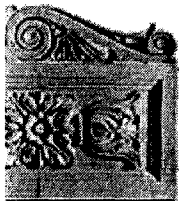
Cheryl Tremblay/HC-SC/GC/CA  
2009-03-19 03:42 PM

To Jocelyn Kula/HC-SC/GC/CA@HWC  
cc  
bcc  
Subject Re: It's Your Health - Salvia divinorum - Draft One

Hi Jocelyn,

Have you had a chance to look at this yet? I know that you've been CRAZY (or should I say CRAZIER) busy since you've been back, but I told Sue that we would try and get back to her as soon as possible and then she'll forward the revised version back to us for our review.

Thanks,  
Cheryl  
Cheryl Tremblay/HC-SC/GC/CA



Cheryl Tremblay/HC-SC/GC/CA  
2009-03-13 11:13 AM

To Jocelyn Kula/HC-SC/GC/CA@HWC  
cc  
Subject Re: It's Your Health - Salvia divinorum - Draft One

Hi Jocelyn,

I spoke to Sue this am regarding our comments on the IYH for Salvia and she is in agreement with the majority of our suggestions, but would like us to consider the following:

(1) We had suggested removing the following paragraph from the Risks section as it was deemed too complicated for this document. We do address the fact that NHPs that have been approved by HC are labelled as (...) and have undergone a rigorous review, however, Sue still thinks that it is important that we capture the "buyer-beware" notion.

Also, <sup>as</sup> ~~since~~ no *S. divinorum* products have been approved for sale in Canada, products that ~~claim~~ contain this substance have not been reviewed ~~by Health Canada~~. As such, they may be ~~counterfeit~~ or may contain other ingredients that pose risks to health. ~~In cases like this, it is always a matter of~~ "buyer-beware".

for safety, efficacy or quality.

and consumers should heed the buyer beware principle

(2) We had suggesting moving the following paragraph from the Legal Status section to the HC's Role section. Sue has suggested that we either (1) re-consider the move as the paragraphs before this one speak to the scheduling factors and the fact that we don't have enough information to determine whether scheduling is the best option, and thus beg the question, "well then what is being done to get more information." and flows nicely, OR (2) move to HC's Role section and elaborate on what exactly HC's Role is with respect to these surveys (i.e. funding, etc.) or how HC is going to use the information obtained from these surveys.

Questions about the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. The survey results will help fill some of the information gaps, but the data will not likely be available until 2010.

(3) We inserted the following sentence under the Risks section, however, the term psychoactive drugs has not been described elsewhere in the document and Sue has suggested that either (1) change the term to hallucinogens, which has been described previously in the document, or (2)

can't condemn all the products out there until we know/ have evidence

well what is your recommendation?

again what do you think I don't have a firm view

provide some examples of psychoactive drugs (i.e. LSD and PCP perhaps)

S. divinorum does not appear to cause the euphoria often associated with other psychoactive drugs, so many people who try it do not repeat the experience.

Sue also wanted to let us know that her contract expires on March 31st and the RFP for the competition to refill the contract has not gone out yet. So....if we want to ensure that there is not a hiatus on the publication of this article she suggested that we request a rush to Lisa MacKay.

who is this?

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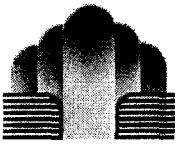


IYH - Salvia Divinorum - Draft One\_DSCSD\_NHPD Comments.doc

Thanks,  
Cheryl

s.19(1)

Jocelyn Kula/HC-SC/GC/CA



Jocelyn Kula/HC-SC/GC/CA  
2009-03-11 05:35 AM

To Cheryl Tremblay/HC-SC/GC/CA@HWC  
cc

Subject Re: It's Your Health - Salvia divinorum - Draft One

Hi there pls make sure I see next draft before it goes back to Sue  
Cheryl Tremblay

----- Original Message -----

From: Cheryl Tremblay  
Sent: 2009-03-10 08:09 AM EDT  
To: "Sue Lumsden"  
Cc: Cheryl Tremblay; Jocelyn Kula; Valerie Hurry; Brittany Sauvé  
Subject: Re: It's Your Health - Salvia divinorum - Draft One

Hi Sue,

Sorry for the delay in getting back to you with our suggestions/revisions on the It's Your Health Article on Salvia Divinorum. I was out of the office all of last week and yesterday

[attachment "IYH - Salvia Divinorum - Draft One\_DSCSD\_NHPD Comments.doc" deleted by Jocelyn Kula/HC-SC/GC/CA]

We are happy to discuss any of the changes we have suggested. Please do not hesitate to call me if you have any questions. Jocelyn will be away from March 5-15th.

Brittney's Comments

## Salvia Divinorum

### The Issue

Recently there have been reports suggesting that Canadian teens and young adults are using a substance called *Salvia divinorum* (*S. divinorum*) specifically for its ability to produce hallucinations (i.e., “seeing” objects that are not there). Certain Web sites are also promoting the use of *S. divinorum* as a “legal” alternative to street drugs.

Health Canada recommends that you avoid using this substance because very little is known about the effect it has ~~how it acts~~ (we know how it acts on the brain... salvinorin A on the k-opioid receptor) on the brain and there is no way to predict how it will affect you.

### Background

*S. divinorum* is a species of sage that belongs to the mint family. It is known to have psychotropic effects, which means it affects ~~is capable of acting on~~ the mind and mental processes.

The leaves of this plant have been used traditionally by the Mazatec Indians in Mexico for medicinal and spiritual purposes. Traditional use involves chewing the leaves or using them to make a tea to treat such conditions as headache or stomach upset, or to induce a “mystical” or hallucinogenic experience for spiritual purposes.

Products that claim to contain *S. divinorum* – or its main active ingredient, salvinorin A – are widely available on the Internet and are sold in various “head shops” and natural food stores, etc. The products are sold in a number of formats, including seeds and plant cuttings for growing purposes. Fresh or dried leaves are intended to be chewed, swallowed or smoked, and liquid preparations are also available for consumption. Street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastra, ~~ska Maria pastora, ska pastora~~, diviner’s sage, magic mint, puff encens special, and salvia.

### Risks of using *Salvia Divinorum*

*S. divinorum* acts as a hallucinogen, which means that it distorts reality. The effects, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations
- out-of-body experiences
- loss of consciousness
- short-term memory loss
- uncontrollable laughter
- impaired ability to speak

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product

- how much is used
- how it is taken (e.g., ingested or smoked)
- the user's mood and expectations

~~*S. divinorum* does not appear to cause the euphoria often associated with other hallucinogenic drugs, so many people who try it do not repeat the experience. (While this is true, due to some of the scary experiences some people have, I don't think it's a good idea to put it. People may understand that they can try this drug once without consequence... )~~

A major concern about *S. divinorum* is the fact that there have been so few scientific studies about the way it affects the body and the brain. For example, very little is known about the following:

- how it affects the brain and if it causes permanent damage
- whether it causes physical dependence or addiction
- how it interacts with other substances (including other drugs and alcohol)

### **Minimizing Your Risk**

Health Canada recommends that you avoid using *S. divinorum*. Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs and other substances that distort reality. (See the "Need More Info?" section below for links to resources that can help you with this.)

Also, remember that just because a drug is plant-based or "natural" does not mean it is safe. *S. divinorum* meets the definition of a "natural health product" (NHP) under Health Canada's *Natural Health Products Regulations*, but no NHPs containing this substance have been approved for sale in Canada. This means that products which that contain *S. divinorum* have not been reviewed by Health Canada for safety, efficacy or quality. As such, they may contain other ingredients that pose risks to health, and consumers should heed the "buyer beware" principle. X

Natural health products that have been approved by Health Canada will be labelled with one of the following:

- a Natural Product Number (NPN) or
- a Drug Identification Number - Homeopathic Medicine (DIN-HM)

These numbers let you know that a product has undergone a rigorous review of formulation, labelling and instructions for use.

### **The Legal Status of *Salvia Divinorum***

Neither *S. divinorum* nor salvinorin A is controlled in Canada under the *Controlled Drugs and Substances Act* (CDSA). When assessing whether to regulate a substance under the CDSA, Health Canada considers the following factors:

- international requirements and trends in controlling the substance

discussed  
in.

- similarity to other substances already regulated under the CDSA
- whether there may be legitimate uses of the substance (e.g., potential health benefits)
- the potential for addiction and abuse/misuse of the substance
- the extent of actual abuse and misuse of the substance in Canada and elsewhere
- overall risk to public health and safety posed by the substance

In the case of *S. divinorum*, there is simply not enough information available to determine whether prohibition is the best option to manage the potential risks associated with its use. Questions about the use of *S. divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. The survey results will help fill some of the information gaps, but the data will not likely be available until 2010.

Several countries (e.g., Australia, Belgium, Denmark, Sweden, Italy, Spain, Finland and South Korea) have placed controls on the import and/or sale of *S. divinorum*. In the United States, *S. divinorum* is not regulated under the *Controlled Substances Act*, although a number of individual states have placed restrictions on its sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution (e.g., no sales to anyone under the age of 18).

### **Health Canada's Role**

Health Canada continues to collect and consider information regarding *S. divinorum* and continues to consult with key stakeholders, including health officials in other countries, and law enforcement officials here at home. This will assist in determining the most appropriate strategy to manage the risks associated with the use of *S. divinorum*.

### **Need More Info?**

---

For information about Health Canada's Drug Strategy and Controlled Substances Directorate, go to: <http://www.hc-sc.gc.ca/ahc-asc/branch-dirigen/hecs-dgsesc/dscsp-psasc/index-eng.php>

Also, see the section on Prevention on the Government of Canada's National Anti-Drug Strategy Web site at: <http://www.nationalantidrugstrategy.gc.ca/>. This site has a number of helpful resources for parents, including "Tips on Talking to Your Teenager" and "What to do if Your Teen is using Drugs."

Information on natural health products and the *Natural Health Products Regulations* can be found at: <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php>

For more on the surveys that are collecting information about *Salvia divinorum* use in Canada, see:

The 2008-2009 Youth Smoking Survey, at:

[http://www.yss.uwaterloo.ca/ysssite\\_app/controller/index.cfm](http://www.yss.uwaterloo.ca/ysssite_app/controller/index.cfm) and

The Ontario Student Drug Use and Health Survey, at: <http://www.camh.net/Research/osdus.html>

Additional Resources:

U.S. Drug Enforcement Administration: Drugs and Chemicals of Concern: *Salvia divinorum* and Salvinorin A at: [http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)

U.S. Department of Health & Human Services, National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006 at:  
<http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf>

For additional articles on health and safety issues go to the *It's Your Health* Web section at:  
<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/index-eng.php>

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

Original:


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Catalogue#

ISBN#

----- 0 -----

**s.19(1)**

Writer: Sue Lumsden 

Version/date: Draft Two, March 25, 2009

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Contacts: Jocelyn Kula, Cheryl Tremblay, Brittany Sauvé (HECSB)  
Valerie Hurry (NHPD - HPFB)  
No input from MHPD, but draft is being sent to Scott Jordan for review



Mint  
Sage  
S

## Salvia Divinorum

### The Issue

Recently there have been reports suggesting that Canadian teens and young adults are using a substance called *Salvia divinorum* (*S. divinorum*) specifically for its ability to produce hallucinations (i.e., "seeing" objects that are not there). Certain Web sites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs.

Health Canada recommends that you avoid using this substance because very little is known about how it acts on the brain and there is no way to predict how it will affect you.

### Background

*S. divinorum* is a species of sage that belongs to the mint family. It is known to have psychotropic effects, which means it is capable of acting on the mind.

could we say "acts on the brain"? just capable

The leaves of this plant have been used traditionally by the Mazatec Indians in Mexico for medicinal and spiritual purposes. Traditional use involves chewing the leaves or using them to make a tea to treat such conditions as headache or stomach upset, or to induce a "mystical" or hallucinogenic experience.

acting sounds kind of probal rather than known

Products that claim to contain *S. divinorum* – or its main active ingredient, salvinin A – are widely available on the Internet and are sold in various "head shops" and natural food stores, etc. The products are sold in a number of formats, including seeds and plant cuttings for growing purposes. Fresh or dried leaves are intended to be chewed, swallowed or smoked, and liquid preparations are also available for consumption. Street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastra, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff encens special, and salvia.

start new para? just didn't flow all in one para?

### Risks of Using *Salvia Divinorum*

*S. divinorum* acts as a hallucinogen, which means that it distorts reality. The effects, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations – seems weird to include when substance is listed as hallucinogen
- out-of-body experiences
- loss of consciousness
- short-term memory loss
- uncontrollable laughter
- impaired ability to speak

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product
- how much is used

- how it is taken (e.g., ingested or smoked)
- the user's mood and expectations

*S. divinorum* does not appear to cause the euphoria often associated with other hallucinogenic drugs, so many people who try it do not repeat the experience.

A major concern about *S. divinorum* is the fact that there have been so few scientific studies about the way it affects the body and the brain. For example, very little is known about the following:

- how it affects the brain and if it causes permanent damage
- whether it causes physical dependence or addiction
- how it interacts with other substances (including other drugs and alcohol)

### Minimizing Your Risk

Health Canada recommends that you avoid using *S. divinorum*. Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs and other substances that distort reality. (See the "Need More Info?" section below for links to resources that can help you with this.)

Also, remember that just because a drug is <sup>that</sup> plant-based or "natural", <sup>it</sup> does not mean it is safe. *S. divinorum* meets the definition of a "natural health product" (NHP) under Health Canada's *Natural Health Products Regulations*, but no NHPs containing this substance have been approved for sale in Canada. This means products that contain *S. divinorum* have not been reviewed by Health Canada for safety, efficacy or quality. As such, they may contain other ingredients that pose risks to health, and consumers should heed the "buyer beware" principle.

Natural health products that have been approved by Health Canada will be labelled with one of the following:

- a Natural Product Number (NPN) or
- a Drug Identification Number - Homeopathic Medicine (DIN-HM)

These numbers let you know that a product has undergone a rigorous review of formulation, labelling and instructions for use.

### The Legal Status of *Salvia Divinorum* in Canada

Neither *S. divinorum* nor salvinorin A ~~is controlled~~ <sup>are currently regulated</sup> in Canada under the *Controlled Drugs and Substances Act* (CDSA). When assessing whether to ~~regulate~~ <sup>add</sup> a substance ~~under~~ <sup>to one of the Schedules</sup> the CDSA, Health Canada considers the following factors:

- international requirements and trends in controlling the substance
- similarity to other substances already regulated under the CDSA
- whether there may be legitimate uses of the substance (e.g., potential health benefits)
- the potential for addiction and abuse <sup>liability?</sup> of the substance

Potential for abuse (accessibility) stability

can use use dependence? or is she suggesting that

use in manufacturing

(str.)

the use of that technology

- the extent of actual abuse ~~and misuse~~ of the substance in Canada and elsewhere
- overall risk to public health and safety posed by the substance

we are moving away from a misuse of as covers more than what we are interested in

regulation under the CDSA

In the case of *S. divinorum*, there is simply not enough information available to determine whether ~~prohibition~~ is the best option to manage the potential risks associated with its use. Questions about the use of *S. divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. The survey results will help fill some of the information gaps, but the data will not likely be available until 2010.

Several countries (e.g., Australia, Belgium, Denmark, Sweden, Italy, Spain, Finland and South Korea) have placed controls on the import and/or sale of *S. divinorum*. In the United States, *S. divinorum* is not regulated under the *Controlled Substances Act*, although a number of individual states have placed restrictions on its sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution (e.g., no sales to anyone under the age of 18).

### Health Canada's Role

Health Canada continues to collect and consider information regarding *S. divinorum* and continues to consult with key stakeholders, including health officials in other countries, and law enforcement officials here at home. This will assist in determining the most appropriate strategy to manage the risks associated with the use of *S. divinorum*.

### Need More Info?

For information about Health Canada's Drug Strategy and Controlled Substances Directorate, go to: <http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hecs-dgsesc/dscsp-psasc/index-eng.php>

Also, see the ~~section on~~ <sup>section</sup> Prevention on the Government of Canada's National Anti-Drug Strategy Web site at: <http://www.nationalantidrugstrategy.gc.ca/>. This site has a number of helpful resources for parents, including "Tips on Talking to Your Teenager" and "What to ~~Do~~ if Your Teen is ~~Using~~ <sup>Using</sup> Drugs."

Information on natural health products and the *Natural Health Products Regulations* can be found at: <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php>

For more on the surveys that are collecting information about *Salvia divinorum* use in Canada, see:

The 2008-2009 Youth Smoking Survey, at: [http://www.yss.uwaterloo.ca/ysss/site\\_app/controller/index.cfm](http://www.yss.uwaterloo.ca/ysss/site_app/controller/index.cfm) and

The Ontario Student Drug Use and Health Survey, at: <http://www.camh.net/Research/osdus.html>

Additional Resources:

U.S. Drug Enforcement Administration: Drugs and Chemicals of Concern: *Salvia divinorum* and  
Salvinorin A at: [http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)

U.S. Department of Health & Human Services, National Survey on Drug Use and Health: Use of  
Specific Hallucinogens: 2006 at:  
<http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf>

For additional articles on health and safety issues go to the *It's Your Health* Web section at:  
<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/index-eng.php>

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**s.19(1)**

Writer: Sue Lumsden

Version/date: Draft Two, March 25, 2009

Contacts: Jocelyn Kula, Cheryl Tremblay, Brittany Sauvé (HECSB)  
Valerie Hurry (NHPD - HPFB)  
No input from MHPD, but draft is being sent to Scott Jordan for review



"Sue Lumsden"

2009-03-25 02:11 PM

To "Jocelyn Kula" <jocelyn\_kula@hc-sc.gc.ca>, "Cheryl Tremblay" <Cheryl\_Tremblay@hc-sc.gc.ca>, Brittany Sauvé <brittany\_sauve@hc-sc.gc.ca>, "Valerie Hurry" <Scott\_Jordan@hc-sc.gc.ca>

bcc

Subject It's Your Health - Salvia Divinorum - Draft Two

Good afternoon,

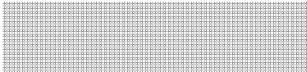
Thank you for your thoughtful comments on the first draft of this IYH article. Some of the comments could not be incorporated due to IYH format issues, but I've discussed matters with Cheryl, and we think this version, Draft Two, is a good compromise in terms of the order in which various bits of information are presented. Valerie, you'll see that I added a link to HC's NHP Web site in the "Need More Info?" section.

If you have any questions about why a specific comment was not incorporated, please contact me directly so we can chat about it.

Otherwise, I look forward to hearing back from you with your thoughts on this version.

The draft article will not be sent into the formal IYH approvals process until you are satisfied with the content and tone.

Thanks again,  
Sue



IYH - Salvia Divinorum - Draft Two.wpd

## **Salvia Divinorum**

### **The Issue**

Recently there have been reports suggesting that Canadian teens and young adults are using a substance called *Salvia divinorum* (*S. divinorum*) specifically for its ability to produce hallucinations (i.e., “seeing” objects that are not there). Certain Web sites are also promoting the use of *S. divinorum* as a “legal” alternative to street drugs.

Health Canada recommends that you avoid using this substance because very little is known about how it acts on the brain and there is no way to predict how it will affect you.

### **Background**

*S. divinorum* is a species of sage that belongs to the mint family. It is known to have psychotropic effects, which means it is capable of acting on the mind.

The leaves of this plant have been used traditionally by the Mazatec Indians in Mexico for medicinal and spiritual purposes. Traditional use involves chewing the leaves or using them to make a tea to treat such conditions as headache or stomach upset, or to induce a “mystical” or hallucinogenic experience.

Products that claim to contain *S. divinorum* – or its main active ingredient, salvinorin A – are widely available on the Internet and are sold in various “head shops” and natural food stores, etc. The products are sold in a number of formats, including seeds and plant cuttings for growing purposes. Fresh or dried leaves are intended to be chewed, swallowed or smoked, and liquid preparations are also available for consumption. Street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastra, ska Maria pastora, ska pastora, diviner’s sage, magic mint, puff encens special, and salvia.

### **Risks of using *Salvia Divinorum***

*S. divinorum* acts as a hallucinogen, which means that it distorts reality. The effects, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations
- out-of-body experiences
- loss of consciousness
- short-term memory loss
- uncontrollable laughter
- impaired ability to speak

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product
- how much is used

- how it is taken (e.g., ingested or smoked)
- the user's mood and expectations

*S. divinorum* does not appear to cause the euphoria often associated with other hallucinogenic drugs, so many people who try it do not repeat the experience.

A major concern about *S. divinorum* is the fact that there have been so few scientific studies about the way it affects the body and the brain. For example, very little is known about the following:

- how it affects the brain and if it causes permanent damage
- whether it causes physical dependence or addiction
- how it interacts with other substances (including other drugs and alcohol)

### **Minimizing Your Risk**

Health Canada recommends that you avoid using *S. divinorum*. Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs and other substances that distort reality. (See the "Need More Info?" section below for links to resources that can help you with this.)

Also, remember that just because a drug is plant-based or "natural" does not mean it is safe. *S. divinorum* meets the definition of a "natural health product" (NHP) under Health Canada's *Natural Health Products Regulations*, but no NHPs containing this substance have been approved for sale in Canada. This means products that contain *S. divinorum* have not been reviewed by Health Canada for safety, efficacy or quality. As such, they may contain other ingredients that pose risks to health, and consumers should heed the "buyer beware" principle.

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- a Drug Identification Number - Homeopathic Medicine (DIN-HM)

These numbers let you know that a product has undergone a rigorous review of formulation, labelling and instructions for use.

### **The Legal Status of *Salvia Divinorum***

Neither *S. divinorum* nor salvinorin A is controlled in Canada under the *Controlled Drugs and Substances Act* (CDSA). When assessing whether to regulate a substance under the CDSA, Health Canada considers the following factors:

- international requirements and trends in controlling the substance
- similarity to other substances already regulated under the CDSA
- whether there may be legitimate uses of the substance (e.g., potential health benefits)
- the potential for addiction and abuse/misuse of the substance

- the extent of actual abuse and misuse of the substance in Canada and elsewhere
- overall risk to public health and safety posed by the substance

In the case of *S. divinorum*, there is simply not enough information available to determine whether prohibition is the best option to manage the potential risks associated with its use. Questions about the use of *S. divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. The survey results will help fill some of the information gaps, but the data will not likely be available until 2010.

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### **Health Canada's Role**

Health Canada continues to collect and consider information regarding *S. divinorum* and continues to consult with key stakeholders, including health officials in other countries, and law enforcement officials here at home. This will assist in determining the most appropriate strategy to manage the risks associated with the use of *S. divinorum*.

### **Need More Info?**

For information about Health Canada's Drug Strategy and Controlled Substances Directorate, go to: <http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hecs-dgsec/dscsp-psasc/index-eng.php>

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The 2008-2009 Youth Smoking Survey, at:

[http://www.yss.uwaterloo.ca/ysssite\\_app/controller/index.cfm](http://www.yss.uwaterloo.ca/ysssite_app/controller/index.cfm) and

The Ontario Student Drug Use and Health Survey, at: <http://www.camh.net/Research/osdus.html>

Additional Resources:



U.S. Drug Enforcement Administration: Drugs and Chemicals of Concern: *Salvia divinorum* and  
Salvinorin A at: [http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)

U.S. Department of Health & Human Services, National Survey on Drug Use and Health: Use of  
Specific Hallucinogens: 2006 at:  
<http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf>

For additional articles on health and safety issues go to the *It's Your Health* Web section at:  
<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/index-eng.php>

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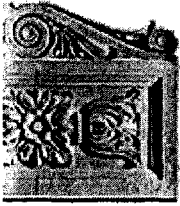
**s.19(1)**

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Writer: Sue Lumsden [REDACTED]

Version/date: Draft Two, March 25, 2009

Contacts: Jocelyn Kula, Cheryl Tremblay, Brittany Sauvé (HECSB)  
Valerie Hurry (NHPD - HPFB)  
No input from MHPD, but draft is being sent to Scott Jordan for review



Cheryl  
Tremblay/HC-SC/GC/CA  
2009-03-27 11:35 AM

To Stephanie Mitchell/HC-SC/GC/CA@HWC  
cc Bronwyn Cline/HC-SC/GC/CA@HWC, Jay  
Jacobson/HC-SC/GC/CA@HWC, Jocelyn  
Kula/HC-SC/GC/CA@HWC  
bcc Cheryl Tremblay/HC-SC/GC/CA  
Subject Re: Fw: Media Lines for Salvia Divinorum

Hi Stephanie,

We're fine with the changes that HPFB has proposed to the media lines on *Salvia divinorum*. One more small change on our end under the Background section...

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. While no validated data exist regarding usage in Canada, data from a 2006 National Survey on Drug Use and Health Report, published by the U.S. Substance Abuse and Mental Health Services Administration has estimated that:

- 1.8 million persons aged 12 or older have used *Salvia divinorum* at least once in their lifetime, and approximately 750,000 did so in the past year.

Just wondering what the next step is approval process wise? To our ADM via communications?

Thanks,  
Cheryl Tremblay  
Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Drug Strategy and Controlled Substances Directorate  
Health Canada  
Tel: (613) 954-6527  
Fax: (613) 946-4224  
Stephanie Mitchell/HC-SC/GC/CA

Stephanie  
Mitchell/HC-SC/GC/CA  
2009-03-25 03:46 PM

To Jocelyn Kula/HC-SC/GC/CA@HWC, Cheryl  
Tremblay/HC-SC/GC/CA@HWC  
cc Jay Jacobson/HC-SC/GC/CA@HWC, Bronwyn  
Cline/HC-SC/GC/CA@HWC  
Subject Fw: Media Lines for Salvia Divinorum

Hi Jocelyn and Cheryl,

HPFB has come back with one major change for the salvia lines. Could you please see below and let me know whether you approve?

Thanks,

Stephanie Mitchell

Communications Advisor  
Conseillère des communications  
Health Canada | Santé Canada

DSCSD's Comments: March 31, 2009

## Salvia Divinorum

### The Issue

Recently there have been reports suggesting that Canadian teens and young adults are using a substance called *Salvia divinorum* (*S. divinorum*) specifically for its ability to produce hallucinations (i.e., "seeing" objects that are not there). Certain Web sites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs.

Health Canada recommends that you avoid using this substance because very little is known about the effect it has on the brain and there is no way to predict how it will affect you.

**Comment:** We know how it acts on the brain...salvinorin A on the k-opioid receptor

**Deleted:** how it acts

### Background

*S. divinorum* is a species of sage that belongs to the mint family. It is known to have psychotropic effects, which means it affects the mind and mental processes.

**Comment:** "capable" sounded probable rather than known.

**Deleted:** is capable of acting on

The leaves of this plant have been used traditionally by the Mazatec Indians in Mexico for medicinal and spiritual purposes. Traditional use involves chewing the leaves or using them to make a tea to treat such conditions as headache or stomach upset, or to induce a "mystical" or hallucinogenic experience for spiritual purposes.

Products that claim to contain *S. divinorum* – or its main active ingredient, salvinorin A – are widely available on the Internet and are sold in various "head shops" and natural food stores, etc. The products are sold in a number of formats, including seeds and plant cuttings for growing purposes. Fresh or dried leaves are intended to be chewed, swallowed or smoked, but liquid preparations are also available.

**Deleted:** and

**Deleted:** for consumption

Street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastra, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff encens special, and salvia.

**Comment:** New paragraph

### Risks of Using *Salvia Divinorum*

**Deleted:** u

*S. divinorum* acts as a hallucinogen, which means that it distorts reality. The effects, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations
- out-of-body experiences
- loss of consciousness
- short-term memory loss
- uncontrollable laughter
- impaired ability to speak

**Comment:** Do we need to list when we already describe substance as a hallucinogen?

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product
- how much is used
- how it is taken (e.g., ingested or smoked)
- the user's mood and expectations

A major concern about *S. divinorum* is the fact that there have been so few scientific studies about the way it affects the body and the brain. For example, very little is known about the following:

- how it affects the brain and if it causes permanent damage
- whether it causes physical dependence or addiction
- how it interacts with other substances (including other drugs and alcohol)

**Comment:** May be misinterpreted as drug could be tried once without consequence.

**Deleted:** *S. divinorum* does not appear to cause the euphoria often associated with other hallucinogenic drugs, so many people who try it do not repeat the experience.¶

### Minimizing Your Risk

Health Canada recommends that you avoid using *S. divinorum*. Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs and other substances that distort reality. (See the "Need More Info?" section below for links to resources that can help you with this.)

Also, remember that just because a drug is plant-based or "natural", it does not mean it is safe. *S. divinorum* meets the definition of a "natural health product" (NHP) under Health Canada's *Natural Health Products Regulations*, but no NHPs containing this substance have been approved for sale in Canada. This means that products which contain *S. divinorum* have not been reviewed by Health Canada for safety, efficacy or quality. As such, they may contain other ingredients that pose risks to health, and consumers should heed the "buyer beware" principle.

**Deleted:** that

Natural health products that have been approved by Health Canada will be labelled with one of the following:

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These numbers let you know that a product has undergone a rigorous review of formulation, labelling and instructions for use.

### The Legal Status of *Salvia Divinorum* in Canada

Neither *S. divinorum* nor salvinorin A is currently regulated under the *Controlled Drugs and Substances Act* (CDSA). When assessing whether to add a substance to one of the Schedules to the CDSA, Health Canada considers the following factors:

**Deleted:** controlled in Canada

**Deleted:** regulate

**Deleted:** under

- international requirements and trends in controlling the substance
- similarity to other substances already regulated under the CDSA
- whether there may be legitimate uses of the substance (e.g., potential health benefits, use in manufacturing, etc.)
- the abuse liability and potential for addiction of the substance

**Deleted:** and abuse/misuse

- the extent of actual abuse of the substance in Canada and elsewhere
- overall risk to public health and safety posed by the substance

Deleted: and misuse

In the case of *S. divinorum*, there is simply not enough information available to determine whether regulation under the CDSA is the best option to manage the potential risks associated with its use. Questions about the use of *S. divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. The survey results will help fill some of the information gaps, but the data will not likely be available until 2010.

Deleted: prohibition

Several countries (e.g., Australia, Belgium, Denmark, Sweden, Italy, Spain, Finland and South Korea) have placed controls on the import and/or sale of *S. divinorum*. In the United States, *S. divinorum* is not regulated under the *Controlled Substances Act*, although a number of individual states have placed restrictions on its sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution (e.g., no sales to anyone under the age of 18).

### Health Canada's Role

Health Canada continues to collect and consider information regarding *S. divinorum* and continues to consult with key stakeholders, including health officials in other countries, and law enforcement officials here at home. This will assist in determining the most appropriate strategy to manage the risks associated with the use of *S. divinorum*.

### Need More Info?

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Deleted: section on

Deleted: d

Deleted: u

Information on natural health products and the *Natural Health Products Regulations* can be found at: <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php>

For more on the surveys that are collecting information about *Salvia divinorum* use in Canada, see:

The 2008-2009 Youth Smoking Survey, at: [http://www.yss.uwaterloo.ca/ysssite\\_app/controller/index.cfm](http://www.yss.uwaterloo.ca/ysssite_app/controller/index.cfm) and

2 memos  
charges both  
Q. Is it good  
A. Yes to Sue  
with the  
with the  
of the

Sue will be  
happy to discuss  
charges - she  
can call you  
and will be  
away March  
5-15th. The

The Ontario Student Drug Use and Health Survey, at: <http://www.camh.net/Research/osdus.html>

Additional Resources:

U.S. Drug Enforcement Administration: Drugs and Chemicals of Concern: *Salvia divinorum* and Salvinorin A at: [http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)

U.S. Department of Health & Human Services, National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006 at: <http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf>

For additional articles on health and safety issues go to the *It's Your Health* Web section at:

<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/index-eng.php>

<http://www.hc-sc.gc.ca/english/iyh/index.html>

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Writer: Sue Lumsden [REDACTED]

Version/date: Draft Two, March 25, 2009

Contacts: Jocelyn Kula, Cheryl Tremblay, Brittany Sauvé (HECSB)  
Valerie Hurry (NHPD - HPFB)  
No input from MHPD, but draft is being sent to Scott Jordan for review

# Issue Analysis Summary

## Scheduling *Salvia Divinorum*

Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Tobacco and Drugs Directorate

Eliz.

Some comments and suggested changes.

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5. ASSESSMENT OF RISKS AND BENEFITS
6. IDENTIFICATION AND ANALYSIS OF INTERESTED PARTIES
7. CONSIDERATIONS
8. RECOMMENDATION(S)
9. CONSULTATIONS
10. IMPLEMENTATION AND MONITORING

Pls fix up and send back to me. I would also have thought that you would have at least progressed the options section a bit there really are not many to choose from

### 1. APPROVALS

This Issue Analysis Summary is approved by

Happy to discuss  
JK

etc. ?  
x lab?  
es

Ronald

~~Gary Condran~~, A/Director  
Office of Controlled Substances  
Tobacco and Drugs Directorate

[DD/MM/2009]

### 2. ISSUE

Health Canada has received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum* (*S. divinorum*), particularly given reports from scientific and media sources suggesting that *S. divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has also observed a steady increase in the amount of media interest regarding the availability of *S. divinorum* in Canada.

Comment - text warrens between items on salvinorin A and items on salvia (the plant) need to be careful not to be confusing inadvertently

(noted ongoing (probably increasing 1 yr ago but pretty level since !..))



# Issue Analysis Summary

DRAFT

## Scheduling *Salvia Divinorum* under the CDSA

Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Tobacco and Drugs Directorate

April 2, 2009

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4. CONTEXT
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7. CONSIDERATIONS
8. RECOMMENDATION(S)
9. CONSULTATIONS
10. IMPLEMENTATION AND EVALUATION

#### 1. APPROVALS

This Issue Analysis Summary is approved.

Ronald

Gary Condron, A/Director  
Office of Controlled Substances  
Tobacco and Drugs Directorate

[DD/MM/2009]

#### 2. ISSUE

Health Canada has received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum* (*S. divinorum*), particularly given reports from scientific and media sources suggesting that *S. divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has also ~~observed~~ a steady increase in the amount of media interest regarding the availability of *S. divinorum* in Canada. X

Q: Info on abuse from US  
DAWN, NFLIS etc. ?

Q: DAS seizures, CBSA tox lab?  
Samples

Comment - text warrens between  
items on salvinorin A and  
items on salvia (the plant)  
need to be careful not to be  
confusing inadvertently

(noted ongoing (probably increasing  
1 yr ago but pretty  
D.O. red since 1.))

### 3. PURPOSE

To assess *Salvia divinorum* against the criteria for the addition of a substance to one of the Schedules to the *Controlled Drugs and Substances Act* (CDSA), in order to determine whether or not *S. divinorum*, and/or its psychoactive ingredient, salvinorin A, should be regulated as controlled substances in Canada.

### 4. CONTEXT

*Salvia divinorum* is a species of sage which belongs to the mint family, and which is found in the form of dried leaves, extract and plant cuttings. Also known as "diviner's sage", the plant is known to induce illusions and hallucinations when chewed or smoked. Salvinorin A, the psychoactive ingredient in *S. divinorum*, which is also referred to chemically as a neoclerodane diterpene, is found primarily in the leaves, and to a lesser extent in the stems.<sup>1</sup>

*S. divinorum* is widely touted as a "legal" alternative to street drugs on the Internet, and has also been reported to be one of the most prevalently marketed herbal dietary supplements available for use as an alternative to illicit drugs of abuse among adolescents and young adults.<sup>2</sup>

In Canada, neither the herb *S. divinorum* nor its main active ingredient, salvinorin A, are controlled under the CDSA. *S. divinorum* does however meet the definition of a natural health product (NHP) under the *Natural Health Product Regulations* (NHPR). This means that products containing *S. divinorum* must be approved by Health Canada prior to sale in Canada and that ~~these~~ products that are not in compliance with the NHPR may be subject to compliance and enforcement actions. Health Canada has yet to receive and/or approve any applications for natural health products containing *S. divinorum* for sale on the Canadian market. ~~As such,~~ it is difficult to ascertain how much *S. divinorum* is currently sold or consumed in Canada at the present time. Several challenges also arise with respect to the importation and domestic movement of such products as they are often declared as incense and therefore cannot be considered non-market natural health products. In addition, compliance and enforcement actions, such as voluntary stop-sales, forfeiture, destruction, and administrative seizure, cannot be implemented unless the labeling clearly indicates that the product is to be used for consumption and/or pharmacological effects (ie. statements regarding contraindications or restrictions on use) upon which the product will no longer meet the definition of a consumer product (i.e. incense) and will meet the definition of a NHP. The NHPR are therefore limited in their capacity to control the availability of *S. divinorum* beyond the scope of scenarios listed above. While very little is known about how and where *S. divinorum* is sold in Canada, it is suspected that it is mainly purchased over the Internet and/or bought at head shops, and alternative life style stores, etc. *OK*

should go to top of issue statement

As

There is good content here but dear

Mixed

up a

dit -

2009

but it is also hard to know because no have tool to track or cant find but can relate two ideas so clear

1 U.S. Department of Justice Drug Enforcement Administration. 2002. Drugs and Chemicals of Concern: Salvia Divinorum (salvinorin A, divinorin A) URL:

[http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm) Nov 2008

2 Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.

SR wonder whether all this detail re. NHP status shouldn't go under description or

The use of *S. divinorum* as a psychotropic agent first came to Health Canada's attention in 2002. In 2004, Health Canada received four adverse drug reaction event reports (ADRs) associated with the use of *S. divinorum* as a hallucinogen, with three being considered non-serious (requiring no medical attention) and the fourth being considered serious (medical intervention was required) and involving the concomitant use of alcohol ~~and the concomitant condition of~~ Attention Deficit Disorder.

*in a person diagnosed with*

Further to the receipt of the aforementioned ADRs ~~and with due regard to the limitations of the NHPR with regards to the regulation of *S. divinorum*~~, the Marketed Health Products Directorate (MHPD) and the Natural Health Products Directorate (NHPD), of the Health Products and Food Branch (HPFB), prepared an issue analysis summary (IAS), which recommended that *S. divinorum* be regulated as a controlled substance. This recommendation was maintained when the IAS was updated in November 2006.

Later, in June 2007, MHPD and NHPD developed a Signal Assessment (SA) that eventually led to the preparation of a Health Risk Assessment (HRA), which concluded that products containing *S. divinorum* should be restricted from over the counter sale because they constitute a Type II health risk (reasonable probability that the use of or exposure to the product will have mild or moderate adverse health consequences).

*But if you are going to go through history need to complete story i.e. rec that*

#### 4.1 Legislative Frameworks for Drug Control in Canada

*regulate as cont. subst.*

##### 4.1.1 Food and Drug Regulations

*+ meetings between HPFB and HFECSB; clarification of CDSA and*

*Add left of drug*

The *Food and Drug Regulations* (F&DR) serve to ensure the safety, efficacy, and quality of health products offered for sale in Canada, including drugs and medical devices. Prior to being given market authorization, a manufacturer must present substantive scientific evidence of a product's safety, efficacy and quality and Health Canada reviews this information carefully. If the review is satisfactory, a Notice of Compliance (NOC) is issued and appropriate Drug Identification Numbers (DINs) are assigned. *If agreement to do this sched. assessment*

##### 4.1.2 Natural Health Product Regulations

*Add line on what eye led*

The definition of a natural health product (NHP) under the *Natural Health Product Regulations* (NHPR) has both a function and substance component.

The function component refers to those substances that are manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
- (b) restoring or correcting organic functions in humans; or

*4.1.1 + 4.1.2 - sections shld have consideration L 1 1 000228  
So why no definition in 4.1.1*

- (c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

The substance component refers to whether the product or medicinal ingredient therein, is safe for consideration as an over-the-counter product, can be available for self-care and self-selection, and does not require a prescription to be sold.

#### 4.1.3 Controlled Drugs and Substances Act and its Regulations

The ~~Controlled Drugs and Substances Act~~ (CDSA) provides a legislative framework for the control of substances that can alter mental processes and that may produce harm to the health of an individual or to society when diverted or misused. Except as authorized under its regulations, activities such as possession, possession for the purposes of trafficking, trafficking, importation, exportation, possession for the purposes of exportation and production of controlled substances are prohibited under the CDSA.

The substances regulated under the CDSA are grouped into eight Schedules, and each Schedule is associated with particular penalties as described in Part I of the CDSA.

In determining whether a substance should be regulated as a controlled substance, and into which Schedule to the CDSA is should be placed, Health Canada considers the following factors:

- International requirements and trends in control/scheduling;
- Chemical and pharmacological similarity to other substances already scheduled under the CDSA;
- Legitimate uses of the substance (i.e. therapeutic, industrial or commercial);
- Abuse liability and potential for addiction of the substance;
- Extent of actual abuse in Canada and internationally; and
- Overall risk to public health and safety of Canadians.

#### 4.2 **Assessment of *Salvia Divinorum* for Scheduling Purposes**

##### 4.2.1 International Requirements and Trends in Control/Scheduling

At the present time, neither *Salvia divinorum* nor salvinorin A <sup>are</sup> listed under the United Nations Drug Control Conventions and therefore do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these conventions.

*S. divinorum* and salvinorin A are not included in the Schedules to the United States *Controlled Substances Act*, although some individual states have implemented laws restricting its use, sale and/or distribution. As of November 2008, thirteen states have enacted legislation placing regulatory controls on *S. divinorum* and/or salvinorin A. Delaware, Florida, Illinois, Kansas, Mississippi, Missouri, North Dakota, Oklahoma, and Virginia have placed *S. divinorum* and/or salvinorin A into Schedule I of state law. California, Louisiana, Maine and Tennessee have

consisting of what is

meaning what

eighteen years of New para  
age or over

enacted other forms of legislation restricting the distribution of the plant. For example, effective January 1, 2009, the sale or distribution of *S. divinorum* or salvinorin A, or any substance or material containing *S. divinorum* or salvinorin A, to any person under 18 years of age became a misdemeanor in the state of California that is now punishable by imprisonment in a county jail for not more than 6 months, by a fine of no more than \$1,000, or both. In 2005, Louisiana passed a bill, which made 40 plants, including *S. divinorum*, illegal if sold for human consumption. In Maine, *S. divinorum* and salvinorin A are regulated similar to how tobacco products are controlled. Adults 18 and over can legally purchase and use the material, but selling or providing *S. divinorum* or salvinorin A to anyone under the age of 18 is a criminal offense. Possession by a minor is a civil violation, punishable by a fine, community service, or both. On July 1, 2006, Tennessee classified the knowing production, manufacture, distribution, or possession of the active chemical ingredient in the hallucinogenic plant *S. divinorum* as a Class A misdemeanor. It is however not a criminal offense to possess, plant, cultivate, grow, or harvest *S. divinorum* for aesthetic, landscaping, or decorative purposes, and does not apply to any dosage that is legally obtainable from a retail establishment without a prescription when it is recognized by the FDA as a homeopathic drug. Legislative bills proposing regulatory controls are pending in Michigan, New Jersey, New York, Ohio, Pennsylvania, Texas and Wisconsin. In addition, the U.S. Department of Justice Drug Enforcement Agency (DEA) has also placed *S. divinorum* and salvinorin A on a list of drugs and chemicals "of concern," without legal implication.

new para

new para

new para

The law also

?

should go with so federal consent i.e. after sentence about CSA...

Although

possession of?  
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deliberate

In June, 2002, Australia became the first country to prohibit *S. divinorum* and salvinorin A. Both *S. divinorum* and salvinorin A are listed on Schedule 9 of Australia's Standard for the Uniform Scheduling of Drugs and Poisons on the basis of "high potential for abuse and risk to public health and safety", but no substantiation of this risk was provided at the time of this scheduling decision.

Shortly after, in 2003, Denmark prohibited *S. divinorum* and salvinorin A by adding them to their list of "category B" controlled substances, a category which also includes psilocybin mushrooms, cocaine, amphetamine, and several others substances that are only legal for medicinal and scientific purposes. Possession carries a penalty of up to two years in prison.

On June 25, 2004, the Italian Ministry of Health issued an ordinance prohibiting the sale of *S. divinorum*, and its active constituent salvinorin A. On January 11, 2005, the Ministry of Health made possession of *S. divinorum* and salvinorin A illegal by placing them in "Tabella I" of the *Tabella Sostanze Stupefacenti o Psicotrope*. (only possession?)

On January 28, 2004 the Spanish Ministry of Health and Consumption issued an order prohibiting the sale of *S. divinorum*, along with a long list of other alleged "toxic" herbs. The regulation went into effect on May 6, 2004 and only prohibits activities related to commerce. Possession and/or use is not subject to criminal offences.

A decree was passed in Belgium on October 22, 2006 which added *S. divinorum* to the list of controlled substances.

On November 9, 2006, the Japanese government added a group of thirty-three drugs to its list of

selection should be chronological so more ahead of text on US situation

are considered to be

including

persons involved in illegal

text is before to

controlled substances. Salvinorin A ~~was one of the newly listed substances.~~ The drugs will be banned under a revised pharmaceutical law, under which their import, production, and sale, ~~except for~~ <sup>ie., that</sup> medical treatment or research purposes, will be subject to up to 5 years imprisonment or to a fine of up to five million yen. <sup>beyond</sup>

*S. divinorum* (plant and plant parts) was added to Appendix I of the Narcotics Act in Germany on March 1, 2008, making it illegal to produce, traffic, or possess. The law does not specifically mention salvinorin A. <sup>italies</sup>

In Norway, Finland, Estonia, and Iceland *S. divinorum* is treated as a medicinal herb and it is illegal to import it without a relevant prescription from a doctor.

possession too?

#### 4.2.2 Chemical and Pharmacological Similarity to Other Substances Listed in the CDSA

The psychoactive ingredient in *Salvia divinorum* is salvinorin A. Other plants which contain psychotropic terpenoid <sup>are</sup> *Artemisia absinthium* (wormwood) and *Cannabis sativa*. Salvinorin A is considered by some as the most potent natural hallucinogen ever isolated.<sup>3</sup>

Unlike all other hallucinogens, salvinorin A is structurally distinct and does not interact with the serotonin-2A receptor or any other molecular target of classical hallucinogens, <sup>and</sup> affects the brain in a way that is quite unique.<sup>4</sup> Recent pharmacological screenings of receptors have found it to be a highly potent and selective  $\kappa$ -opioid receptor (KOR) agonist.<sup>5</sup> <sup>IT laws</sup>

The psychomimetic effects of *S. divinorum* closely resemble schizophrenia symptoms induced by LSD or PCP.<sup>6</sup> Yet, it is said to have only weak influence on the prevailing mood of the user which differentiates it from other hallucinogens such as LSD and psilocybin.<sup>7</sup> Its strong dissociative effects are often compared to those of ketamine. Users ~~felt~~ <sup>have</sup> that the psychedelic effects of *S. divinorum* were most similar to psilocybin mushrooms.<sup>8</sup> However, users familiar with the effects of other hallucinogens agree that despite certain similarities to classical <sup>reported</sup>

those caused by

<sup>3</sup> Ott J. Ethnopharmacognosy and human pharmacology of *Salvia divinorum* and salvinorin A. *Curare*. 1995 18: 103-129. Unofficial transcription available online. URL <http://www.sagewisdom.org/ott2.html>

<sup>4</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>5</sup> Roth BL, Baner K, Westkaemper R, Siebert D, Rice KC, Steinberg S, Ernsberger P, Rothman RB. Salvinorin A: a potent naturally occurring nonnitrogenous kappa opioid selective agonist. *Proc Natl Acad Sci U S A*. 2002 Sep 3;99(18):11934-9.

<sup>6</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>7</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>8</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

causes  
new para  
In addition, while

hallucinogens, the visions and overall experience is quite unique.<sup>9</sup> The psychedelic effects of *S. divinorum* are similar to those of classical psychedelics regarding changes in perception, mood and somatic sensations. However, *S. divinorum* has an unusually high degree of sedation, weakness and fatigue, ~~for a psychedelic which is usually reported in individuals after alcohol, benzodiazepines or opioid use.~~<sup>10</sup> In addition, the increased de-realization is not commonly reported for classical psychedelics. The combination of these effects seems to correlate with that of other KOR agonists such as pentazocine.<sup>11</sup>

while are generally accepted to be

Reliable, systematic and controlled observations on the psychotropic activities of *S. divinorum* are scarce. Although the various modes of administration lead to variable onset and duration of the effects, the effects of *S. divinorum* show overall the same characteristics which include: becoming objects, visions of various two-dimensional surfaces, films and membranes, revisiting places of the past (particularly childhood) loss of the body and/or identity, various sensations of motion (being pulled or twisted by a force of some kind), uncontrollable hysterical laughter, and overlapping realities (perceptions of being in more than one place).<sup>12</sup>

Laughter, happiness, sense of well-being and dissociative effects were deemed the best aspects of *S. divinorum* by users, second only to the "trip" that the drug elicits.<sup>13</sup> Depersonalization, speaking gibberish, widening of consciousness, subjective illusions of rapid movements, flying or hovering have also been reported.<sup>14</sup>

however [Not sure about placement of two last paras b/c does not really seem to go with chem + pharm similarity?]

4.2.3 Legitimate Uses of *Salvia Divinorum*

3  
order paras

*Salvia divinorum* has traditionally been used for spiritual and medicinal purposes by the Mazatec Indians in Oaxaca, Mexico.<sup>15</sup> An infusion of the leaves or ingestion of the leaves ~~has~~ is traditionally been used to treat gastrointestinal problems, headaches, rheumatism, anemia and

<sup>9</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6 and González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>10</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>11</sup> Arasteh K, Poudevida S, Farre M, Roset PN, Cami J. Response patterns of the Spanish version of the 49-item short form of the Addiction Research Center Inventory after the use of sedatives, stimulants, and opioids. *Drug Alcohol Depend.* 1999 Jun 1;55(1-2):117-25.

<sup>12</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>13</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>14</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry.* 2005 Jan;38(1):1-5 and Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>15</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

swelling of the stomach.<sup>16</sup> Its main use is for its psychoactive properties in the aid of ~~spiritual~~ ~~rituals~~ to produce "mystical" or hallucinogenic experiences.<sup>17</sup> *is however* *as part of spiritual rituals*

②

Although selective kappa receptor agonists have been shown to produce analgesic effects, adverse effects such as psychotomimesis, dysphoria and diuresis have been observed in studies investigating their therapeutic use.<sup>18</sup>

①

There are no legitimate medical or industrial uses for *S. divinorum* in Canada.

Dependence and Abuse  
4.2.4 Abuse Liability and Potential for Addiction

The onset and intensity of the effects of *Salvia divinorum* are related to the route of administration by which it is taken. Traditional uses generally produce mild effects because the leaves are rolled *and* *chewed* ~~masticated and swallowed~~ or crushed and prepared as a foamy infusion whereby the salvinorin A is degraded in the gastrointestinal system before being absorbed into the bloodstream. These methods rely on ~~the~~ contact with the oral mucosa for absorption and the level of effect relates quite closely to the length of time the material spends in the mouth. Onset of effect generally takes 5-10 minutes which build over the next hour and last for another hour before the effects begin to subside.<sup>19</sup> *appear to be*

Routes that avoid the hepatic first-pass effect are the quickest and most intense.<sup>20</sup> Salvinorin A can be isolated from the plant to make a powder which can be vaporized and inhaled. This method of administration is the most powerful and only requires 200-500µg of salvinorin A powder to produce an effect. ~~Its effects are identical to those of the fresh leaves.~~ The onset of effect felt from vaporizing ~~the~~ salvinorin A powder is about 30 seconds and last for about 5-10 minutes and subside over the next 30 minutes.<sup>21</sup> *effects*

*the same can't say this implies that any use is abuse*

~~For abuse purposes.~~ Smoking is by far the most popular method of administration.<sup>22</sup> ~~People~~ *and this is accomplished by smoking* smoke the dried leaves or a concentrated extract using a pipe or bong. ~~The~~ dried leaves may be *also*

<sup>16</sup> Munro, T. The Chemistry of *Salvia divinorum*. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.  
<sup>17</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage *Salvia divinorum*. Life Sci. 2005 Dec 22;78(5):527-31.  
<sup>18</sup> **Error! Main Document Only.** Barker RL, Fawcett J, Barkin SJ. 2002. Chronic pain management with a focus on the role of newer antidepressants and centrally acting agents. In: Pain Management: A Practical Guide for Clinicians, 6th edition, Weiner RS ed. CRC Press, Boca Raton, FL. pp. 415-34 and **Error! Main Document Only.** Tidgewell et al., 2004. A facile method for the preparation of deuterium labelled salvinorin A: Biorganic & Medicinal Chemistry Letters, 14: 5099-5102.  
<sup>19</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.  
<sup>20</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. Pharmacotherapy. 2006 Sep;26(9):1268-72.  
<sup>21</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.  
<sup>22</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62 and Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.



Salvia non  
Salvinorin A  
are not

and/or a

be

fortified with a concentrated extract of salvinorin A. ~~The concentrated extract can be~~ also used sublingually. ~~It is not injected because the powder is insoluble in water.~~<sup>23</sup>

What powder?

Most clinically used opioid analgesics (e.g. codeine, oxycodone, morphine) are selective for the  $\mu$ -opioid receptor (MOR) and can be habit-forming.<sup>24</sup> ~~Therefore, while these opioid drugs are effective pain relievers, activation of the MORs causes euphoria which implicates these drugs in the development of dependence. An increase in dopamine release in the brain's reward pathway mediated by MOR activation is thought to play a role in the process of addiction.~~<sup>25</sup> As previously mentioned, salvinorin A is a potent, selective agonist of the  $\kappa$ -opioid receptor (KOR). In contrast to the euphoria produced by MOR agonists, the KOR agonists are negatively reinforcing and aversive.<sup>26</sup> In addition, KOR agonists have analgesic properties but are not associated with respiratory depression like MOR agonists. Initially, these effects provided hope for the development of an analgesic absent of addiction liability and respiratory depression, however, it was soon discovered that KOR agonists produced dysphoria and psychomimetic effects such as confusion, hallucinations and depersonalization.<sup>27</sup> Finally, while MOR increases the release of dopamine, the activation of KOR decreases dopamine release in the nucleus accumbens.<sup>28</sup>

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Few studies have looked at salvinorin A and its abuse liability. Recent animal studies have attempted to address the aversive and dysphoric effects that are induced from salvinorin A use, however, there are some inconsistencies as these studies were performed in different animal models and various evaluation tools were used, therefore, it is difficult to assess the nature of the conflicting results. Further studies on the mediated decrease of dopamine as well as the impact of dose on the reward and aversive effects are warranted.

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Human studies on the use of *S. divinorum* are scarce and their attempt to elucidate addiction liability and abuse potential are poor and inconsistent. The aversive effects of previously studied KOR

very critical

<sup>23</sup> Valdès LJ 3rd. Salvia divinorum and the unique diterpene hallucinogen, Salvinorin (divinorin) A. J Psychoactive Drugs. 1994 Jul-Sep;26(3):277-83.

<sup>24</sup> Gustein HB & Akil H. Opioid Analgesics. In: Goodman and Gilman's The Pharmacological Basis of Therapeutics 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.

<sup>25</sup> Herz A. Opioid reward mechanisms: a key role in drug abuse? Can J Physiol Pharmacol. 1998 Mar;76(3):252-8.

<sup>26</sup> Gustein HB & Akil H. Opioid Analgesics. In: Goodman and Gilman's The Pharmacological Basis of Therapeutics 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590, Cooper S. Interactions between endogenous opioids and dopamine: Implications for reward and aversion. In: The Mesolimbic Dopamine System: From Motivation to Action. Willner P and Scheel-Kruger J (editors) Wiley, Chester, England, 1991, pp. 331-366, and Shippenberg TS, Herz A, Spanagel R, Bals-Kubik R, Stein C. Conditioning of opioid reinforcement: neuroanatomical and neurochemical substrates. Ann N Y Acad Sci. 1992 Jun 28;654:347-56.

<sup>27</sup> Pfeiffer A, Brantl V, Herz A, Emrich HM. Psychotomimesis mediated by kappa opiate receptors. Science. 1986 Aug 15;233(4765):774-6, Rimoy GH, Wright DM, Bhaskar NK, Rubin PC. The cardiovascular and central nervous system effects in the human of U-62066E. A selective opioid receptor agonist. Eur J Clin Pharmacol. 1994;46(3):203-7, and Walsh SL, Strain EC, Abreu ME, Bigelow GE. Enadoline, a selective kappa opioid agonist: comparison with butorphanol and hydromorphone in humans. Psychopharmacology (Berl). 2001 Sep;157(2):151-62.

<sup>28</sup> Gustein HB & Akil H. Opioid Analgesics. In: Goodman and Gilman's The Pharmacological Basis of Therapeutics 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.

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agonists would predict that the risk of addiction to *S. divinorum* is negligible. However, there is conflicting information around the addiction liability of *S. divinorum* in both animals and humans. Therefore it is sometimes difficult to predict abuse liability in humans from animal studies. More controlled, systematic research in this area is needed.

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*S. divinorum*'s KOR-mediated aversive and dysphoric effects do not appear to be hampering its use. Young adults have begun smoking the leaves and leaf extract recreationally.<sup>29</sup> It can be purchased through online botanical companies and other drug promotional sites and is often touted as a legal alternative to substances such as cannabis and mescaline.<sup>30</sup> Interestingly though, after being widely available for over a decade, the drug has not had any extreme social impact as did LSD or MDMA.<sup>31</sup> Unfortunately, to our knowledge, there is no current prevalence data on *S. divinorum* use.

Originally the concerns for the abuse potential were minimal since it was concluded that 1 kg of dried leaves yielded only 3 to 6 human doses of salvinorin A. However, it was discovered that vaporizing and inhaling 200-500 µg had profound hallucinogenic effects.<sup>32</sup> The extraction of salvinorin A from the plant is very easy and with care, approximately 1.5 grams of pure salvinorin A per kilogram of dried leaves (8kg of fresh leaves) can be isolated. Therefore, even poor yields of a gram per kilograms of dried leaves would provide a dose for 2000 human doses.<sup>33</sup>

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This easy isolation makes buying the drug quite affordable. *S. divinorum* leaves sell for \$0.50-7 per gram, plants for \$20-45 and the liquid extract for \$4-10 per millilitre.<sup>34</sup>

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#### 4.2.5 Extent of Actual Abuse in Canada and Internationally

- ① Health Canada does not currently have statistics on the actual population use of *Salvia divinorum* across the Canadian population. In an effort to address this lack of data, questions regarding the use of *S. divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. <sup>20</sup> <sup>21</sup> But data from these surveys will not likely be available until 2010. <sup>22</sup> In addition, a general open-ended question about the use of other substances has been included in the 2008 Canadian Alcohol and Drug Use Monitoring Survey. Results from that survey will be available in the summer of 2009.

however.

Health Canada has only received a limited number of communications regarding *S. divinorum*

<sup>29</sup> Hazelden Foundation, 2004. Drug Abuse Trends. June 2004. URL: [www.reserach.hazelden.org](http://www.reserach.hazelden.org).

<sup>30</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

<sup>31</sup> Munro, T. The Chemistry of *Salvia divinorum*. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

<sup>32</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>33</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs*. 1994 Jul-Sep;26(3):277-83.

<sup>34</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

from law enforcement agencies, and none has advised that the use of *S. divinorum* poses any particular threat to public safety.

As mentioned above, Health Canada received four adverse drug reaction event reports (ADRs) in 2004 associated with the use of *S. divinorum* as a hallucinogen, with three being considered non-serious (requiring no medical attention) and the fourth being considered serious (medical intervention was required) and involving the concomitant use of alcohol and the concomitant condition of Attention Deficit Disorder.

In the United States, a 2006 National Survey on Drug Use and Health Report, published in February 2008 by the Substance Abuse and Mental Health Administration estimated that:

- 1.8 million persons aged 12 or older used *Salvia divinorum* in their lifetime, with approximately 750,000 having done so in the past year;
- Use was more common among young adults (18 to 25 years old) as opposed to older adults (> 26 years of age);
- Young adults were nearly three times more likely than youths, aged 12 to 17, to have used *Salvia divinorum* in the past year; and
- Use was more common in males than in females.

Two reports regarding the abuse of *S. divinorum* have been published in the academic literature. The first was an international case report in which a young man (19 years of age) described his perceptions after inhaling the smoke from *S. divinorum*. The peak psychotropic effects, including prickling of the skin, fever-like hot flashes, muscular tremor, and depersonalization, were reached in less than five minutes after inhalation of an unknown amount of dried leaves.<sup>35</sup> The second case involved a 15-year-old male who presented to psychiatric emergency services with acute onset of paranoia, déjà vu, blunted affect, thought blocking and slowed speech, after smoking *Salvia divinorum* over an unknown period of time. During his hospitalization all symptoms improved significantly except the feeling of déjà vu. Based on this case presentation, the author suggested that the feelings of déjà vu may be considered long-term effects of *Salvia* use.<sup>36</sup> However, given that this is the only case report in which déjà vu was associated with the use of *S. divinorum*, more reports are needed to substantiate this finding.

In addition to the above-mentioned case reports, in 2006, a case ~~report~~ was reported in the U.S. in which a 17-year-old boy committed suicide after smoking *S. divinorum* for unknown period of time.<sup>37</sup> It should be noted that alcohol and general depression were the main confounders in this case. This case did, however, result in the state of Delaware passing a law outlawing *S. divinorum*, and classifying it as a Schedule I controlled substance with other hallucinogenic substances.

<sup>35</sup> **Error! Main Document Only.** Bucheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>36</sup> **Error! Main Document Only.** Singh S. (2007) Adolescent salvia substance abuse. *Addiction*. 102, 823-824.

<sup>37</sup> <http://www.kvbc.com/Global/story.asp?S=4893692>

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It has been suggested that *S. divinorum* is the most marketed herbal substances available for use as a legal alternative to illicit drugs of abuse, among adolescents and young adults.<sup>38</sup> In 2000, a large number of *S. divinorum* plants were seized at a large scale plantation in Switzerland, which may suggest that its use as a recreational drug in Europe may be increasing.<sup>39</sup>

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#### 4.2.6 Overall Risk to Public Health and Safety of Canadians

The increase in the number of enquiries from various municipalities and members of the public and in the amount of media interest regarding the availability of *Salvia divinorum* in Canada may be an indication that the recreational use of *S. divinorum* as a hallucinogen may be on the rise in Canada. It is, however, premature to make this assumption as Health Canada presently does not have any viable statistics on the actual population use of *S. divinorum* across the Canadian population.

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Part of *S. divinorum*'s abuse potential stems from its availability. As previously mentioned it is widely available for purchase on the Internet through drug promotional sites and is also sold in various "head shops" and corner stores. In addition, the potential for high yields and ease of extraction may make buying and selling the drug quite affordable and attractive.

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It is difficult to determine the abuse liability of *S. divinorum* as human studies on its use are scarce, and while most websites tout the drug as being "nothing for beginners", recommend that one has a 'sitter' to watch him/her while on the drug due to its profound dissociative effects,<sup>40</sup> and experiences are described by users as being "intense", "very intense" or "extremely intense"<sup>41</sup> there appear to be inconsistencies in the literature regarding risk aversion. For example, one author states: "Many who have used salvinorin A find the experience extremely unnerving, frightening and overly intense and most have no desire to repeat the experience."<sup>42</sup> however, this aversion to the drug is not an effect being echoed in other studies and reports.<sup>43</sup> Moreover, over eighty percent of users surveyed on a web-based questionnaire about their

<sup>38</sup> **Error! Main Document Only.** Siemann et al., *Salvia divinorum*-representation of a new drug in the internet. 2006; *Gesundheitswesen*, 68(5):323-7 and **Error! Main Document Only.** Dennehy CE, Tsourounis C, Miller AE. 2005. Evaluation of herbal dietary supplements marketed on the internet for recreational use. *Ann Pharmacother*. Oct;39(10):1634-9. Epub 2005 Sep 13.

<sup>39</sup> **Error! Main Document Only.** Giroud C, Felber F, Augsburg M, Horisberger B, Rivier L, Mangin P. 2000. *Salvia divinorum*: an hallucinogenic mint which might become a new recreational drug in Switzerland. *Forensic Science International* 112: 143-150.

<sup>40</sup> <http://www.sagewisdom.org>

<sup>41</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>42</sup> Turner DM. *Salvinorin - The Psychedelic Essence of Salvia Divinorum*. Panther Press, San Francisco, CA 1996.

<sup>43</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62, Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5, and Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs*. 1994 Jul-Sep;26(3):277-83.

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*S. divinorum* use said they would probably or definitely use *S. divinorum* again.<sup>44</sup> Therefore, despite the fact that users have reported the negative effects of *S. divinorum* as: the short duration of action, lack of control over the experience, persisting negative effects (most often anxiety)<sup>45</sup> sweating, chills, increased diuresis, impaired vigilance,<sup>46</sup> and negative after-effects including tiredness, feeling head heavy, dizziness, physical exhaustion, and some degree of malaise or 'hangover' as they 'comedown' from the drug,<sup>47</sup> it is difficult to determine the influence these effects on the use of *S. divinorum*.

~~In addition,~~ the potential for harm to the user and/or other individuals may be increased as users may get up and walk around without apparent awareness of their movements, behaviour or surroundings, distinction between self and surroundings is lost, and at doses greater than 1mg of salvinorin A, out of body experiences are frequent and loss of consciousness has been reported.<sup>48</sup>

As stated earlier, there are no approved medical uses for *S. divinorum* in Canada. Health Canada has also not received nor approved any submissions for natural health products for sale in Canada. Therefore, products that claim to contain this substance have not been extensively reviewed by Health Canada and as such, may be counterfeit or may contain other ingredients that may pose risks to health. For example, like all drugs of abuse, the users are often unaware of the potency and adulterants in the products they are purchasing. A study by Wolowich *et al.* (2006)<sup>49</sup>, showed that the salvinorin A content in five out of five *S. divinorum* products were falsely indicated on the label and 4 out of 5 products contained unidentified adulterants (i.e. vitamin E, caffeine).

✓ Health Canada has only anecdotal information about the use of *S. divinorum* in Canada and the risk of abuse and/or risk that *S. divinorum* poses to the health and safety of Canadians. Although reports of domestic adverse reactions related to the use of *S. divinorum* as a hallucinogen have been received through the Canada Vigilance database, it is important to note that the number of reports and the nature of reactions reported are not adequate to characterize the risk to the general population. These data cannot be used to determine incidence of use in the general population, as Health Canada does not have any information about the number of individuals using or who have used *S. divinorum*.

## 5. ASSESSMENT OF RISKS AND BENEFITS (OPTIONAL)

<sup>44</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>45</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>46</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>47</sup> González D, Ribá J, Bouso JC, Gomez-Jarabó G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>48</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>49</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

**Page(s) 000239 to\à 000244**

**Is(Are) exempted pursuant to section(s)  
est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**

DRAFT  
April 7, 2009

## **Media Lines Regulatory Control of *Salvia Divinorum***

### **Issue**

Since 2006, Health Canada has observed a steady increase in the amount of media interest regarding the availability of *Salvia divinorum* on the Canadian market. Health Canada has also received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum*, particularly given reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties.

### **Key Messages:**

- Health Canada continues to collect relevant information about *Salvia divinorum* and its active ingredient, Salvinorin A, from both national and international sources in order to determine what, if any, regulatory controls are needed.
- While the media have reported that use of *Salvia divinorum* is on the rise in certain parts of the country, Health Canada does not currently have statistics on its use across the Canadian population.
- Health Canada is taking steps to address this lack of data. Questions regarding the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. A general open-ended question about the use of other substances was also included in the 2008 Canadian Alcohol and Drug Use Monitoring Survey.

### **Supplementary Messages:**

#### ***On the classification of *Salvia divinorum*:***

- In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, Salvinorin A, are controlled under the *Controlled Drugs and Substances Act* (CDSA).
- *Salvia divinorum* is not listed under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these conventions.
- Several countries (Australia, Belgium, Denmark, Sweden, Italy, Spain, Finland and South Korea) have placed controls on the import and/or sale of *Salvia divinorum*. Although some individual U.S. states have implemented laws restricting its use,

sale and/or distribution, *Salvia divinorum* is not federally regulated under the *Controlled Substances Act* in the United States.

- *Salvia divinorum*, when associated with health claims, could meet the definition of a natural health product under the *Natural Health Product Regulations* (NHPR). This means that *Salvia* products that are not in compliance with the NHPR may be subject to compliance and enforcement actions.
- As of January 2009, Health Canada had not issued any Natural Product Numbers (NPN) or Drug Identification Numbers – Homeopathic Medicine (DIN-HM) for *Salvia divinorum* products.

***If asked for specifics on when the survey data will be available:***

- Data from the Canadian Alcohol and Drug Use Monitoring Survey will be available in summer 2009, while the results of the Youth Smoking Survey and the Ontario Student Drug Use and Health Survey likely will not be available until 2010.

## **Questions and Answers**

**Q1 – If Health Canada is aware of *Salvia divinorum*'s ill-effects, why isn't it illegal?**

A1 – Very few controlled scientific studies of the physical and psychotropic effects of *Salvia divinorum* on humans have been carried out, and using these studies to predict the potential for addiction and abuse associated with *Salvia divinorum* is difficult. More controlled systematic research in this area is needed.

Health Canada has only received a limited number of communications regarding *Salvia divinorum* from law enforcement agencies, and none of these has advised that the use of *Salvia divinorum* poses any particular threat to public safety.

**Q2 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?**

A2 – The *Natural Health Product Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *Salvia divinorum*.

**Q3 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A3 – *Salvia divinorum* products that are not in compliance with the *Natural Health Product Regulations* and/or are found to pose a risk to the health of Canadians may be subject to compliance and enforcement action by Health Canada. An import target for products with *Salvia divinorum* has already been placed with Canada Border Services Agency.



**Q4 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum*. What does that involve and what stage is it at?**

A4 - Health Canada considers several factors in determining whether scheduling a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in control and scheduling;
- Chemical and pharmacological similarity to other substances already scheduled under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Abuse liability and addiction potential of the substance;
- Extent of actual abuse and misuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada has only anecdotal information about the last three of the above-mentioned factors, and thus is not yet convinced that the controls imposed by the CDSA are an appropriate strategy for managing the risks associated with the use of *Salvia divinorum*.

Health Canada will, however, continue to collect and consider information regarding *Salvia divinorum* as it becomes available.

**Q5 – Didn't an internal report from Health Canada's Marketed Health Products Directorate recommend that *Salvia divinorum* be scheduled under the CDSA? Why has that recommendation not been acted upon?**

A5 – See A4

**Q6 – What is the significance of the adverse reaction reports that Health Canada has received with respect to the use of *Salvia divinorum*?**

A6 – Health Canada has received four domestic adverse reaction reports related to the use of *Salvia divinorum* as a hallucinogen through the Canada Vigilance database. The number of reports and the nature of reactions reported are not adequate to characterize the risk to the general population. These data cannot be used to determine incidence of use in the general population, as Health Canada does not have any information about the number of individuals using or who have used *Salvia divinorum*.

**Background**

*Salvia divinorum* is a species of sage belonging to the mint family that is chewed or smoked in order to induce its psychotropic effects. These effects are short-acting in nature and include hallucinations, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are often described as unpleasant.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. While no validated data exist regarding usage in Canada, data from a 2006 National Survey on Drug Use and Health Report, published by the U.S. Substance Abuse and Mental Health Services Administration has estimated that:

- 1.8 million persons aged 12 or older used *Salvia divinorum* at least once in their lifetime, and approximately 750,000 did so in the past year.
- Use was more common among young adults (18 to 25 years old) as opposed to older adults (>26 years of age).
- Young adults were three times more likely than youths aged 12 to 17 to have used *Salvia divinorum* in the past year.
- Use was more common in males than females.

*Salvia divinorum* is widely advertised and promoted on the Internet as a "legal" alternative to street drugs.

While some users have reported that the psychotropic effects of *Salvia divinorum* resemble those induced by other hallucinogens, such as LSD and phencyclidine, the overall experience appears to be quite unique. *Salvia divinorum* does not appear to cause the euphoria often associated with other psychoactive drugs, so many people who try it do not repeat the experience.

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**Reviewed by:** Mano Murty (MHPD – March 11, 2009)

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Approved Chris Turner, DG, MHPD (March 13, 2009)  
Approved Michelle Boudreau, DG, NHPD (March 19, 2009)  
Approved Sharon Mullins, A/DG, HPFBI (April 3, 2009)  
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Pending Peter Yendall, Director, Public Affairs, PACCB

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Pending Meena Ballantyne, ADM, HPFB  
Pending Anne Lamar, ADM, PACCB

Pending DMO  
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DRAFT  
April 7, 2009

## Media Lines Regulatory Control of *Salvia Divinorum*

### Issue

Since 2006, Health Canada has noted ongoing media interest regarding the availability of *Salvia divinorum* on the Canadian market. Health Canada has also received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum*, particularly given reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties.

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### Key Messages:

- Health Canada continues to collect and consider information about *Salvia divinorum* and its active ingredient, salvinorin A, from both national and international sources in order to determine what, if any, regulatory controls are needed.
- While the media have reported that use of *Salvia divinorum* is on the rise in certain parts of the country, Health Canada does not currently have statistics on its use across the Canadian population.
- Health Canada is taking steps to address this lack of data. Questions regarding the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey. A general open-ended question about the use of other substances was also included in the 2008 Canadian Alcohol and Drug Use Monitoring Survey.

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### Supplementary Messages:

#### *On the classification of *Salvia divinorum*:*

- In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA).
- *Salvia divinorum* is not listed under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these conventions.
- Several countries (Australia, Belgium, Denmark, Sweden, Italy, Spain, Finland and South Korea) have placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Although some individual U.S. states have implemented laws

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restricting its use, sale and/or distribution, *Salvia divinorum* and salvinorin A are not federally regulated under the *Controlled Substances Act* in the United States.

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- *Salvia divinorum* meets the definition of a natural health product under the *Natural Health Product Regulations* (NHPR). This means that *Salvia* products that are not in compliance with the NHPR may be subject to compliance and enforcement actions.
- As of January 2009, Health Canada had not issued any Natural Product Numbers (NPN) or Drug Identification Numbers – Homeopathic Medicine (DIN-HM) for *Salvia divinorum* products.

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***If asked for specifics on when the survey data will be available:***

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**Questions and Answers**

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Health Canada has only received a limited number of communications regarding *Salvia divinorum* from law enforcement agencies, and none of these has advised that the use of *Salvia divinorum* poses any particular threat to public safety.

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A4 - Health Canada considers several factors in determining whether scheduling a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in regulatory status;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

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Health Canada has only anecdotal information about the last three of the above-mentioned factors, and thus is not yet convinced that the controls imposed by the CDSA are an appropriate strategy for managing the risks associated with the use of *Salvia divinorum*. The survey results from the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey will help fill some of the information gaps. The data, however, will not likely be available until 2010. In the interim, Health Canada will continue to collect and consider information regarding *Salvia divinorum* as it becomes available.

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**Q5 – Didn't an internal report from Health Canada's Marketed Health Products Directorate recommend that *Salvia divinorum* be scheduled under the CDSA? Why has that recommendation not been acted upon?**

A5 – See A4

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- Use was more common in males than females.

*Salvia divinorum* is widely advertised and promoted on the Internet and sold in various "head shops" and natural food stores as a "legal" alternative to street drugs.

While some users have reported that the psychotropic effects of *Salvia divinorum* resemble those induced by other hallucinogens, such as LSD and phencyclidine, the overall experience appears to be quite unique.

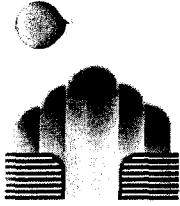
**Deleted:** *Salvia divinorum* does not appear to cause the euphoria often associated with other psychoactive drugs, so many people who try it do not repeat the experience.

**Prepared by:** Cheryl Tremblay, Policy and Regulatory Affairs Division, DSCSD  
Stephanie Mitchell, Communications Advisor (HECSB)  
Darrin Denne, Communications Officer (HPFB)

**Reviewed by:** Mano Murty (MHPD – March 11, 2009)

**Approved by :**

Approved	Andrew Adams, Director, OCS, DSCSD (March 1 <sup>st</sup> , 2009)
	Nancy Richards, Director, Bureau of Policy and Regulatory Affairs, NHPD (January 23, 2009)
	Duc Vu, Director, Marketed Biologics, Biotechnology and Natural Health Products Bureau, MHPD (February 3, 2009)
Approved	Cathy Sabiston, DG, TDD, HECS (April 7, 2009)
Approved	Chris Turner, DG, MHPD (March 13, 2009)
Approved	Michelle Boudreau, DG, NHPD (March 19, 2009)
Approved	Sharon Mullins, A/DG, HPFBI (April 3, 2009)
Approved	Ken Polk, Communications Executive, HPFB (April 3, 2009)
Approved	Kathleen Malone, Senior Media Relations, PACCB (April 7, 2009)
Pending	Warren Braun, Director, Strategic Communications, PACCB
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Pending	Meena Ballantyne, ADM, HPFB
Pending	Anne Lamar, ADM, PACCB
Pending	DMO
Pending	MO
Pending	PCO



Jocelyn Kula/HC-SC/GC/CA  
2009-04-14 04:19 PM

To Cheryl Tremblay/HC-SC/GC/CA@HWC  
cc  
bcc

Subject Fw: CP - B.C. survey of teens shows marijuana use down but  
prescription drug abuse up

may want to look up the report of this survey- hopefully on BC MoH website??

just be interesting to see what is in report re. increased incidence of hallucinogenic intake

JK

---

Jocelyn Kula  
Manager/ Gestionnaire  
Policy and Regulatory Affairs Division/ Division des politiques et affaires réglementaires  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0125 Fax: (613) 946-4224  
---- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2009-04-14 04:18 PM ----

HC\_Media\_SC/HC-SC/GC/C

A To  
Sent by: Gabriel Barbeau  
cc

2009-04-14 04:17 PM

Subject CP - B.C. survey of teens shows marijuana use down but  
prescription drug abuse up

Apr 14 2009 15:37:00 - Source: HEA [The Canadian Press]

B.C. survey of teens shows marijuana use down but prescription drug abuse up  
(Adolescent-Health)  
VANCOUVER \_ A survey of B.C. teens suggests fewer are using  
marijuana but more are abusing prescription and hallucinogenic drugs  
such as ecstasy.

The study by the McCreary Centre Society suggests pot smoking  
among teens has fallen for the 10th year in a row \_ down to 30 per  
cent from 37 per cent in 2003.

But according to the survey of 29,000 students, there's been a  
six per cent jump in adolescents trying prescription drugs without a  
doctor's supervision and a nine per cent increase in use of  
hallucinogens since 2003.

Executive director Annie Smith says the survey of Grades seven to  
12 students doesn't explain why more are abusing prescription drugs  
and hallucinogens.

She says recent studies in other provinces have found a similar  
trend and the society will explore that further in future workshops  
with teens.

The 2008 survey of physical and emotional health also suggests

that the majority of B.C. youth are in good health, feel connected to their family, school and community and are smoking and drinking less than teens in 2003.

Media Monitoring Unit / Unité de surveillance des médias  
Health Canada / Santé Canada



Draft Three

Cheng's  
Comments

## ***Salvia divinorum***

### **The Issue**

Recently there have been reports suggesting that Canadian teens and young adults are using a substance called *Salvia divinorum* (*S. divinorum*) specifically for its ability to produce hallucinations. Certain Web sites are also promoting the use of *S. divinorum* as a “legal” alternative to street drugs.

Health Canada recommends that you avoid using this substance because very little is known about the effect it has on the brain and there is no way to predict how it will affect you.

### **Background**

*Salvia divinorum* is a species of sage that belongs to the mint family. It is known to have psychotropic effects, which means it affects the mind and mental processes.

The leaves of this plant have been used traditionally by the Mazatec Indians in Mexico for many years. Traditional use involves chewing the leaves or using them to make a tea for medicinal purposes (e.g., to treat such conditions as headache or stomach upset), or to induce a “mystical” or hallucinogenic experience for spiritual purposes.

Products that claim to contain *S. divinorum* – or its main active ingredient, salvinorin A – are widely available on the Internet and are sold in various “head shops” and natural food stores. The products are sold in a number of formats, including seeds and plant cuttings for growing purposes. Fresh or dried leaves are intended to be chewed, swallowed or smoked. Liquid preparations are also available.

Street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastra, ska Maria pastora, ska pastora, diviner’s sage, magic mint, puff encens special, and salvia.

### **Risks of Using *Salvia divinorum***

*Salvia divinorum*’s effects, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations;
- out-of-body experiences;
- loss of consciousness;
- short-term memory loss;
- uncontrollable laughter;
- impaired ability to speak.

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product;

- how much is used;
- how it is taken (e.g., ingested or smoked);
- the user's mood and expectations.

A major concern about *S. divinorum* is the fact that there have been so few scientific studies about the way it affects the body and the brain. For example, very little is known about the following:

- how it affects the brain and if it causes permanent damage;
- whether it causes physical dependence or addiction;
- how it interacts with other substances (including other drugs and alcohol).

### Minimizing Your Risk

Health Canada recommends that you avoid using *S. divinorum*. Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs and other substances that distort reality. (See the "Need More Info?" section below for links to resources that can help you with this.)

Also, remember that just because a drug is plant-based or "natural," it does not mean it is safe. Under certain conditions of use, *Salvia divinorum* may meet the definition of a "natural health product" (NHP) under Health Canada's *Natural Health Products Regulations*, but no NHPs containing this substance have been approved for sale in Canada. This means products that contain *S. divinorum* have not been reviewed by Health Canada for safety, efficacy or quality. As such, they may be counterfeit or contain other ingredients that pose risks to health, and consumers should heed the "buyer beware" principle.

OK  
remember  
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of use?

Natural health products that have been reviewed and approved by Health Canada will be labelled with one of the following:

- a Natural Product Number (NPN); or
- a Drug Identification Number - Homeopathic Medicine (DIN-HM).

### The Legal Status of *Salvia divinorum*

#### In Canada

Neither *S. divinorum* nor salvinorin A is currently regulated under the *Controlled Drugs and Substances Act* (CDSA). When assessing whether to add a substance to one of the Schedules to the CDSA, Health Canada considers the following factors:

- international requirements and trends in controlling the substance;
- similarity to other substances already regulated under the CDSA;
- whether there may be legitimate uses of the substance (e.g., potential health benefits, use in manufacturing, etc.);
- the abuse liability of the substance and the potential for addiction;
- the extent of actual abuse of the substance in Canada and elsewhere;
- overall risk to public health and safety posed by the substance.

In the case of *S. divinorum*, there is simply not enough information available to determine whether regulation under the CDSA is the best option to manage the potential risks associated with its use. Questions about the use of *S. divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. The survey results will help fill some of the information gaps, but the data will not likely be available until 2010.

#### In Other Countries

Several countries (e.g., Australia, Belgium, Denmark, Sweden, Italy, Spain, Finland and South Korea) have placed controls on the import and/or sale of *S. divinorum*. In the United States, it is not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on its sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution (e.g., no sales to anyone under the age of 18).

#### **Health Canada's Role**

Health Canada continues to collect and consider information regarding *S. divinorum* and continues to consult with key stakeholders, including health officials in other countries, and law enforcement officials here at home. This will assist in determining the most appropriate strategy to manage the risks associated with the use of *S. divinorum*.

#### **Need More Info?**

→ TO DO?

For information about Health Canada's Drug Strategy and Controlled Substances Directorate, go to: <http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hecs-dgsesc/dscsp-psasc/index-eng.php>

Also, see the Prevention section on the Government of Canada's National Anti-Drug Strategy Web site at: <http://www.nationalantidrugstrategy.gc.ca/>. This site has a number of helpful resources for parents, including "Tips on Talking to Your Teenager" and "What to Do if Your Teen is Using Drugs."

Information on natural health products and the *Natural Health Products Regulations* can be found at: <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php>

For more on the surveys that are collecting information about *Salvia divinorum* use in Canada, see:

The 2008-2009 Youth Smoking Survey, at:

[http://www.yss.uwaterloo.ca/ysss/site\\_app/controller/index.cfm](http://www.yss.uwaterloo.ca/ysss/site_app/controller/index.cfm) and

The Ontario Student Drug Use and Health Survey, at: <http://www.camh.net/Research/osdus.html>

Additional Resources:

U.S. Drug Enforcement Administration: Drugs and Chemicals of Concern: *Salvia divinorum* and

Salvinorin A at: [http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)

U.S. Department of Health & Human Services, National Survey on Drug Use and Health: Use of  
Specific Hallucinogens: 2006 at:  
<http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf>

For additional articles on health and safety issues go to the *It's Your Health* Web section at:  
<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/index-eng.php>

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

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Writer: Sue Lumsden

Version/date: Draft Three, April 14, 2009. Incorporates comments forwarded by Cheryl Tremblay and Robin Marles, as well as input from a conversation with Brittany Sauvé.

Contacts: HECSB: Jocelyn Kula, Cheryl Tremblay, Brittany Sauvé  
HPFB-NHPD: Valerie Hurry, Robin Marles  
~~HPFB-MHPD: Scott Jordan (Draft Two only), Robert Leitch, Mano Murty~~

Cheryl + Jocelyn's  
Comments

## ***Salvia divinorum* - Draft Three**

### **The Issue**

Recently there have been reports suggesting that Canadian teens and young adults are using a substance called *Salvia divinorum* (*S. divinorum*) specifically for its ability to produce hallucinations. Certain Web sites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs.

Health Canada recommends that you avoid using this substance because very little is known about the effect it has on the brain and there is no way to predict how it will affect you.

### **Background**

*Salvia divinorum* is a species of sage that belongs to the mint family. It is known to have psychotropic effects, which means it affects the mind and mental processes.

The leaves of this plant have been used traditionally by the Mazatec Indians in Mexico for many years. Traditional use involves chewing the leaves or using them to make a tea for medicinal purposes (e.g., to treat such conditions as headache or stomach upset), or to induce a "mystical" or hallucinogenic experience for spiritual purposes.

Products that claim to contain *S. divinorum* – or its main active ingredient, salvinorin A – are widely available on the Internet and are sold in various "head shops" and natural food stores. The products are sold in a number of formats, including seeds and plant cuttings for growing purposes. Fresh or dried leaves are intended to be chewed, swallowed or smoked. Liquid preparations are also available.

Street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastra, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff encens special, and salvia.

### **Risks of Using *Salvia divinorum***

*Salvia divinorum*'s effects, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations;
- out-of-body experiences;
- loss of consciousness;
- short-term memory loss;
- uncontrollable laughter;
- impaired ability to speak.

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product;

- how much is used;
- how it is taken (e.g., ingested or smoked);
- the user's mood and expectations.

A major concern about *S. divinorum* is the fact that there have been so few scientific studies about the way it affects the body and the brain. For example, very little is known about the following:

- how it affects the brain and if it causes permanent damage;
- whether it causes physical dependence or addiction;
- how it interacts with other substances (including other drugs and alcohol).

### Minimizing Your Risk

Health Canada recommends that you avoid using *S. divinorum*. Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs and other substances that distort reality. (See the "Need More Info?" section below for links to resources that can help you with <sup>however</sup> this.)

OK, because talking about addiction or use i.e. (homeopathic) but take out the way.

Also, remember that just because a drug is plant-based or "natural," it does not mean it is safe. Under certain conditions of use, *Salvia divinorum* may meet the definition of a "natural health product" (NHP) under Health Canada's *Natural Health Products Regulations*, <sup>although</sup> ~~but~~ <sup>that</sup> no NHPs containing this substance have been approved for sale in Canada. This means ~~products that contain S. divinorum~~ <sup>or may not contain Salvia divinorum</sup> have not been reviewed by Health Canada for safety, efficacy or quality. As such, they may ~~be counterfeit or~~ <sup>and</sup> contain other ingredients that pose risks to health, <sup>and</sup> consumers should heed the "buyer beware" principle.

Natural health products that have been reviewed and approved by Health Canada will be labelled with one of the following:

- a Natural Product Number (NPN); or
- a Drug Identification Number - Homeopathic Medicine (DIN-HM).

### The Legal Status of *Salvia divinorum*

#### In Canada

Neither *S. divinorum* nor salvinorin A <sup>are</sup> currently regulated under the *Controlled Drugs and Substances Act* (CDSA). When assessing whether to add a substance to one of the Schedules to the CDSA, Health Canada considers the following factors:

have tried it, generally correct. (gets at counterfeit point without using word which is often misunderstood)

- international requirements and trends in controlling the substance;
- similarity to other substances already regulated under the CDSA;
- whether there may be legitimate uses of the substance (e.g., potential health benefits, use in manufacturing, etc.);
- the abuse liability of the substance and the potential for addiction;
- the extent of actual abuse of the substance in Canada and elsewhere;
- overall risk to public health and safety posed by the substance.

In the case of *S. divinorum*, there is simply not enough information available to determine whether regulation under the CDSA is the best option to manage the potential risks associated with its use. Questions about the use of *S. divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey, ~~the~~ survey results will help fill some of the information gaps, ~~but the data will not~~ likely be available until 2010,

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In Other Countries

Several countries (e.g., Australia, Belgium, Denmark, Sweden, Italy, Spain, Finland and South Korea) have placed controls on the import and/or sale of *S. divinorum*. In the United States, it is not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on its sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution (e.g., no sales to anyone under the age of 18).

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**Health Canada's Role**

Health Canada continues to collect and consider information regarding *S. divinorum* and continues to consult with key stakeholders, including health officials in other countries, and law enforcement officials here at home. This will assist in determining the most appropriate strategy to manage the risks associated with the use of *S. divinorum*.

**Need More Info?**

(not a web site yet)  
Tobacco + Drugs Directorate

For information about ~~Health Canada's Drug Strategy and Controlled Substances Directorate~~, go to: <http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hecs-dgsesc/dscsp-psasc/index-eng.php>

For information about  
Also, see the Prevention section on

the Government of Canada's National Anti-Drug Strategy, go to  
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The Ontario Student Drug Use and Health Survey, at: <http://www.camh.net/Research/osdus.html>

**Additional Resources:**

U.S. Drug Enforcement Administration: Drugs and Chemicals of Concern: *Salvia divinorum* and

Salvinorin A at: [http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)

U.S. Department of Health & Human Services, National Survey on Drug Use and Health: Use of  
Specific Hallucinogens: 2006 at:

<http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf>

For additional articles on health and safety issues go to the *It's Your Health* Web section at:

<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/index-eng.php>

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

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Writer: Sue Lumsden 

Version/date: Draft Three, April 14, 2009. Incorporates comments forwarded by Cheryl Tremblay and Robin Marles, as well as input from a conversation with Brittany Sauvé.

Contacts: HECSB: Jocelyn Kula, Cheryl Tremblay, Brittany Sauvé  
HPFB-NHPD: Valerie Hurry, Robin Marles  
HPFB-MHPD: Scott Jordan (Draft Two only), Robert Leitch, Mano Murty



## ***Salvia divinorum* - Draft Three - NHPD Comments**

### **The Issue**

Recently there have been reports suggesting that Canadian teens and young adults are using a substance called *Salvia divinorum* (*S. divinorum*) specifically for its ability to produce hallucinations. Certain Web sites are also promoting the use of *S. divinorum* as a “legal” alternative to street drugs.

Street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastra, ska Maria pastora, ska pastora, diviner’s sage, magic mint, puff encens special, and salvia.

Health Canada recommends that you avoid using this substance because very little is known about the effect it has on the brain and there is no way to predict how it will affect you.

### **Background**

*Salva divinorum* is a species of sage that belongs to the mint family. It is known to have psychotropic effects, which means it affects the mind and mental processes.

The leaves of this plant have been used traditionally by the Mazatec Indians in Mexico for many years. Traditional use involves chewing the leaves or using them to make a tea for medicinal purposes (e.g., to treat such conditions as headache or stomach upset), or to induce a “mystical” or hallucinogenic experience for spiritual purposes.

Products that claim to contain *S. divinorum* – or its main active ingredient, salvinorin A – are widely available on the Internet and are sold in various “head shops” and natural food stores. The products are sold in a number of formats, including seeds and plant cuttings for growing purposes. Fresh or dried leaves are intended to be chewed, swallowed or smoked. Liquid preparations are also available.

### **Risks of Using *Salvia divinorum***

*Saliva divinorum*’s effects, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations;
- dysphoria (feeling unwell, uneasy or unhappy);
- out-of-body experiences;
- uncontrollable laughter;
- loss of consciousness;
- short-term memory loss;
- incoordination;
- ~~impaired ability to speak~~: slurred speech.

ack to  
Brittany

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product;
- how much is used;
- the purity of the product (it may be adulterated with other substances);
- how it is taken (e.g., ingested or smoked);
- the user's mood and expectations.

A major concern about *S. divinorum* is the fact that there have been only a few scientific studies about the way it affects the body and the brain. For example, it is known which brain receptors are targeted by the active ingredient, Salvinorin A, but very little is known about the following:

- how it affects the brain overall, what are the long-term effects, and if it causes permanent damage;
- what effects it has on physical dependence or addiction;
- how it interacts with other substances (including other drugs and alcohol).

### **Minimizing Your Risk**

Health Canada recommends that you avoid using *S. divinorum*. Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs and other substances that distort reality. (See the "Need More Info?" section below for links to resources that can help you with this.)

Also, remember that just because a drug is plant-based or "natural," it does not mean it is safe. Under certain conditions of use, *Salvia divinorum* may meet the definition of a "natural health product" (NHP) under Health Canada's *Natural Health Products Regulations*, but no NHPs containing this substance have been approved for sale in Canada. This means products that contain *S. divinorum* have not been reviewed by Health Canada for safety, efficacy or quality. As such, they may be counterfeit or contain other ingredients that pose risks to health, and consumers should heed the "buyer beware" principle.

Natural health products that have been reviewed and approved by Health Canada will be labelled with one of the following:

- a Natural Product Number (NPN); or
- a Drug Identification Number - Homeopathic Medicine (DIN-HM).

### **The Legal Status of *Salvia divinorum***

#### In Canada

Neither *S. divinorum* nor salvinorin A is currently regulated under the *Controlled Drugs and Substances Act* (CDSA). When assessing whether to add a substance to one of the Schedules to the CDSA, Health Canada considers the following factors:

- international requirements and trends in controlling the substance;
- similarity to other substances already regulated under the CDSA;

- whether there may be legitimate uses of the substance (e.g., potential health benefits, use in manufacturing, etc.);
- the abuse liability of the substance and the potential for addiction;
- the extent of actual abuse of the substance in Canada and elsewhere;
- overall risk to public health and safety posed by the substance.

In the case of *S. divinorum*, there is simply not enough information available to determine whether regulation under the CDSA is the best option to manage the potential risks associated with its use. Questions about the use of *S. divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. The survey results will help fill some of the information gaps, but the data will not likely be available until 2010.

#### In Other Countries

Several countries (e.g., Australia, Belgium, Denmark, Sweden, Italy, Spain, Finland and South Korea) have placed controls on the import and/or sale of *S. divinorum*. In the United States, it is not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on its sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution (e.g., no sales to anyone under the age of 18).

#### **Health Canada's Role**

Health Canada continues to collect and consider information regarding *S. divinorum* and continues to consult with key stakeholders, including health officials in other countries, and law enforcement officials here at home. This will assist in determining the most appropriate strategy to manage the risks associated with the use of *S. divinorum*.

#### **Need More Info?**

For information about Health Canada's Drug Strategy and Controlled Substances Directorate, go to: <http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hecs-dgsesc/dscsp-psasc/index-eng.php>

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[http://www.yss.uwaterloo.ca/ysss/site\\_app/controller/index.cfm](http://www.yss.uwaterloo.ca/ysss/site_app/controller/index.cfm) and

The Ontario Student Drug Use and Health Survey, at: <http://www.camh.net/Research/osdus.html>

**Additional Resources:**

U.S. Drug Enforcement Administration: Drugs and Chemicals of Concern: *Salvia divinorum* and Salvinorin A at: [http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)

U.S. Department of Health & Human Services, National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006 at:  
<http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf>

For additional articles on health and safety issues go to the *It's Your Health* Web section at:  
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HPFB-NHPD: Valerie Hurry, Robin Marles  
HPFB-MHPD: Scott Jordan (Draft Two only), Robert Leitch, Mano Murty

## ***Salvia divinorum* - Draft Three - MHPD Comments**

### **The Issue**

Recently there have been reports suggesting that Canadian teens and young adults are using a substance called *Salvia divinorum* (*S. divinorum*) specifically for its ability to produce hallucinations. Certain Web sites are also promoting the use of *S. divinorum* as a “legal” alternative to street drugs.

Health Canada recommends that you avoid using this substance because very little is known about the effect it has on the brain, specifically with respect to permanent damage. There is also ~~and there is~~ no way to predict how it will affect you with each use.

### **Background**

*Salvia divinorum* is a species of sage that belongs to the mint family. It is known to have psychotropic effects, which means it affects the mind and mental processes.

The leaves of this plant have been used traditionally by the Mazatec Indians in Mexico for many years. Traditional use involves chewing the leaves or using them to make a tea for medicinal purposes (e.g., to treat such conditions as headache or stomach upset), or to induce a “mystical” or hallucinogenic experience for spiritual purposes.

Products that claim to contain *S. divinorum* – or its main active ingredient, salvinorin A – are widely available on the Internet and are sold in various “head shops” and natural food stores. The products are sold in a number of formats, including seeds and plant cuttings for growing purposes. Fresh or dried leaves are intended to be chewed, swallowed or smoked. Liquid preparations are also available.

Street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastra, ska Maria pastora, ska pastora, diviner’s sage, magic mint, puff encens special, and salvia.

### **Risks of Using *Salvia divinorum***

*Salvia divinorum*’s effects, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations;
- out-of-body experiences;
- loss of consciousness;
- short-term memory loss;
- uncontrollable laughter;
- impaired ability to speak.

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product;
- how much is used;
- how it is taken (e.g., ingested [*For consideration - the term 'eaten' may be easily understood by the public*] or smoked);
- the user's mood and expectations.

A major concern about *S. divinorum* is the fact that there have been so few scientific studies about the way it affects the body and the brain. For example, very little is known about the following:

- how it affects the brain and if it causes permanent damage;
- whether it causes physical dependence or addiction;
- how it interacts with other substances (including other drugs and alcohol).

### **Minimizing Your Risk**

Health Canada recommends that you avoid using *S. divinorum*. Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs and other substances that distort reality. (See the "Need More Info?" section below for links to resources that can help you with this.)

Also, remember that just because a drug is plant-based or "natural," it does not mean it is safe. Under certain conditions of use, *Salvia divinorum* may meet the definition of a "natural health product" (NHP) under Health Canada's *Natural Health Products Regulations*, but no NHPs containing this substance have been approved for sale in Canada. This means products that contain *S. divinorum* have not been reviewed by Health Canada for safety, efficacy or quality. As such, they may be counterfeit or contain other ingredients that pose risks to health, and consumers should heed the "buyer beware" principle.

Natural health products that have been reviewed and approved by Health Canada will be labelled with one of the following:

- a Natural Product Number (NPN); or
- a Drug Identification Number - Homeopathic Medicine (DIN-HM).

### **The Legal Status of *Salvia divinorum***

#### In Canada

Neither *S. divinorum* nor salvinorin A is currently regulated under the *Controlled Drugs and Substances Act* (CDSA). When assessing whether to add a substance to one of the Schedules to the CDSA, Health Canada considers the following factors:

- international requirements and trends in controlling the substance;
- similarity to other substances already regulated under the CDSA;
- whether there may be legitimate uses of the substance (e.g., potential health benefits, use in manufacturing, etc.);
- the abuse liability of the substance and the potential for addiction;
- the extent of actual abuse of the substance in Canada and elsewhere;

- overall risk to public health and safety posed by the substance.

In the case of *S. divinorum*, there is simply not enough information available to determine whether regulation under the CDSA is the best option to manage the potential risks associated with its use. Questions about the use of *S. divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. The survey results will help fill some of the information gaps, but the data will not likely be available until 2010.

#### In Other Countries

Several countries (e.g., Australia, Belgium, Denmark, Sweden, Italy, Spain, Finland and South Korea) have placed controls on the import and/or sale of *S. divinorum*. In the United States, it is not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on its sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution (e.g., no sales to anyone under the age of 18).

#### **Health Canada's Role**

Health Canada continues to collect and consider information regarding *S. divinorum* and continues to consult with key stakeholders, including health officials in other countries, and law enforcement officials here at home. This will assist in determining the most appropriate strategy to manage the risks associated with the use of *S. divinorum*.

#### **Need More Info?**

For information about Health Canada's Drug Strategy and Controlled Substances Directorate, go to: <http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hecs-dgesc/dscsp-psasc/index-eng.php>

Also, see the Prevention section on the Government of Canada's National Anti-Drug Strategy Web site at: <http://www.nationalantidrugstrategy.gc.ca/>. This site has a number of helpful resources for parents, including "Tips on Talking to Your Teenager" and "What to Do if Your Teen is Using Drugs."

Information on natural health products and the *Natural Health Products Regulations* can be found at: <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php>

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Additional Resources:

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U.S. Department of Health & Human Services, National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006 at:  
<http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf>

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Writer: Sue Lumsden 

Version/date: Draft Three, April 14, 2009. Incorporates comments forwarded by Cheryl Tremblay and Robin Marles, as well as input from a conversation with Brittany Sauvé.

Contacts: HECSB: Jocelyn Kula, Cheryl Tremblay, Brittany Sauvé  
HPFB-NHPD: Valerie Hurry, Robin Marles  
HPFB-MHPD: Scott Jordan (Draft Two only), Robert Leitch, Mano Murty



## ***Salvia divinorum***

### **The Issue**

Recently there have been reports suggesting that Canadian teens and young adults are using a substance called *Salvia divinorum* (*S. divinorum*) for its ability to produce hallucinations. Certain Web sites are also promoting the use of *S. divinorum* as a “legal” alternative to street drugs.

Street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastra, ska Maria pastora, ska pastora, diviner’s sage, magic mint, puff encens special, and salvia.

Health Canada recommends that you avoid using this substance because very little is known about the damage it may cause to the body, including the brain. There is also no way to predict how it will affect you with each use.

### **Background**

*S. divinorum* is a species of sage that belongs to the mint family. It is known to have psychotropic effects, which means it affects the mind and mental processes.

The leaves of this plant have been used traditionally by the Mazatec Indians in Mexico for many years. Traditional use involves chewing the leaves or using them to make a tea for medicinal purposes (e.g., to treat such conditions as headache or stomach upset), or to induce a “mystical” or hallucinogenic experience for spiritual purposes.

Products that claim to contain *S. divinorum* – or its main active ingredient, salvinorin A – are widely available on the Internet and are sold in various “head shops” and natural food stores. The products are sold in a number of formats, including seeds and plant cuttings for growing purposes. Fresh or dried leaves are intended to be chewed, swallowed or smoked. Liquid preparations are also available.

### **Risks of Using *Salvia divinorum***

*S. divinorum*’s effects, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations;
- dysphoria (feeling unwell, uneasy or unhappy);
- out-of-body experiences;
- uncontrollable laughter;
- loss of consciousness;
- short-term memory loss;
- lack of physical coordination;
- slurred speech and awkward sentence patterns.

There is no way to predict what effect this substance may have on you. In addition, the effects

may differ from one use to the next, depending on factors such as:

- the potency of the product;
- how much is used;
- the purity of the product (it may be mixed with other substances);
- how it is taken (e.g., chewed, swallowed or smoked);
- the user's mood and expectations.

A major concern about *S. divinorum* is the fact that there have only been a few scientific studies about the way it affects the body and the brain. Scientists know which brain receptors are targeted by the active ingredient, salvinorin A, but very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or permanent damage;
- how it interacts with other substances, including other drugs, natural health products and alcohol.

The information regarding physical dependence or addiction to *S. divinorum* is unclear, although it appears the potential for either is low.

### **Minimizing Your Risk**

Health Canada recommends that you avoid using *S. divinorum*. Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs and other substances that distort reality. (See the "Need More Info?" section below for links to resources that can help you with this.)

Also, remember that just because a drug is plant-based or "natural," it does not mean it is safe. Under certain conditions of use, *S. divinorum* meets the definition of a "natural health product" (NHP) under Health Canada's *Natural Health Products Regulations*. However, no NHPs containing this substance have been approved for sale in Canada. This means that products claiming to contain *S. divinorum* have not been reviewed by Health Canada for safety, efficacy or quality. As such, they may be counterfeit or contain other ingredients that pose risks to health, and consumers should heed the "buyer beware" principle.

Natural health products that have been reviewed and approved by Health Canada are labelled with one of the following:

- a Natural Product Number (NPN); or
- a Drug Identification Number - Homeopathic Medicine (DIN-HM).

### **The Legal Status of *Salvia divinorum***

#### In Canada

Neither *S. divinorum* nor salvinorin A is currently regulated under the *Controlled Drugs and Substances Act* (CDSA). When assessing whether to add a substance to one of the Schedules to the CDSA, Health Canada considers the following factors:

- international requirements and trends in controlling the substance;

- similarity to other substances already regulated under the CDSA;
- whether there may be legitimate uses of the substance (e.g., potential health benefits, use in manufacturing, etc.);
- the potential for abuse and the risk of addiction associated with the substance;
- the extent of actual abuse of the substance in Canada and elsewhere;
- overall risk to public health and safety posed by the substance.

In the case of *S. divinorum*, there is simply not enough information available to determine whether regulation under the CDSA is the best option to manage the potential risks. Questions about the use of *S. divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey, and these survey results will help fill some of the information gaps. The data, however, will not likely be available until 2010.

#### In Other Countries

Several countries (e.g., Australia, Belgium, Denmark, Sweden, Italy, Spain, Finland and South Korea) have placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on their sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution (e.g., no sales to anyone under the age of 18).

#### **Health Canada's Role**

Health Canada continues to collect and consider information regarding *S. divinorum* and continues to consult with key stakeholders, including health officials in other countries, and law enforcement officials here at home. This will assist in determining the most appropriate strategy to manage the risks associated with the use of *S. divinorum*.

#### **Reporting Adverse Reactions**

You can report any adverse reactions to the Canada Vigilance Program by one of the following three ways:

- Report online at the MedEffect™ Canada Web site
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and either:
- Fax toll-free to 1-866-678-6789
- Mail to: Canada Vigilance Program

Health Canada  
AL 0701C  
Ottawa, ON K1A 0K9

To have postage pre-paid, download the postage paid label from the MedEffect™ Canada Web site. The Canada Vigilance Reporting Form and the adverse reaction reporting guidelines may also be obtained via this Web site.

## Need More Info?

For information about the Government of Canada's Anti-Drug Strategy, go to:

<http://www.nationalantidrugstrategy.gc.ca/>. The Prevention section on this site has a number of helpful resources for parents, including "Tips on Talking to Your Teenager" and "What to Do if Your Teen is Using Drugs."

Information on natural health products and the *Natural Health Products Regulations* can be found at: <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php>

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[http://www.yss.uwaterloo.ca/ysssite\\_app/controller/index.cfm](http://www.yss.uwaterloo.ca/ysssite_app/controller/index.cfm) and

The Canadian Alcohol and Drug Use Monitoring Survey, at:

<http://www.hc-sc.gc.ca/hl-vs/drug-drogues/cadums-escad-eng.php>

## Additional Resources:

U.S. Drug Enforcement Administration: Drugs and Chemicals of Concern: *Salvia divinorum* and Salvinorin A at: [http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)

U.S. Department of Health & Human Services, National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006 at:

<http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf>

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Original:

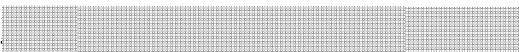
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Writer: Sue Lumsden 

Version/date: Draft Seven. May 27, 2009. Removes highlighter marking changes in Draft Six,

which have been agreed to by the Program Contacts. Replaces reference (and link) to the Ontario Student Drug Use and Health Survey with a reference (and link) to the (national) Canadian Alcohol and Drug Use Monitoring Survey.

Contacts: HECSB: Jocelyn Kula, Cheryl Tremblay, Brittany Sauvé  
HPFB-NHPD: Valerie Hurry, Robin Marles  
HPFB-MHPD: Scott Jordan (Draft Two only), Robert Leitch, Mano Murty



"Sue Lumsden"

2009-05-21 03:35 PM

To Brittany Sauvé <brittany\_sauve@hc-sc.gc.ca>, "Cheryl Tremblay" <Cheryl\_Tremblay@hc-sc.gc.ca>, "Jocelyn Kula" <jocelyn\_kula@hc-sc.gc.ca>, "Mano Murty"

cc

bcc

Subject IYH - Salvia divinorum - Draft Six

Good afternoon to all,

I've attached Draft Six of the IYH on Salvia divinorum, which incorporates the latest comments and revisions received from you.

Through discussions and e-mail communications, we have been able to reach a consensus on a number of proposed revisions and/or deletions suggested in Draft Five. For example, Draft Six accepts the insertion of "awkward sentence patterns" as an effect of using Salvia divinorum and puts back the bullet indicating that "the user's mood and expectations" play a role in the way the effects may differ from one use to the next.

Based on comments from R. Marles and B. Sauvé, Draft Six also removes the reference to "abuse" in the sentence stating that the potential for physical dependence or addiction appears to be low.

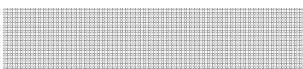
There is no highlighter marking changes/items on which consensus has been reached.

In the attached version, there are a couple of minor but important proposed revisions. So that you can find these quickly and easily, the proposed insertions are highlighted in green, while proposed deletions are highlighted in yellow.

Please let me know whether you accept the proposed revisions. If so, I will clean up the draft and send it to the IYH Manager for the formal approvals process.

Thank you very much for all of the work you have put into this article to date.

Best regards,  
Sue



IYH - Salvia divinorum - Draft Six (May 21, 2009).wpd

## ***Salvia divinorum***

### **The Issue**

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Health Canada recommends that you avoid using this substance because very little is known about the damage it may cause to the body, including the brain.

There is also no way to predict how it will affect you with each use.

**Deleted:** effect it has on

**Comment:** Agree with Brittany's suggestion to rewrite as indicated.

### **Background**

*Salvia divinorum* is a species of sage that belongs to the mint family. It is known to have psychotropic effects, which means it affects the mind and mental processes.

The leaves of this plant have been used traditionally by the Mazatec Indians in Mexico for many years. Traditional use involves chewing the leaves or using them to make a tea for medicinal purposes (e.g., to treat such conditions as headache or stomach upset), or to induce a "mystical" or hallucinogenic experience for spiritual purposes.

Products that claim to contain *S. divinorum* – or its main active ingredient, salvinorin A – are widely available on the Internet and are sold in various "head shops" and natural food stores. The products are sold in a number of formats, including seeds and plant cuttings for growing purposes. Fresh or dried leaves are intended to be chewed, swallowed or smoked. Liquid preparations are also available.

### Risks of Using *Salvia divinorum*

*Salvia divinorum*'s effects, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations;
- dysphoria (feeling unwell, uneasy or unhappy);
- out-of-body experiences;
- uncontrollable laughter;
- loss of consciousness;
- short-term memory loss;
- lack of physical coordination;
- slurred speech and awkward sentence patterns.

**Comment:** ✓ Agree with proposed addition.

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product;
- how much is used;
- the purity of the product (it may be mixed [redacted] with other substances);
- how it is taken (e.g., chewed, swallowed or smoked);
- [redacted]

**Comment:** ✓ Agree with proposed addition.

**Comment:** ✗ Disagree with proposed deletion as per Brittany's rationale.

**Comment:** ✓ Agree with proposed change.

A major concern about *S. divinorum* is the fact that there have only been [redacted] a few scientific studies about the way it affects the body and the brain. Scientists know which brain receptors are targeted by the active ingredient, salvinorin A, but very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or permanent damage;
- how it interacts with other substances, including other drugs, natural health products and alcohol.

**Comment:** ✓ Agree with proposed addition.

The information regarding physical dependence or addiction of *S. divinorum* is unclear, although it appears the potential for this is low.

**Deleted:** or abuse

**Comment:** ✓ Agree with proposed addition and with removal of "of abuse", with one more small change.

**Deleted:** of such issues



## Minimizing Your Risk

Health Canada recommends that you avoid using *S. divinorum*. Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs and other substances that distort reality. (See the "Need More Info?" section below for links to resources that can help you with this.)

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Deleted: of the substance

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Writer: Sue Lumsden [REDACTED]

Version/date: Draft Five, May 1, 2009. Incorporates comments forwarded by Cheryl Tremblay, Brittany Sauvé, Robin Marles, Valerie Hurry and Robert Leitch. Text added is marked with yellow highlighter, while text deleted is highlighted in green.

Contacts: HECSB: Jocelyn Kula, Cheryl Tremblay, Brittany Sauvé  
HPFB-NHPD: Valerie Hurry, Robin Marles  
HPFB-MHPD: Scott Jordan (Draft Two only), Robert Leitch, Mano Murty

OK  
JKM  
May 26/09

## ***Salvia divinorum***

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- lack of physical coordination;
- slurred speech and awkward sentence patterns.

There is no way to predict what effect this substance may have on you. In addition, the effects

may differ from one use to the next, depending on factors such as:

- the potency of the product;
- how much is used;
- the purity of the product (it may be mixed with other substances);
- how it is taken (e.g., chewed, swallowed or smoked);
- the user's mood and expectations.

A major concern about *S. divinorum* is the fact that there have only been a few scientific studies about the way it affects the body and the brain. Scientists know which brain receptors are targeted by the active ingredient, salvinorin A, but very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or permanent damage;
- how it interacts with other substances, including other drugs, natural health products and alcohol.

The information regarding physical dependence or addiction to *S. divinorum* is unclear, although it appears the potential for ~~either of such issues~~ is low.

### **Minimizing Your Risk**

Health Canada recommends that you avoid using *S. divinorum*. Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs and other substances that distort reality. (See the "Need More Info?" section below for links to resources that can help you with this.)

Also, remember that just because a drug is plant-based or "natural," it does not mean it is safe. Under certain conditions of use, *Salvia divinorum* meets the definition of a "natural health product" (NHP) under Health Canada's *Natural Health Products Regulations*. However, no NHPs containing this substance have been approved for sale in Canada. This means that products claiming to contain *S. divinorum* have not been reviewed by Health Canada for safety, efficacy or quality. As such, they may be counterfeit or contain other ingredients that pose risks to health, and consumers should heed the "buyer beware" principle.

Natural health products that have been reviewed and approved by Health Canada are labelled with one of the following:

- a Natural Product Number (NPN); or
- a Drug Identification Number - Homeopathic Medicine (DIN-HM).

### **The Legal Status of *Salvia divinorum***

#### In Canada

Neither *S. divinorum* nor salvinorin A is currently regulated under the *Controlled Drugs and Substances Act* (CDSA). When assessing whether to add a substance to one of the Schedules to the CDSA, Health Canada considers the following factors:

- international requirements and trends in controlling the substance;

- similarity to other substances already regulated under the CDSA;
- whether there may be legitimate uses of the substance (e.g., potential health benefits, use in manufacturing, etc.);
- the potential for abuse liability of the substance and the potential for risk of addiction associated with the substance;
- the extent of actual abuse of the substance in Canada and elsewhere;
- overall risk to public health and safety posed by the substance.

In the case of *S. divinorum*, there is simply not enough information available to determine whether regulation under the CDSA is the best option to manage the potential risks. Questions about the use of *S. divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey, and these survey results will help fill some of the information gaps. The data, however, will not likely be available until 2010.

#### In Other Countries

Several countries (e.g., Australia, Belgium, Denmark, Sweden, Italy, Spain, Finland and South Korea) have placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on their sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution (e.g., no sales to anyone under the age of 18).

#### **Health Canada's Role**

Health Canada continues to collect and consider information regarding *S. divinorum* and continues to consult with key stakeholders, including health officials in other countries, and law enforcement officials here at home. This will assist in determining the most appropriate strategy to manage the risks associated with the use of *S. divinorum*.

#### **Need More Info?**

For information about the Government of Canada's Anti-Drug Strategy, go to: <http://www.nationalantidrugstrategy.gc.ca/>. The Prevention section on this site has a number of helpful resources for parents, including "Tips on Talking to Your Teenager" and "What to Do if Your Teen is Using Drugs."

Information on natural health products and the *Natural Health Products Regulations* can be found at: <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php>

For more on the surveys that are collecting information about *Salvia divinorum* use in Canada, see:

The 2008-2009 Youth Smoking Survey, at:

[http://www.yss.uwaterloo.ca/ysss/site\\_app/controller/index.cfm](http://www.yss.uwaterloo.ca/ysss/site_app/controller/index.cfm) and

The Ontario Student Drug Use and Health Survey, at: <http://www.camh.net/Research/osdus.html>

Additional Resources:

U.S. Drug Enforcement Administration: Drugs and Chemicals of Concern: *Salvia divinorum* and Salvinorin A at: [http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)

U.S. Department of Health & Human Services, National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006 at: <http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf>

For additional articles on health and safety issues go to the *It's Your Health* Web section at: <http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/index-eng.php>

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

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ISBN#

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**s.19(1)**

Writer: Sue Lumsden [REDACTED]

Version/date: Draft Six. May 21, 2009. Incorporates comments forwarded by Cheryl Tremblay, Brittany Sauvé, Robin Marles, Valerie Hurry and Robert Leitch. Text added is marked with green highlighter, while text deleted is highlighted in yellow.

Contacts: HECSB: Jocelyn Kula, Cheryl Tremblay, Brittany Sauvé  
HPFB-NHPD: Valerie Hurry, Robin Marles  
HPFB-MHPD: Scott Jordan (Draft Two only), Robert Leitch, Mano Murty



Brittany  
Sauvé/HC-SC/GC/CA  
2009-05-05 03:54 PM

To [REDACTED]  
cc "Cheryl Tremblay" <Cheryl\_Tremblay@hc-sc.gc.ca>,  
"Jocelyn Kula" <jocelyn\_kula@hc-sc.gc.ca>, "Sue Lumsden"  
[REDACTED] "Mano Murty"  
bcc

Subject Re: IYH - Salvia divinorum - Draft Five

Dear Sue,

I agree with Robin's comment below. I think that its abuse is well-known.

I do not agree with the proposed deletion of "the user's mood and expectations." This is common knowledge for any substance of abuse-legal or illicit. It plays a role in the experience and consequently, the abuse potential of a drug. I have a number of references which state this... I have added one below:

**Potential factors associated with prescription drug  
abuse and addiction**

From a pharmacological perspective, prescription drugs fit into the same drug classes as the usual illicit drugs.

Methylphenidate and amphetamines fit into the stimulant category, like cocaine and methamphetamine, while hydrocodone and oxycodone fit into the category of opioids, like heroin. Thus, the same general pharmacological factors associated with abuse and addiction to non-prescription drugs apply to prescription drug abuse. Key variables that influence the abuse and addiction potential of these agents are: dose, route of administration, co-administration with other drugs, context and expectations.

Compton WM, Volkow ND. Abuse of prescription drugs and the risk of addiction. Drug Alcohol Depend. 2006 Jun;83 Suppl 1:S4-7.

The deletion 'in regards to permanent damage' - I feel with this removed we are back to sounding like we don't know how the drug exerts its effects, when we do. Perhaps, we could write it slightly differently to include the word damage... so it is clear that we are talking about the damage that it causes to the brain. Health Canada recommends that you avoid using this substance because very little is known about the damage it may cause to the body, including the brain., ~~specifically with respect to permanent damage.~~

Thank you again, I know that it has been more than challenges incorporating all these comments.

Sincerely,  
Brittany



s.19(1)

Robin  
Marles/HC-SC  
/GC/CA  
2009-05-01  
05:29 PM  
To "Sue Lumsden" <[REDACTED]>  
cc Brittany Sauvé <brittany\_sauve@hc-sc.gc.ca>, "Cheryl Tremblay" <Cheryl\_Tremblay@hc-sc.gc.ca>, "Jocelyn Kula" <jocelyn\_kula@hc-sc.gc.ca>, "Mano Murty" <Mano\_Murty@hc-sc.gc.ca>, Robert\_Leitch@hc-sc.gc.ca, "Robin Marles" <robin\_marles@hc-sc.gc.ca>, "Valerie Hurry" <Valerie\_Hurry@hc-sc.gc.ca>  
Subj Re: IYH - Salvia divinorum - Draft Five [Link](#)  
ect

Dear Sue,

Thank you for your patience in dealing with all the changes we have been suggesting. It must seem like herding cats to get us all going in the same direction.

Most of these changes I agree with -- just one exception:

"The information regarding physical dependence or addiction or abuse to *S. divinorum* is unclear, although it appears the potential of such issues is low."

I think it is clear that *S. divinorum* is being abused, it is just that the potential for dependence or addiction is low.

Robin

"Sue Lumsden"  
[REDACTED]  
2009-05-01 10:20  
AM  
To "Valerie Hurry" <Valerie\_Hurry@hc-sc.gc.ca>, "Robin Marles" <robin\_marles@hc-sc.gc.ca>, <Robert\_Leitch@hc-sc.gc.ca>, "Mano Murty" <Mano\_Murty@hc-sc.gc.ca>, "Jocelyn Kula" <jocelyn\_kula@hc-sc.gc.ca>, "Cheryl Tremblay" <Cheryl\_Tremblay@hc-sc.gc.ca>, Brittany Sauvé <brittany\_sauve@hc-sc.gc.ca>  
cc [REDACTED]  
Subj IYH - Salvia divinorum - Draft Five  
ect

Good morning all,

I've attached Draft Five of the IYH on *Salvia divinorum*, which incorporates a series of comments received regarding Draft Four.

000287

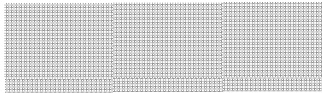
To make the proposed changes apparent, I've used yellow highlighter to mark proposed additions, and green highlighter to mark proposed deletions.

Some of the proposed changes are minor (although important), but two proposed changes appear to be more significant in terms of altering the content:

- 1) MHPD has proposed the addition of a sentence regarding the potential for physical dependence, addiction and abuse. This sentence is found at the end of the "Risks" section.
- 2) MHPD has proposed the deletion of a bullet in the "Risks" section describing why the effects of using the substance may differ from one use to the next. The proposed deletion is "the user's mood and expectations." The reason given for deleting the text is lack of evidence.

Thank you for the time you have spent to date reviewing drafts and providing comments. I think we are close to having a version to submit for formal approvals, and I look forward to seeing/hearing your comments on Draft Five.

Thanks,  
Sue



[attachment "IYH - Salvia divinorum - Draft Five.wpd" deleted by Robin Marles/HC-SC/GC/CA]

s.19(1)



"Sue Lumsden"

2009-05-01 10:20 AM

To "Valerie Hurry" <Valerie\_Hurry@hc-sc.gc.ca>, "Robin Marles" <robin\_marles@hc-sc.gc.ca>, <Robert\_Leitch@hc-sc.gc.ca>, "Mano Murty"

cc

bcc

Subject IYH - Salvia divinorum - Draft Five

Good morning all,

I've attached Draft Five of the IYH on *Salvia divinorum*, which incorporates a series of comments received regarding Draft Four.

To make the proposed changes apparent, I've used yellow highlighter to mark proposed additions, and green highlighter to mark proposed deletions.

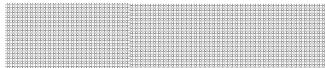
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Thank you for the time you have spent to date reviewing drafts and providing comments. I think we are close to having a version to submit for formal approvals, and I look forward to seeing/hearing your comments on Draft Five.

Thanks,  
Sue



IYH - Salvia divinorum - Draft Five.wpd

Draft File

For your review and approval.

Thats, chyl.

## ***Salvia divinorum***

### **The Issue**

Recently there have been reports suggesting that Canadian teens and young adults are using a substance called *Salvia divinorum* (*S. divinorum*) for its ability to produce hallucinations. Certain Web sites are also promoting the use of *S. divinorum* as a “legal” alternative to street drugs.

Street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastra, ska Maria pastora, ska pastora, diviner’s sage, magic mint, puff encens special, and salvia.

Health Canada recommends that you avoid using this substance because very little is known about the effect it has on the brain; ~~specifically with respect to permanent damage~~. There is also no way to predict how it will affect you with each use.

### **Background**

*Salvia divinorum* is a species of sage that belongs to the mint family. It is known to have psychotropic effects, which means it affects the mind and mental processes.

The leaves of this plant have been used traditionally by the Mazatec Indians in Mexico for many years. Traditional use involves chewing the leaves or using them to make a tea for medicinal purposes (e.g., to treat such conditions as headache or stomach upset), or to induce a “mystical” or hallucinogenic experience for spiritual purposes.

Products that claim to contain *S. divinorum* – or its main active ingredient, salvinorin A – are widely available on the Internet and are sold in various “head shops” and natural food stores. The products are sold in a number of formats, including seeds and plant cuttings for growing purposes. Fresh or dried leaves are intended to be chewed, swallowed or smoked. Liquid preparations are also available.

### **Risks of Using *Salvia divinorum***

*Salvia divinorum*’s effects, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations;
- dysphoria (feeling unwell, uneasy or unhappy);
- out-of-body experiences;
- uncontrollable laughter;
- loss of consciousness;
- short-term memory loss;
- lack of physical coordination;
- slurred speech and awkward sentence patterns.

There is no way to predict what effect this substance may have on you. In addition, the effects

may differ from one use to the next, depending on factors such as:

- the potency of the product;
- how much is used;
- the purity of the product (it may be mixed ~~adulterated~~ with other substances);
- how it is taken (e.g., chewed, swallowed or smoked);
- ~~the user's mood and expectations~~

A major concern about *S. divinorum* is the fact that there have only been ~~one~~ a few scientific studies about the way it affects the body and the brain. Scientists know which brain receptors are targeted by the active ingredient, salvinorin A, but very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or permanent damage;
- how it interacts with other substances, including other drugs, natural health products and alcohol.

The information regarding physical dependence or addiction (or abuse) of *S. divinorum* is unclear, although it appears the potential of such issues is low.

### Minimizing Your Risk

for this?

Health Canada recommends that you avoid using *S. divinorum*. Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs and other substances that distort reality. (See the "Need More Info?" section below for links to resources that can help you with this.)

Also, remember that just because a drug is plant-based or "natural," it does not mean it is safe. Under certain conditions of use, *Salvia divinorum* meets the definition of a "natural health product" (NHP) under Health Canada's *Natural Health Products Regulations*. However, no NHPs containing this substance have been approved for sale in Canada. This means that products claiming to contain *S. divinorum* have not been reviewed by Health Canada for safety, efficacy or quality. As such, they may be counterfeit or contain other ingredients that pose risks to health, and consumers should heed the "buyer beware" principle.

Natural health products that have been reviewed and approved by Health Canada are labelled with one of the following:

- a Natural Product Number (NPN); or
- a Drug Identification Number - Homeopathic Medicine (DIN-HM).

### The Legal Status of *Salvia divinorum*

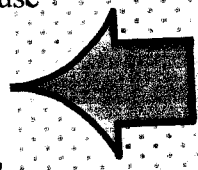
#### In Canada

Neither *S. divinorum* nor salvinorin A is currently regulated under the *Controlled Drugs and Substances Act* (CDSA). When assessing whether to add a substance to one of the Schedules to the CDSA, Health Canada considers the following factors:

- international requirements and trends in controlling the substance;

add. the liability potential for abuse

- similarity to other substances already regulated under the CDSA;
- whether there may be legitimate uses of the substance (e.g., potential health benefits, use in manufacturing, etc.);
- the abuse liability of the substance and the potential for addiction <sup>associated</sup> with the substance;
- the extent of actual abuse of the substance in Canada and elsewhere;
- overall risk to public health and safety posed by the substance.



In the case of *S. divinorum*, there is simply not enough information available to determine whether regulation under the CDSA is the best option to manage the potential risks. Questions about the use of *S. divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey, and these survey results will help fill some of the information gaps. The data, however, will not likely be available until 2010.

### In Other Countries

Several countries (e.g., Australia, Belgium, Denmark, Sweden, Italy, Spain, Finland and South Korea) have placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on their sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution (e.g., no sales to anyone under the age of 18).

### **Health Canada's Role**

Health Canada continues to collect and consider information regarding *S. divinorum* and continues to consult with key stakeholders, including health officials in other countries, and law enforcement officials here at home. This will assist in determining the most appropriate strategy to manage the risks associated with the use of *S. divinorum*.

### **Need More Info?**

For information about the Government of Canada's Anti-Drug Strategy, go to:

<http://www.nationalantidrugstrategy.gc.ca/>. The Prevention section on this site has a number of helpful resources for parents, including "Tips on Talking to Your Teenager" and "What to Do if Your Teen is Using Drugs."

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The Ontario Student Drug Use and Health Survey, at: <http://www.camh.net/Research/osdus.html>

**Additional Resources:**

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**s.19(1)**

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**Writer:** Sue Lumsden [REDACTED]

**Version/date:** Draft Five, May 1, 2009. Incorporates comments forwarded by Cheryl Tremblay, Brittany Sauvé, Robin Marles, Valerie Hurry and Robert Leitch. Text added is marked with yellow highlighter, while text deleted is highlighted in green.

**Contacts:** HECSB: Jocelyn Kula, Cheryl Tremblay, Brittany Sauvé  
HPFB-NHPD: Valerie Hurry, Robin Marles  
HPFB-MHPD: Scott Jordan (Draft Two only), Robert Leitch, Mano Murty



"Sue Lumsden"

2009-04-21 04:02 PM

To "Valerie Hurry" <Valerie\_Hurry@hc-sc.gc.ca>, "Robin Marles" <robin\_marles@hc-sc.gc.ca>, "Jocelyn Kula" <jocelyn\_kula@hc-sc.gc.ca>, "Cheryl Tremblay"

cc

bcc

Subject IYH - Salvia divinorum - Draft Four

Good afternoon,

Thank you everyone for your thoughtful comments on Draft Three of the IYH on Salvia divinorum. I've attached Draft Four for review.

Please note that in the section on "Risks of Using Salvia divinorum," the bullet referring to physical dependence and addiction has been removed.

I removed the bullet for the following reasons:

- Robin Marles pointed out that it is not true to state that very little is known about whether or not use of S. divinorum causes physical dependence or addiction. There is information about the brain receptors it acts on, and since use of the substance causes dysphoria, the likelihood of the substance being addictive is relatively low. There is apparently some evidence that use of S. divinorum may have effects on addictions to other substances, but this would be very complicated to explain.
- Brittany Sauvé agreed that it would not be credible to state that little is known about whether or not use of S. divinorum causes physical dependence or addiction. She further stated that, "The information regarding physical dependence or addiction is unclear, although it appears the potential is low."

It would seem that if we want to reference addiction as a risk, we would have to qualify that based on what is known, the potential for physical dependence and addiction is low, although it cannot be ruled out entirely. This may not be a message that HC wants to convey, so for now, I've left out any reference to the potential for addiction. Both R. Marles and B. Sauvé have agreed with this approach, although they would be open to other suggestions.

I'm interested in feedback and perhaps suggested wording if someone thinks that the IYH should contain messages about the potential for addiction. If a message about addiction is going to be put into the article, it would probably fit in best as a separate sentence at the very end of the "Risks of Using Salvia divinorum" section.

When you've had a chance to review this draft, please send back comments or a thumbs up to put this version into the formal approvals process. I am happy to work with you via e-mail or telephone, whichever you prefer.

Thank you very much.  
Sue



IYH - Salvia divinorum - Draft Four.wpd



## ***Salvia divinorum* - Draft Four**

### **The Issue**

Recently there have been reports suggesting that Canadian teens and young adults are using a substance called *Salvia divinorum* (*S. divinorum*) for its ability to produce hallucinations. Certain Web sites are also promoting the use of *S. divinorum* as a “legal” alternative to street drugs.

Street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastra, ska Maria pastora, ska pastora, diviner’s sage, magic mint, puff encens special, and salvia.

Health Canada recommends that you avoid using this substance because very little is known about the effect it has on the brain, specifically with respect to permanent damage. There is also no way to predict how it will affect you with each use.

### **Background**

*Salvia divinorum* is a species of sage that belongs to the mint family. It is known to have psychotropic effects, which means it affects the mind and mental processes.

The leaves of this plant have been used traditionally by the Mazatec Indians in Mexico for many years. Traditional use involves chewing the leaves or using them to make a tea for medicinal purposes (e.g., to treat such conditions as headache or stomach upset), or to induce a “mystical” or hallucinogenic experience for spiritual purposes.

Products that claim to contain *S. divinorum* – or its main active ingredient, salvinorin A – are widely available on the Internet and are sold in various “head shops” and natural food stores. The products are sold in a number of formats, including seeds and plant cuttings for growing purposes. Fresh or dried leaves are intended to be chewed, swallowed or smoked. Liquid preparations are also available.

### **Risks of Using *Salvia divinorum***

*Salvia divinorum*’s effects, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations;
- dysphoria (feeling unwell, uneasy or unhappy);
- out-of-body experiences;
- uncontrollable laughter;
- loss of consciousness;
- short-term memory loss;
- lack of physical coordination;
- slurred speech.

There is no way to predict what effect this substance may have on you. In addition, the effects

may differ from one use to the next, depending on factors such as:

- the potency of the product;
- how much is used;
- the purity of the product (it may be adulterated with other substances)
- how it is taken (e.g., chewed, swallowed or smoked);
- the user's mood and expectations.

A major concern about *S. divinorum* is the fact that there have been only a few scientific studies about the way it affects the body and the brain. Scientists know which brain receptors are targeted by the active ingredient, salvinorin A, but very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or permanent damage;
- how it interacts with other substances, including other drugs and alcohol.

### **Minimizing Your Risk**

Health Canada recommends that you avoid using *S. divinorum*. Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs and other substances that distort reality. (See the "Need More Info?" section below for links to resources that can help you with this.)

Also, remember that just because a drug is plant-based or "natural," it does not mean it is safe. Under certain conditions of use, *Salvia divinorum* meets the definition of a "natural health product" (NHP) under Health Canada's *Natural Health Products Regulations*. However, no NHPs containing this substance have been approved for sale in Canada. This means that products claiming to contain *S. divinorum* have not been reviewed by Health Canada for safety, efficacy or quality. As such, they may be counterfeit or contain other ingredients that pose risks to health, and consumers should heed the "buyer beware" principle.

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### **The Legal Status of *Salvia divinorum***

#### In Canada

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Health Canada recommends that you avoid using *S. divinorum*. Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs and other substances that distort reality. (See the "Need More Info?" section below for links to resources that can help you with this.)

NOTE



Also, remember that just because a drug is plant-based or "natural," it does not mean it is safe. Under certain conditions of use, *Salvia divinorum* meets the definition of a "natural health product" (NHP) under Health Canada's *Natural Health Products Regulations*. However, no NHPs containing this substance have been approved for sale in Canada. This means that products claiming to contain *S. divinorum* have not been reviewed by Health Canada for safety, efficacy or quality. As such, they may be counterfeit or contain other ingredients that pose risks to health, and consumers should heed the "buyer beware" principle.

Jocelyn, It looks like all of our comments were included with the exception of removing the word "counterfeit" as Sue mentioned that this term has been used in previous LYH articles and wanted to give NHPD some of their ~~inclusions~~

are you ok with that?  
 As per Sue's email they also removed like we: physical dependence / addiction under risks section.  
 Thanks, asked Cheryl Sue to consult with Britney is fine with a note.

whether there may be legitimate uses of the substance (e.g., potential health benefits, use in manufacturing, etc.);

- the abuse liability of the substance and the potential for addiction;
- the extent of actual abuse of the substance in Canada and elsewhere;
- overall risk to public health and safety posed by the substance.

In the case of *S. divinorum*, there is simply not enough information available to determine whether regulation under the CDSA is the best option to manage the potential risks. Questions about the use of *S. divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey, and these survey results will help fill some of the information gaps. The data, however, will not likely be available until 2010.

#### In Other Countries

Several countries (e.g., Australia, Belgium, Denmark, Sweden, Italy, Spain, Finland and South Korea) have placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on their sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution (e.g., no sales to anyone under the age of 18).

#### **Health Canada's Role**

Health Canada continues to collect and consider information regarding *S. divinorum* and continues to consult with key stakeholders, including health officials in other countries, and law enforcement officials here at home. This will assist in determining the most appropriate strategy to manage the risks associated with the use of *S. divinorum*.

#### **Need More Info?**

For information about the Government of Canada's Anti-Drug Strategy, go to: <http://www.nationalantidrugstrategy.gc.ca/>. The Prevention section on this site has a number of helpful resources for parents, including "Tips on Talking to Your Teenager" and "What to Do if Your Teen is Using Drugs."

Information on natural health products and the *Natural Health Products Regulations* can be found at: <http://www.hc-sc.gc.ca/dhp-mpps/prodnatur/index-eng.php>

For more on the surveys that are collecting information about *Salvia divinorum* use in Canada, see:

The 2008-2009 Youth Smoking Survey, at:

[http://www.yss.uwaterloo.ca/ysss/site\\_app/controller/index.cfm](http://www.yss.uwaterloo.ca/ysss/site_app/controller/index.cfm) and

The Ontario Student Drug Use and Health Survey, at: <http://www.camh.net/Research/osdus.html>

Additional Resources:

U.S. Drug Enforcement Administration: Drugs and Chemicals of Concern: *Salvia divinorum* and Salvinorin A at: [http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)

U.S. Department of Health & Human Services, National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006 at:  
<http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf>

For additional articles on health and safety issues go to the *It's Your Health* Web section at:  
<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/index-eng.php>

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

Original:

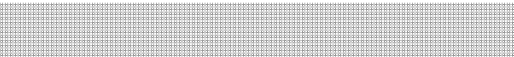
©Her Majesty the Queen in Right of Canada, represented by the Minister of Health, 2009

Catalogue#

ISBN#

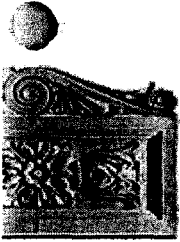
----- 0 -----

**s.19(1)**

Writer: Sue Lumsden 

Version/date: Draft Four, April 20, 2009. Incorporates comments forwarded by Cheryl Tremblay, Robin Marles and Mano Murty, as well as input received during conversations with Robin Marles and Brittany Sauvé.

Contacts: HECSB: Jocelyn Kula, Cheryl Tremblay, Brittany Sauvé  
HPFB-NHPD: Valerie Hurry, Robin Marles  
HPFB-MHPD: Scott Jordan (Draft Two only), Robert Leitch, Mano Murty



Cheryl  
Tremblay/HC-SC/GC/CA  
2009-04-17 08:45 AM

To mcreary@mcs.bc.ca  
cc  
bcc

Subject 2008 BC Adolescent Health Survey

Good morning,

I was just reading through the highlights from the 2008 BC Adolescent Health Survey and would like to if you have any more information with respect to the following key findings, particularity with respect to whether you have a break down on the increase of what specific hallucinogens are being abused.

- Alcohol and marijuana use declined over the past decade, as did the use of some drugs such as cocaine, amphetamines and mushrooms. However, the use of other drugs, including hallucinogens, rose. (Page 7)
- However, there was a rise in the use of hallucinogens, prescription pills without a doctor's consent, steroids and a small rise in heroin use. (Page 33)
- Ever Used Other Drugs Chart - Hallucinogens rose from 7% in 2003 to 9% in 2008 (Page 36)

Thank you,

Cheryl Tremblay  
Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Drug Strategy and Controlled Substances Directorate  
Health Canada  
Tel: (613) 954-6527  
Fax: (613) 946-4224



Brittany  
Sauvé/HC-SC/GC/CA  
2009-04-15 10:22 AM

To Cheryl Tremblay/HC-SC/GC/CA@HWC  
cc  
bcc  
Subject Re: Fw: It's Your Health - Salvia divinorum - Draft Three

Hi Cheryl,

I was just having a look at everyone's comments. I am okay with the comments made by Mano's group. I think that there may be a simplified way to say "specifically with regards to permanent damage..." but that is for plain language I guess.

As for NHPD, I am okay with most...I trust that what they have added can be found in a reference somewhere. I have a couple of comments on the text below.

A major concern about *S. divinorum* is the fact that there have been ~~only a~~ (seems unnecessary- if to keep... I would say, there have only been a few) few scientific studies about the way it affects the body and the brain. For example, it is known which brain receptors are targeted by the active ingredient, Ssalvinorin A, but very little is known about the following:

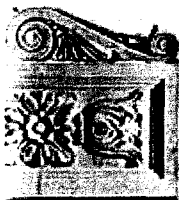
- ~~how it affects the brain overall, what are the~~ <sup>what are there</sup> are any long-term effects on the brain and if it causes permanent damage;
- ~~what effects it has on~~ whether or not it causes physical dependence and/or addiction;
- how it interacts with other substances (including other drugs and alcohol).

Other than that I am satisfied with the text....

If you have any questions about my comments just give me a call 948-9405.

THanks,  
Brittany

Cheryl Tremblay/HC-SC/GC/CA



Cheryl  
Tremblay/HC-SC/GC/CA  
2009-04-15 08:50 AM

To Brittany Sauvé/HC-SC/GC/CA@HWC  
cc  
Subject Fw: It's Your Health - Salvia divinorum - Draft Three

Are you okay with the changes that NHPD is proposing to the Risks section? (see below)

Thanks,  
Cheryl

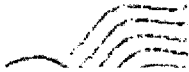
----- Forwarded by Cheryl Tremblay/HC-SC/GC/CA on 2009-04-15 08:49 AM -----



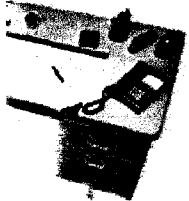
Valerie Hurry/HC-SC/GC/CA  
2009-04-14 03:42 PM

To Cheryl Tremblay/HC-SC/GC/CA@HWC  
cc  
Subject Fw: It's Your Health - Salvia divinorum - Draft Three

s.19(1)



----- Forwarded by Valerie Hurry/HC-SC/GC/CA on 2009-04-14 03:42 PM -----



**Robin Marles/HC-SC/GC/CA**

2009-04-14 03:36 PM

To "Sue Lumsden" <[redacted]>

cc Valerie Hurry/HC-SC/GC/CA@HWC, Stephanie Lessard/HC-SC/GC/CA@HWC

Subject Fw: It's Your Health - Salvia divinorum - Draft Three

Here are the further comments from NHPD, in blue and red.

Robin



IYH - Salvia divinorum - Draft Three\_NHPD.wpd

----- Forwarded by Robin Marles/HC-SC/GC/CA on 2009-04-14 03:34 PM -----



**Valerie Hurry/HC-SC/GC/CA**

2009-04-14 01:20 PM

To Robin Marles/HC-SC/GC/CA@HWC

cc Stephanie Lessard/HC-SC/GC/CA@HWC

Subject Fw: It's Your Health - Salvia divinorum - Draft Three

Hi Robin,

In case you are interested in draft 3...

There doesn't appear to be agreement with moving the street names to the first paragraph of the Background section. I suggested a more specific description of the effects on speech (i.e. slurred speech) as mentioned in this DEA document:

[http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm).

Please send your comments to Cheryl Tremblay.

[attachment "IYH - Salvia divinorum - Draft Three\_NHPD.wpd" deleted by Robin Marles/HC-SC/GC/CA]

Thanks.

Valerie

----- Forwarded by Valerie Hurry/HC-SC/GC/CA on 2009-04-14 01:06 PM -----



**"Sue Lumsden"**

2009-04-14 10:08 AM

To "Valerie Hurry" <Valerie\_Hurry@hc-sc.gc.ca>, "Robin Marles" <robin\_marles@hc-sc.gc.ca>, Brittany Sauvé <brittany\_sauve@hc-sc.gc.ca>, "Jocelyn Kula" <jocelyn\_kula@hc-sc.gc.ca>, "Cheryl Tremblay" <Cheryl\_Tremblay@hc-sc.gc.ca>



***Salvia divinorum* – Draft Three – TDD Comments (April 14, 2009)**

**The Issue**

Recently there have been reports suggesting that Canadian teens and young adults are using a substance called *Salvia divinorum* (*S. divinorum*) specifically for its ability to produce hallucinations. Certain Web sites are also promoting the use of *S. divinorum* as a “legal” alternative to street drugs.

Health Canada recommends that you avoid using this substance because very little is known about the effect it has on the brain and there is no way to predict how it will affect you.

**Background**

*Salva divinorum* is a species of sage that belongs to the mint family. It is known to have psychotropic effects, which means it affects the mind and mental processes.

The leaves of this plant have been used traditionally by the Mazatec Indians in Mexico for many years. Traditional use involves chewing the leaves or using them to make a tea for medicinal purposes (e.g., to treat such conditions as headache or stomach upset), or to induce a “mystical” or hallucinogenic experience for spiritual purposes.

Products that claim to contain *S. divinorum* – or its main active ingredient, salvinorin A – are widely available on the Internet and are sold in various “head shops” and natural food stores. The products are sold in a number of formats, including seeds and plant cuttings for growing purposes. Fresh or dried leaves are intended to be chewed, swallowed or smoked. Liquid preparations are also available.

Street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastra, ska Maria pastora, ska pastora, diviner’s sage, magic mint, puff encens special, and salvia.

**Risks of Using *Salvia divinorum***

*Saliva divinorum*’s effects, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations;
- out-of-body experiences;
- loss of consciousness;
- short-term memory loss;
- uncontrollable laughter;
- impaired ability to speak.

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product;
- how much is used;
- how it is taken (e.g., ingested or smoked);
- the user's mood and expectations.

A major concern about *S. divinorum* is the fact that there have only been a few scientific studies about the way it affects the body and the brain. For example, it is known which brain receptors are targeted by the active ingredient, salvinorin A, but very little is known about the following:

- whether there are any long-term effects on the brain and if it causes permanent damage;
- whether or not it causes physical dependence or addiction;
- how it interacts with other substances (including other drugs and alcohol).

### Minimizing Your Risk

Health Canada recommends that you avoid using *S. divinorum*. Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs and other substances that distort reality. (See the "Need More Info?" section below for links to resources that can help you with this.)

Also, remember that just because a drug is plant-based or "natural," it does not mean it is safe. Under certain conditions of use, *Salvia divinorum* meets the definition of a "natural health product" (NHP) under Health Canada's *Natural Health Products Regulations*, however, no NHPs containing this substance have been approved for sale in Canada. This means that products containing *S. divinorum* have not been reviewed by Health Canada for safety, efficacy or quality. As such, they may contain other ingredients that pose risks to health, or may not contain *S. divinorum* or salvinorin A at all. Consumers should heed the "buyer beware" principle.

Natural health products that have been reviewed and approved by Health Canada will be labelled with one of the following:

- a Natural Product Number (NPN); or
- a Drug Identification Number - Homeopathic Medicine (DIN-HM).

### The Legal Status of *Salvia divinorum*

#### In Canada

**Comment:** Prefer over "have been only a few" proposed by NHPD.

**Deleted:** so

**Comment:** We're fine with NHPD addition, just changed capital "S" in salvinorin to lowercase.

**Comment:** Prefer

**Deleted:** how it a

**Comment:** Prefer

**Deleted:** may

**Deleted:** but

**Deleted:** that

**Deleted:** be counterfeit or

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Neither *S. divinorum* nor salvinorin A is currently regulated under the *Controlled Drugs and Substances Act* (CDSA). When assessing whether to add a substance to one of the Schedules to the CDSA, Health Canada considers the following factors:

- international requirements and trends in controlling the substance;
- similarity to other substances already regulated under the CDSA;
- whether there may be legitimate uses of the substance (e.g., potential health benefits, use in manufacturing, etc.);
- the abuse liability of the substance and the potential for addiction;
- the extent of actual abuse of the substance in Canada and elsewhere;
- overall risk to public health and safety posed by the substance.

In the case of *S. divinorum*, there is simply not enough information available to determine whether regulation under the CDSA is the best option to manage the potential risks associated with its use. Questions about the use of *S. divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey, and these survey results will help fill some of the information gaps. Data will not, however, likely be available until 2010.

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#### In Other Countries

Several countries (e.g., Australia, Belgium, Denmark, Sweden, Italy, Spain, Finland and South Korea) have placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on their sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution (e.g., no sales to anyone under the age of 18).

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#### **Health Canada's Role**

Health Canada continues to collect and consider information regarding *S. divinorum* and continues to consult with key stakeholders, including health officials in other countries, and law enforcement officials here at home. This will assist in determining the most appropriate strategy to manage the risks associated with the use of *S. divinorum*.

#### **Need More Info?**

For information about the Government of Canada's National Anti-Drug Strategy, go to: <http://www.nationalantidrugstrategy.gc.ca/>. The Prevention section on this site has a number of helpful resources for parents, including "Tips on Talking to Your Teenager" and "What to Do if Your Teen is Using Drugs."

Information on natural health products and the *Natural Health Products Regulations* can be found at: <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php>

Deleted: For information about Health Canada's Drug Strategy and Controlled Substances Directorate, go to: <http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hecs-dgsec/dscsp-psasc/index-eng.php>  
Deleted: Also, see  
Deleted: the Prevention section on  
Deleted: Web site at  
Deleted: his

For more on the surveys that are collecting information about *Salvia divinorum* use in Canada, see:

The 2008-2009 Youth Smoking Survey, at:  
[http://www.yss.uwaterloo.ca/vsssite\\_app/controller/index.cfm](http://www.yss.uwaterloo.ca/vsssite_app/controller/index.cfm) and

The Ontario Student Drug Use and Health Survey, at: <http://www.camh.net/Research/osdus.html>

**Additional Resources:**

U.S. Drug Enforcement Administration: Drugs and Chemicals of Concern: *Salvia divinorum* and Salvinorin A at: [http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)

U.S. Department of Health & Human Services, National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006 at:  
<http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf>

For additional articles on health and safety issues go to the *It's Your Health* Web section at:

<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/index-eng.php>

<http://www.hc-sc.gc.ca/english/iyh/index.html>

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

Original:

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Catalogue#

ISBN#

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**s.19(1)**

Writer: Sue Lumsden [REDACTED]

Version/date: Draft Three, April 14, 2009. Incorporates comments forwarded by Cheryl Tremblay and Robin Marles, as well as input from a conversation with Brittany Sauvé.

Contacts: HECSB: Jocelyn Kula, Cheryl Tremblay, Brittany Sauvé  
HPFB-NHPD: Valerie Hurry, Robin Marles  
HPFB-MHPD: Scott Jordan (Draft Two only), Robert Leitch, Mano Murty

Jocelyn - please be attached

D.

Diane Allan/HC-SC/GC/CA  
2009-06-08 09:27 AM

To "Jennifer Nicholson" <jennifer\_nicholson@hc-sc.gc.ca>  
cc  
bcc

Subject Fw: Fw: For your approval - It's Your Health - Salvia D

Comments discussed with Diane  
June 8/09 - no changes  
required but note for file  
JKula

Please print.  
Ronald Denault

----- Original Message -----

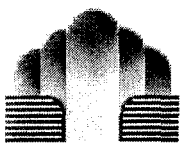
From: Ronald Denault  
Sent: 2009-06-08 08:27 AM EDT  
To: Jocelyn Kula  
Cc: Diane Allan; Carmen Berube  
Subject: Re: Fw: For your approval - It's Your Health - Salvia D

Hi Diane

For your approval, I have no concern to approve this note

Ronald

Jocelyn Kula/HC-SC/GC/CA



Jocelyn Kula/HC-SC/GC/CA  
08/06/2009 08:09 AM

To Ronald Denault/HC-SC/GC/CA@HWC  
cc "Diane Allan" <diane\_allan@hc-sc.gc.ca>  
Subject Re: Fw: For your approval - It's Your Health - Salvia D

Hi Ronald,

I was just about to ask you if this had crossed your desk because I was talking with Lisa Mackay (IYH coordinator for HC) about another IYH document and had asked her where the salvia document was at. In any case, there is no need for me to verify anything, Cheryl Tremblay and I were intimately involved in all stages of the document during development and I am very comfortable with its content, as is Suzanne Desjardin and many different parts of HPFB. If you or Diane can indicate your approval, this should move quite quickly through the approvals process until at least ADM level, where I suppose there may be a need for discussion.

Diane, since you are here now, is there a need to make Paul's office aware that this is coming? In theory, Paul knows because he signed off on the concept paper way back when, but I have just realized that technically, we (as in CSTD) have not communicated with him about this specifically? I will ask Stephanie and see what advice she has.

Jocelyn

Jocelyn Kula  
Manager/ Gestionnaire  
Policy and Regulatory Affairs Division/ Division des politiques et affaires réglementaires

Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0125 Fax: (613) 946-4224  
Ronald Denault/HC-SC/GC/CA



Ronald  
Denault/HC-SC/GC/CA  
2009-06-08 07:50 AM

To Jocelyn Kula/HC-SC/GC/CA  
cc "Diane Allan" <diane\_allan@hc-sc.gc.ca>  
Subject Fw: For your approval - It's Your Health - Salvia D

Hi jocelyn  
I missed this email a while ago  
Please check from point of view if everything is correct  
Thank you  
Ronald  
Bronwyn Cline

----- Original Message -----

**From:** Bronwyn Cline  
**Sent:** 2009-06-07 10:48 PM EDT  
**To:** Ronald Denault  
**Cc:** Carmen Berube; Christine Roush  
**Subject:** Re: For your approval - It's Your Health - Salvia D

Hello Ronald,

Were you able to review the It's Your Health article below? Or should it go to Diane Allen for approval now?

Thanks,

Bronwyn Cline  
Communications Officer | Agente des communications

613-941-2511 | facsimile / télécopieur 613-948-8085  
bronwyn\_cline@hc-sc.gc.ca  
Health Canada | 269 Laurier Ave Ottawa ON K1A 0K9  
Santé Canada | 269 ave Laurier Ottawa ON K1A 0K9  
Government of Canada | Gouvernement du Canada  
Bronwyn Cline/HC-SC/GC/CA



Bronwyn  
Cline/HC-SC/GC/CA  
2009-05-27 11:15 AM

To Ronald Denault/HC-SC/GC/CA  
cc Carmen Berube/HC-SC/GC/CA@HWC, Christine  
Roush/HC-SC/GC/CA@HWC  
Subject For your approval - It's Your Health - Salvia D

Hello Ronald,

Could I please get your approval of this for Tuesday, June 2? We're aiming to have this completely approved by June 12.



Apps Slip DG&ADM HECS Salvia May2009.wpd IYH - Salvia divinatorum - Draft Seven (May 27, 2009).wpd

Thank you,

Bronwyn Cline  
Communications Officer | Agente des communications

613-941-2511 | facsimile / télécopieur 613-948-8085  
bronwyn\_cline@hc-sc.gc.ca  
Health Canada | 269 Laurier Ave Ottawa ON K1A 0K9  
Santé Canada | 269 ave Laurier Ottawa ON K1A 0K9  
Government of Canada | Gouvernement du Canada

des jardins  
group consulted

## Salvia divinorum

### The Issue

Recently there have been reports suggesting that Canadian teens and young adults are using a substance called *Salvia divinorum* (*S. divinorum*) for its ability to produce hallucinations. Certain Web sites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs.

Street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastra, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff encens special, and salvia.

Health Canada recommends that you avoid using this substance because very little is known about the damage it may cause to the body, including the brain. There is also no way to predict how it will affect you with each use.

### Background

*Salvia divinorum* is a species of sage that belongs to the mint family. It is known to have psychotropic effects, which means it affects the mind and mental processes.

The leaves of this plant have been used traditionally by the Mazatec Indians in Mexico for many years. Traditional use involves chewing the leaves or using them to make a tea for medicinal purposes (e.g., to treat such conditions as headache or stomach upset), or to induce a "mystical" or hallucinogenic experience for spiritual purposes.

Products that claim to contain *S. divinorum* – or its main active ingredient, salvinorin A – are widely available on the Internet and are sold in various "head shops" and natural food stores. The products are sold in a number of formats, including seeds and plant cuttings for growing purposes. Fresh or dried leaves are intended to be chewed, swallowed or smoked. Liquid preparations are also available.

### Risks of Using *Salvia divinorum*

*Salvia divinorum*'s effects, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations;
- dysphoria (feeling unwell, uneasy or unhappy);
- out-of-body experiences;
- uncontrollable laughter;
- loss of consciousness;
- short-term memory loss;
- lack of physical coordination;
- slurred speech and awkward sentence patterns.

There is no way to predict what effect this substance may have on you. In addition, the effects

is this true?

see paragraph

on page

define - what is this

Is this true? see next page

parag



may differ from one use to the next, depending on factors such as:

- the potency of the product;
- how much is used;
- the purity of the product (it may be mixed with other substances);
- how it is taken (e.g., chewed, swallowed or smoked);
- the user's mood and expectations.

A major concern about *S. divinorum* is the fact that there have only been a few scientific studies about the way it affects the body and the brain. Scientists know which brain receptors are targeted by the active ingredient, salvinorin A, but very little is known about the following:

A

- how it affects the brain overall, including whether there are any long-term effects or permanent damage;
- how it interacts with other substances, including other drugs, natural health products and alcohol.

The information regarding physical dependence or addiction to *S. divinorum* is unclear, although it appears the potential for either is low.

### Minimizing Your Risk

Health Canada recommends that you avoid using *S. divinorum*. Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs and other substances that distort reality. (See the "Need More Info?" section below for links to resources that can help you with this.)

Also, remember that just because a drug is plant-based or "natural," it does not mean it is safe. Under certain conditions of use, *Salvia divinorum* meets the definition of a "natural health product" (NHP) under Health Canada's *Natural Health Products Regulations*. However, no NHPs containing this substance have been approved for sale in Canada. This means that products claiming to contain *S. divinorum* have not been reviewed by Health Canada for safety, efficacy or quality. As such, they may be counterfeit or contain other ingredients that pose risks to health, and consumers should heed the "buyer beware" principle.

this is confusing please clarify

↳ there are NHPs in the market that have not been approved  
Natural health products that have been reviewed and approved by Health Canada are labelled with one of the following:

- a Natural Product Number (NPN); or
- a Drug Identification Number - Homeopathic Medicine (DIN-HM).

been approved

### The Legal Status of *Salvia divinorum*

#### In Canada

Neither *S. divinorum* nor salvinorin A is currently regulated under the *Controlled Drugs and Substances Act* (CDSA). When assessing whether to add a substance to one of the Schedules to the CDSA, Health Canada considers the following factors:

- international requirements and trends in controlling the substance;

- similarity to other substances already regulated under the CDSA;
- whether there may be legitimate uses of the substance (e.g., potential health benefits, use in manufacturing, etc.);
- the potential for abuse and the risk of addiction associated with the substance;
- the extent of actual abuse of the substance in Canada and elsewhere;
- overall risk to public health and safety posed by the substance.

In the case of *S. divinorum*, there is simply not enough information available to determine whether regulation under the CDSA is the best option to manage the potential risks. Questions about the use of *S. divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey, and these survey results will help fill some of the information gaps. The data, however, will not likely be available until 2010.

↳ data available survey, analysis to 2010

#### In Other Countries

Several countries (e.g., Australia, Belgium, Denmark, Sweden, Italy, Spain, Finland and South Korea) have placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on their sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution (e.g., no sales to anyone under the age of 18).

#### **Health Canada's Role**

Health Canada continues to collect and consider information regarding *S. divinorum* and continues to consult with key stakeholders, including health officials in other countries, and law enforcement officials here at home. This will assist in determining the most appropriate strategy to manage the risks associated with the use of *S. divinorum*.

#### **Need More Info?**

For information about the Government of Canada's Anti-Drug Strategy, go to: <http://www.nationalantidrugstrategy.gc.ca/>. The Prevention section on this site has a number of helpful resources for parents, including "Tips on Talking to Your Teenager" and "What to Do if Your Teen is Using Drugs."

Information on natural health products and the *Natural Health Products Regulations* can be found at: <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php>

For more on the surveys that are collecting information about *Salvia divinorum* use in Canada, see:

The 2008-2009 Youth Smoking Survey, at:

[http://www.yss.uwaterloo.ca/ysss/site\\_app/controller/index.cfm](http://www.yss.uwaterloo.ca/ysss/site_app/controller/index.cfm) and

The Canadian Alcohol and Drug Use Monitoring Survey, at:

<http://www.hc-sc.gc.ca/hl-vs/drug-drogues/cadums-escad-eng.php>

Additional Resources:

U.S. Drug Enforcement Administration: Drugs and Chemicals of Concern: *Salvia divinorum* and Salvinorin A at: [http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)

U.S. Department of Health & Human Services, National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006 at:  
<http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf>

For additional articles on health and safety issues go to the *It's Your Health* Web section at:  
<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/index-eng.php>

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

Original:

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Catalogue#

ISBN#


----- 0 -----

Writer: Sue Lumsden  **s.19(1)**

Version/date: Draft Seven. May 27, 2009. Removes highlighter marking changes in Draft Six, which have been agreed to by the Program Contacts. Replaces reference (and link) to the Ontario Student Drug Use and Health Survey with a reference (and link) to the (national) Canadian Alcohol and Drug Use Monitoring Survey.

Contacts: HECSB: Jocelyn Kula, Cheryl Tremblay, Brittany Sauvé  
HPFB-NHPD: Valerie Hurry, Robin Marles  
HPFB-MHPD: Scott Jordan (Draft Two only), Robert Leitch, Mano Murty

Christine  
Roush/HC-SC/GC/CA  
2009-06-10 10:21 AM

To Cheryl Tremblay/HC-SC/GC/CA@HWC  
cc Bronwyn Cline/HC-SC/GC/CA@HWC  
bcc  
Subject Re: Media Lines for Salvia Divinorum 

Hi Cheryl,

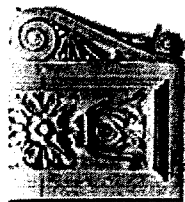
The lines are attached below and they went through all of program approvals, but were put on hold before they got to our DG, Comms and above for approval, as they were not deemed a priority at the time. Please let me know if you would like us to continue with the approval of these lines. I am aware that an It's Your Health article on Salvia will be posted soon on HC's Web site so perhaps it is a good time to finalize these lines now.



Salvia ML v.7 April 2009.doc

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
Health Canada/Santé Canada  
Tel/Tél : (613) 954-0712/Cell: (613) 219-7194  
Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca

Cheryl Tremblay/HC-SC/GC/CA



Cheryl  
Tremblay/HC-SC/GC/CA  
2009-06-10 09:42 AM

To Christine Roush/HC-SC/GC/CA@HWC  
cc  
Subject Media Lines for Salvia Divinorum

Hi Christine,

I work with Jocelyn Kula in the Policy and Regulatory Affairs Division at CSTD and was advised that you have taken over the Salvia Divinorum file. I was just wondering if there are any updates with respect to the status of their progress through the approval process?

Thank you,

Cheryl Tremblay  
Policy and Regulatory Affairs Division / Division des politiques et affaires réglementaires  
Office of Controlled Substances / Bureau des substances contrôlées  
Controlled Substances and Tobacco Directorate / Direction des substances contrôlées et de la lutte au  
tabagisme  
Healthy Environments and Consumer Safety Branch / Direction générale de la santé environnementale et  
de la sécurité consommateurs  
Health Canada / Santé Canada

Tel: (613) 954-6527 Fax: (613) 946-4224

DRAFT  
April 7, 2009

## Media Lines Regulatory Control of *Salvia Divinorum*

### Issue

Since 2006, Health Canada has <sup>noted a steady</sup> ~~observed a steady increase in the amount~~ of media interest regarding the availability of *Salvia divinorum* on the Canadian market. Health Canada has also received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum*, particularly given reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults <sup>specifically</sup> ~~specifically~~ for its <sup>ability to</sup> ~~hallucinogenic~~ properties.

### Key Messages:

- Health Canada continues to collect <sup>and consider</sup> relevant information about *Salvia divinorum* and its active ingredient, Salvinorin A, from both national and international sources in order to determine <sup>the most appropriate strategy</sup> ~~what, if any, regulatory controls are needed.~~
- While the media have reported that use of *Salvia divinorum* is on the rise in certain parts of the country, Health Canada does not currently have statistics on its use across the Canadian population. <sup>to manage the risks associated with its use.</sup>
- Health Canada is taking steps to address this lack of data. Questions regarding the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. A general open-ended question about the use of other substances was also been included in the 2008 Canadian Alcohol and Drug Use Monitoring Survey.

### Supplementary Messages:

#### *On the classification of *Salvia divinorum*:*

- In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, Salvinorin A, are <sup>regulated?</sup> ~~controlled~~ under the *Controlled Drugs and Substances Act* (CDSA).
- Salvia divinorum* is not listed under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these conventions.
- Several countries (Australia, Belgium, Denmark, Sweden, Italy, Spain, Finland and South Korea) have placed controls on the import and/or sale of *Salvia divinorum*. Although some individual U.S. states have implemented laws restricting its use,

sale and/or distribution, *Salvia divinorum* is not federally regulated under the *Controlled Substances Act* in the United States.

~~under certain conditions of use~~

- ✓ *Salvia divinorum*, when associated with health claims, could meet the definition of a natural health product under the *Natural Health Product Regulations* (NHPR). This means that *Salvia* products that are not in compliance with the NHPR may be subject to compliance and enforcement actions.

- ✓ As of January 2009, Health Canada had not issued any Natural Product Numbers (NPN) or Drug Identification Numbers – Homeopathic Medicine (DIN-HM) for *Salvia divinorum* products.

**If asked for specifics on when the survey data will be available:**

- ✓ Data from the Canadian Alcohol and Drug Use Monitoring Survey will be available in summer 2009, while the results of the Youth Smoking Survey and the Ontario ~~Canada~~ <sup>Alcohol and</sup> Student Drug Use and Health Survey likely will not be available until 2010. <sub>Monitoring</sub>

**Questions and Answers**

**Q1 – If Health Canada is aware of *Salvia divinorum*'s ill-effects, why isn't it illegal?**

- ✓ A1 – Very few controlled scientific studies of the physical and psychotropic effects of *Salvia divinorum* on humans have been carried out, and using these studies to predict the potential for addiction and abuse associated with *Salvia divinorum* is difficult. More controlled systematic research in this area is needed.

✓ Health Canada has only received a limited number of communications regarding *Salvia divinorum* from law enforcement agencies, and none of these has advised that the use of *Salvia divinorum* poses any particular threat to public safety.

**Q2 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?**

- ✓ A2 – The *Natural Health Product Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *Salvia divinorum*.

**Q3 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

- ✓ A3 – *Salvia divinorum* products that are not in compliance with the *Natural Health Product Regulations* and/or are found to pose a risk to the health of Canadians may be subject to compliance and enforcement action by Health Canada. An import target for products with *Salvia divinorum* has already been placed with Canada Border Services Agency.

*not permitted*

**Q4 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum*. What does that involve and what stage is it at?**

A4 - Health Canada considers several factors in determining whether scheduling a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in control and scheduling; *like the substance*
- (Chemical and pharmacological) similarity to other substances already scheduled under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Abuse liability and addiction potential of the substance; *not associated with*
- Extent of actual abuse and misuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

\* (Health Canada has only anecdotal information about the last three of the above-mentioned factors, and thus is not yet convinced that the controls imposed by the CDSA are an appropriate strategy for managing the risks associated with the use of *Salvia divinorum*.)

*In the case of SD, there is simply not enough info available to determine*

✓ Health Canada will, however, continue to collect and consider information regarding *Salvia divinorum* as it becomes available.

*whether (...)*  
*survey results*

**Q5 – Didn't an internal report from Health Canada's Marketed Health Products Directorate recommend that *Salvia divinorum* be scheduled under the CDSA? Why has that recommendation not been acted upon?**

A5 – See A4

**Q6 – What is the significance of the adverse reaction reports that Health Canada has received with respect to the use of *Salvia divinorum*?**

✓ A6 – Health Canada has received four domestic adverse reaction reports related to the use of *Salvia divinorum* as a hallucinogen through the Canada Vigilance database. The number of reports and the nature of reactions reported are not adequate to characterize the risk to the general population. These data cannot be used to determine incidence of use in the general population, as Health Canada does not have any information about the number of individuals using or who have used *Salvia divinorum*.

**Background**

✓ *Salvia divinorum* is a species of sage belonging to the mint family that is chewed or smoked in order to induce its psychotropic effects. These effects are short-acting in nature and include hallucinations, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are often described as unpleasant.



The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. While no validated data exist regarding usage in Canada, data from a 2006 National Survey on Drug Use and Health Report, published by the U.S. Substance Abuse and Mental Health Services Administration has estimated that:

- 1.8 million persons aged 12 or older used *Salvia divinorum* at least once in their lifetime, and approximately 750,000 did so in the past year.
- Use was more common among young adults (18 to 25 years old) as opposed to older adults (>26 years of age).
- Young adults were three times more likely than youths aged 12 to 17 to have used *Salvia divinorum* in the past year.
- Use was more common in males than females.

*Salvia divinorum* is widely advertised and promoted on the Internet as a "legal" alternative to street drugs.

*and sold in  
weed shops  
normal  
food  
stores.*

While some users have reported that the psychotropic effects of *Salvia divinorum* resemble those induced by other hallucinogens, such as LSD and phencyclidine, the overall experience appears to be quite unique. (*Salvia divinorum* does not appear to cause the euphoria often associated with other psychoactive drugs, so many people who try it do not repeat the experience.)

*was previously removed*

**Prepared by:** Cheryl Tremblay, Policy and Regulatory Affairs Division, DSCSD  
Stephanie Mitchell, Communications Advisor (HECSB)  
Darrin Denne, Communications Officer (HPFB)

**Reviewed by:** Mano Murty (MHPD – March 11, 2009)

**Approved by :**  
Approved

Andrew Adams, Director, OCS, DSCSD (March 1<sup>st</sup>, 2009)  
Nancy Richards, Director, Bureau of Policy and Regulatory Affairs, NHPD (January 23, 2009)  
Duc Vu, Director, Marketed Biologics, Biotechnology and Natural Health Products Bureau, MHPD (February 3, 2009)

Approved	Cathy Sabiston, DG, TDD, HECS (April 7, 2009)
Approved	Chris Turner, DG, MHPD (March 13, 2009)
Approved	Michelle Boudreau, DG, NHPD (March 19, 2009)
Approved	Sharon Mullins, A/DG, HPFBI (April 3, 2009)
Approved	Ken Polk, Communications Executive, HPFB (April 3, 2009)
Approved	Kathleen Malone, Senior Media Relations, PACCB (April 7, 2009)
Pending	Warren Braun, Director, Strategic Communications, PACCB
Pending	Peter Yendall, Director, Public Affairs, PACCB

Pending	Paul Glover, ADM, HECSB
Pending	Meena Ballantyne, ADM, HPFB
Pending	Anne Lamar, ADM, PACCB

Pending	DMO
Pending	MO
Pending	PCO

DRAFT  
April 7, 2009

### Media Lines Regulatory Control of *Salvia Divinorum*

#### Issue

Since 2006, Health Canada has noted ongoing media interest regarding the availability of *Salvia divinorum* on the Canadian market. Health Canada has also received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum*, particularly given reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults for its ability to produce hallucinations.

Deleted: observed a steady increase in the amount of

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#### Key Messages:

- Health Canada continues to collect and consider information about *Salvia divinorum* and its active ingredient, salvinorin A, from both national and international sources in order to determine the most appropriate strategy to manage the risks associated with its use.

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While the media have reported that use of *Salvia divinorum* is on the rise in certain parts of the country, Health Canada does not currently have statistics on its use across the Canadian population.

- Health Canada is taking steps to address this lack of data. Questions regarding the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey. A general open-ended question about the use of other substances was also included in the 2008 Canadian Alcohol and Drug Use Monitoring Survey.

Deleted: Ontario Student

Deleted: and Health

#### Supplementary Messages:

##### On the classification of *Salvia divinorum*:

- In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA).
- Salvia divinorum* is not listed under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these conventions.
- Several countries (Australia, Belgium, Denmark, Sweden, Italy, Spain, Finland and South Korea) have placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Although some individual U.S. states have implemented laws

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Am not opposed to change but don't really see need as previous text was OK for medical

Same comment re. need for change?

restricting its use, sale and/or distribution, *Salvia divinorum* and salvinorin A are not federally regulated under the *Controlled Substances Act* in the United States.

Deleted: is

Under certain conditions of use, *Salvia divinorum* meets the definition of a natural health product under the *Natural Health Product Regulations* (NHPR). This means that *Salvia* products that are not in compliance with the NHPR may be subject to compliance and enforcement actions.

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As of January 2009, Health Canada had not issued any Natural Product Numbers (NPN) or Drug Identification Numbers – Homeopathic Medicine (DIN-HM) for *Salvia divinorum* products.

If asked for specifics on when the survey data will be available:

- Data from the Canadian Alcohol and Drug Use Monitoring Survey will be available in summer 2009, while the results of the Youth Smoking Survey and the Canadian Alcohol and Drug Use Monitoring Survey likely will not be available until 2010.

Deleted: Ontario Student

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### Questions and Answers

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A1 – Very few controlled scientific studies of the physical and psychotropic effects of *Salvia divinorum* on humans have been carried out, and using these studies to predict the potential for addiction and abuse associated with *Salvia divinorum* is difficult. More controlled systematic research in this area is needed.

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**Q2 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?**

A2 – The *Natural Health Product Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *Salvia divinorum*.

**Q3 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A3 – *Salvia divinorum* products that are not in compliance with the *Natural Health Product Regulations* and/or are found to pose a risk to the health of Canadians may be subject to compliance and enforcement action by Health Canada. An import target for products with *Salvia divinorum* has already been placed with Canada Border Services Agency.

not clear what this means

Comment: Not previously included

is this what 1YH says - not sure I like! implies that salvia has to be sold in certain way or used a certain way to be an NHP and this is just not true!

containing

perhaps last sentence could read:

We can discuss if you like

~~Health Canada~~ The Canada Border Services Agency established an import target for finished ~~salvia~~ products containing salvia... in XXX (year). An import target 000321

**Q4 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum*. What does that involve and what stage is it at?**

A4 - Health Canada considers several factors in determining whether scheduling a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in ~~controlling the substance~~ *regulation (correlative status?)*
- Chemical and pharmacological similarity to other substances already regulated under the CDSA; ✓
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance; ✓
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

- Deleted: control
- Deleted: and scheduling
- Comment: Removed in IYH - but for laymans terms
- Deleted: scheduled
- Deleted: A
- Deleted: liability
- Deleted: potential of
- Deleted: and misuse

Health Canada has only anecdotal information about the last three of the above-mentioned factors, and thus is not yet convinced that the controls imposed by the CDSA are an appropriate strategy for managing the risks associated with the use of *Salvia divinorum*. IYH – In the case of *Salvia divinorum*, there is simply not enough information available to determine whether (controls imposed by CDSA... + mention survey results will help fill some of the information gaps)

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Health Canada will, however, continue to collect and consider information regarding *Salvia divinorum* as it becomes available.

you as long as  
tee up with  
next sentence  
otherwise it  
seems duplicati  
?

**Q5 – Didn't an internal report from Health Canada's Marketed Health Products Directorate recommend that *Salvia divinorum* be scheduled under the CDSA? Why has that recommendation not been acted upon?**

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**Deleted:** *Salvia divinorum* does not appear to cause the euphoria often associated with other psychoactive drugs, so many people who try it do not repeat the experience.

**Prepared by:** Cheryl Tremblay, Policy and Regulatory Affairs Division, DSCSD  
Stephanie Mitchell, Communications Advisor (HECSB)  
Darrin Denne, Communications Officer (HPFB)

**Reviewed by:** Mano Murty (MHPD – March 11, 2009)

**Approved by :**

Approved Andrew Adams, Director, OCS, DSCSD (March 1<sup>st</sup>, 2009)  
Nancy Richards, Director, Bureau of Policy and Regulatory Affairs, NHPD (January 23, 2009)  
Duc Vu, Director, Marketed Biologics, Biotechnology and Natural Health Products Bureau, MHPD (February 3, 2009)

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Pending Anne Lamar, ADM, PACCB

Pending DMO  
Pending MO  
Pending PCO



Jocelyn Kula/HC-SC/GC/CA  
2009-06-10 10:58 AM

To Cheryl Tremblay/HC-SC/GC/CA@HWC  
cc  
bcc

Subject Fw: For your approval - It's Your Health - Salvia D

for the file pls

---

Jocelyn Kula

Manager/ Gestionnaire

Policy and Regulatory Affairs Division/ Division des politiques et affaires réglementaires

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs

Health Canada/ Santé Canada

Tel: (613) 946-0125 Fax: (613) 946-4224

----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2009-06-10 10:58 AM -----

Diane Allan/HC-SC/GC/CA

2009-06-10 10:50 AM

To Bronwyn Cline/HC-SC/GC/CA@HWC

cc Jocelyn Kula/HC-SC/GC/CA@HWC

Subject Fw: For your approval - It's Your Health - Salvia D

Approved, the docket will be going to DGO this morning.

Diane Allan

Director / Directrice

Office of Controlled Substances / Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch / Direction générale de la santé environnementale et  
de la sécurité des consommateurs

Health Canada / Santé Canada

Tel: 613-952-2177

Fax: 613-952-2196

----- Forwarded by Diane Allan/HC-SC/GC/CA on 2009-06-10 10:49 AM -----



Ronald  
Denault/HC-SC/GC/CA  
2009-06-08 07:50 AM

To Jocelyn Kula/HC-SC/GC/CA

cc "Diane Allan" <diane\_allan@hc-sc.gc.ca>

Subject Fw: For your approval - It's Your Health - Salvia D

Hi jocelyn

I missed this email a while ago

Please check from point of view if everything is correct

Thank you

Ronald

Bronwyn Cline

----- Original Message -----

**From:** Bronwyn Cline

**Sent:** 2009-06-07 10:48 PM EDT

**To:** Ronald Denault

**Cc:** Carmen Berube; Christine Roush

**Subject:** Re: For your approval - It's Your Health - Salvia D

Hello Ronald,

Were you able to review the It's Your Health article below? Or should it go to Diane Allen for approval now?

Thanks,

Bronwyn Cline  
Communications Officer | Agente des communications

613-941-2511 | facsimile / télécopieur 613-948-8085  
bronwyn\_cline@hc-sc.gc.ca  
Health Canada | 269 Laurier Ave Ottawa ON K1A 0K9  
Santé Canada | 269 ave Laurier Ottawa ON K1A 0K9  
Government of Canada | Gouvernement du Canada  
Bronwyn Cline/HC-SC/GC/CA



Bronwyn  
Cline/HC-SC/GC/CA  
2009-05-27 11:15 AM

To Ronald Denault/HC-SC/GC/CA

cc Carmen Berube/HC-SC/GC/CA@HWC, Christine  
Roush/HC-SC/GC/CA@HWC

Subject For your approval - It's Your Health - Salvia D

Hello Ronald,

Could I please get your approval of this for Tuesday, June 2? We're aiming to have this completely approved by June 12.



Apps Slip DG&ADM HECS Salvia May2009.wpd IYH - Salvia divinorum - Draft Seven (May 27, 2009).wpd

Thank you,

Bronwyn Cline  
Communications Officer | Agente des communications

613-941-2511 | facsimile / télécopieur 613-948-8085  
bronwyn\_cline@hc-sc.gc.ca  
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Santé Canada | 269 ave Laurier Ottawa ON K1A 0K9  
Government of Canada | Gouvernement du Canada

## *It's Your Health*

(A Health Canada Publication)

Comments ♦ Commentaires			
It's Your Health articles answer frequently asked questions from the general public and provide health protection advice. These publications are distributed to: doctors and their clients, teachers and students, magazine editors and their subscribers, other federal and provincial departments, private firms, and Health Canada employees. This publication is also posted on the Health Canada official Web site.			
Subject ♦ Sujet:  <b>Salvia divinorum</b>		Approval deadline Échéance d'approbation  <b>June 12, 2009</b>	
<b>Branch:</b> HECSB		<b>Comm:</b> Judy Froome/Christine Roush	
<b>Coordinator:</b> Lisa Mackay      954-0105		<b>Writer:</b> Sue Lumsden	
<b>Program Contacts:</b> Jocelyn Kula, Cheryl Tremblay and Brittany Sauvé			
<b>Approvals Approbations</b>	<b>Signing Authority Autorisé par</b>	<b>Signature</b>	<b>Date</b>
1. Programme Director	<del>Ronald Denault</del> <i>Diane Allan</i>		
2. Director General	Cathy A. Sabiston		
3. HECSB Communications Exec	Kathleen Malone		
4. ADM	Paul Glover		
5. Risk Communications	Kathy Howard		
Please return to ♦ Veuillez retourner à : Lisa Mackay 954-0105		Room ♦ Pièce: 1273D BC FAX: 952-8644	



## ***It's Your Health***

***(A Health Canada Publication)***

<b>Comments ♦ Commentaires</b>			
<p>It's Your Health articles answer frequently asked questions from the general public and provide health protection advice. These publications are distributed to: doctors and their clients, teachers and students, magazine editors and their subscribers, other federal and provincial departments, private firms, and Health Canada employees. This publication is also posted on the Health Canada official Web site.</p>			
<b>Subject ♦ Sujet:</b>		<b>Approval deadline Échéance d'approbation</b>	
<b>Salvia divinorum</b>		<b>June 12, 2009</b>	
<b>Branch: HECSB</b>		<b>Comm: Judy Froome/Christine Roush</b>	
<b>Coordinator: Lisa Mackay 954-0105</b>		<b>Writer: Sue Lumsden</b>	
<b>Program Contacts: Jocelyn Kula, Cheryl Tremblay and Brittany Sauvé</b>			
<b>Approvals Approbations</b>	<b>Signing Authority Autorisé par</b>	<b>Signature</b>	<b>Date</b>
1. Programme Director	Diane Allan	Email	June 10, 2009
2. Director General	Cathy A. Sabiston	Email	June 15, 2009
3. HECSB Communications Exec	Kathleen Malone	Signature	June 16, 2009
4. ADM	Paul Glover		
5. Risk Communications	Kathy Howard		
<b>Please return to ♦ Veuillez retourner à :</b> Lisa Mackay 954-0105		<b>Room ♦ Pièce:</b> 1273D BC FAX: 952-8644	

## ***It's Your Health***

**(A Health Canada/Public Health Agency Publication)**

**Comments ♦ Commentaires**

It's Your Health articles answer frequently asked questions from the general public and provide health protection and promotion advice. The articles are distributed to: doctors and their clients, teachers and students, magazine editors and their subscribers, other federal and provincial departments, private firms, and Health Canada/Public Health Agency of Canada employees. This publication is also posted on the Health Canada and Public Health Agency Web sites.

<b>Subject ♦ Sujet:</b>	<b>Approval deadline Échéance d'approbation</b>
<b>Salvia divinorum</b>	<b>June 12, 2009</b>

<b>Branch: HPFB</b>	<b>Comm Contact: Blossom Leung 948-7799</b>
---------------------	---

<b>Coordinator: Lisa Mackay 954-0105</b>	<b>Writer: Sue Lumsden</b>
--	----------------------------

**Program Contact: Valerie Hurry (NHPD), and Robert Leitch and Mano Murty (MHPD)**

Approvals Approbations	Signing Authority Autorisé par	Signature	Date
1. Programme Director	Robin Marles	Approved	June 1, 2009
2. Programme Director	Duc Vu	Approved	June 1, 2009
3. Programme DG	Michelle Boudreau	Approved	June 1, 2009
4. Programme DG	Chris Turner	Approved	June 4, 2009
4. Communications Executive	Jennifer Peddle for Ken Polk	Approved	June 4, 2009
5. ADM	Meena Ballentyne	Approved	June 5, 2009
6. Risk/Crisis Communications	Kathy Howard		

Please return to ♦ Veuillez retourner à : Lisa Mackay 954-0105	Room ♦ Pièce: 000328 1277D BC FAX: 952 8644
--	---

**Response to ADM Questions Regarding the IYH article on *Salvia Divinorum*  
June 23, 2009**

**(1) Where are our standard lines around drug prevention?**

The standard lines on drug prevention were not incorporated in this IYH because the wording of those lines is oriented around illicit drugs which are already regulated as controlled substances. They do not translate well to *Salvia divinorum* in light of the fact that neither this plant nor its active ingredient are regulated as controlled substances at this time. The preliminary findings of our scheduling assessment are that information about the different factors considered, e.g., the potential for abuse and risk of addiction associated with the substance, the extent of actual abuse of the substance in Canada and internationally and the overall risk to public health and safety posed by the substance, is either missing or anecdotal in nature and thus, the controls imposed by the CDSA are likely not warranted. It is because of these preliminary findings that this IYH was contemplated. *Salvia Divinorum* continues to attract moderate media attention and it was thought that it would be beneficial to have information available on the internet that would better inform the general public about the issue, i.e., health effects and what they can do to safe guard their own health. In this regard, the language used in the article is focused on the fact that Health Canada does not know very much about how it acts on the brain and the body and thus does not recommend that people use it.

**Is it normal to include information with respect to the status in other countries in an IYH article? (as written it seems to generate more questions than provide answers)**

The information regarding the status of *Salvia divinorum* and its active ingredient salvinorin A in other countries was included as it pertains to one of the factors that Health Canada considers when assessing whether to add a substance to one of the schedules to the CDSA, i.e., international requirements and trends in controlling the substance. This information could however be removed from the document without disrupting the flow of the article if there are concerns with its inclusion. The content of the article has however already been approved by HPFB and so we would need to go back to them for approval if this type of revision were to be made.

June 23, 2009

## **Its Your Health Proposed Article**

It's Your Health articles answer frequently asked questions from the general public and provide health protection advice. Each IYH article is roughly 2 pages long, with a grade 8 to 10 "readability" level. The target audience is the general public, and plain language is used whenever possible. Links to detailed technical or scientific information can be provided in the "Need More Info?" section. These publications are distributed to: doctors and their clients, teachers and students, magazine editors and their subscribers, other federal and provincial departments, private firms, Health Canada and Public Health Agency of Canada employees. This publication is also posted on Health Canada and PHACs official Web sites.

**Author and Date of Proposal** - *Lisa Holmes - October 17, 2008*

**Proposed Title** - *Salvia divinorum*

**The Issue** - *Salvia Divinorum is a species of sage which belongs to the mint family. It is found in the form of dried leaves, extract and plant cuttings. Salvia Divinorum, also known as "diviner's sage" and/or "magic mint", is chewed or smoked and can induce illusions and hallucinations.*

*Salvia Divinorum continues to attract moderate media attention. It will be beneficial to have an It's Your Health article available on the internet so that the general public can be better informed about the issue, and so that reporters can refer to this article, should they have questions about the issue.*

**Health Canada's Role** - *There are no regulations or laws prohibiting the possession, use or sale of Salvia divinorum in Canada. While many countries across the globe have prohibited Salvia, it remains legal in Canada. Health Canada is currently exploring our options for prohibiting Salvia in Canada.*

**Why is this article needed and why It's Your Health ?-** *The target audience is the general public. It's Your Health is a good vehicle to use to inform individuals about Salvia because the articles are written in plain language and are easily understood by the vast majority of Canadians.*

**Are other communications products being considered, will they be used ?-**  
*Media lines.*

**Is there a deadline for producing the IYH article** - *While it is not part of a larger*

*announcement, it would be beneficial to have this article produced and posted as soon as possible, as there continues to be media attention and public interest on the issue.*

**Who in the department needs to provide input and who would be the lead contact ?-** *Andrew Adams, Director, Drug Analysis Services, HECS; Ranjan Bose, Manager, Marketed Biologicals, Biotechnology and Natural Health Products Bureau, Marketed Health Products Directorate, and Dr. Helmi Hussien, A/Director, Bureau of Clinical Trials and Health Sciences, Natural Health Products Directorate, HPFB.*

**Who in the department or outside of the department should approve this article?** - *Health Canada only.*

**Is there a plan for Stakeholder involvement or dissemination when article is completed?:** *No stakeholder plan - we will refer media to this article.*

If you have any questions regarding this form please contact your Branch or Regional contact listed below:

**HECSB**

Judy Froome  
Lisa Brinston

**HPFB**

Blossom Leung

**PHAC**

Julie Rivard

**ATLANTIC Region**

Eleanor Cameron

**QUEBEC Region**

Caroline Hares

**Ontario Region**

Debbie Paine

**MANITOBA/SASKATCHEWAN Region**

Adele Novak

**ALBERTA Region**

Therese Little

**BC Region**

Erik Bruns

**IYH Manager**

Lisa Mackay

**IYH Publisher**

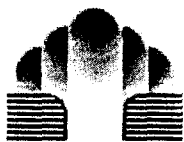
Alastair Sinclair

**IYH Editor**

Sally Fletcher  
Sean Upton

**FNIHB**

Mary Hand



Jocelyn Kula/HC-SC/GC/CA  
2009-06-15 05:00 PM

To Cheryl Tremblay/HC-SC/GC/CA@HWC  
cc  
bcc  
Subject Fw: For your approval - It's Your Health - Salvia D


FYI

---

Jocelyn Kula  
Manager/ Gestionnaire  
Policy and Regulatory Affairs Division/ Division des politiques et affaires réglementaires  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0125 Fax: (613) 946-4224  
----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2009-06-15 05:00 PM -----



Kimberly  
Sorfleet/HC-SC/GC/CA  
2009-06-15 04:40 PM

To Diane Allan/HC-SC/GC/CA@HWC  
cc Bronwyn Cline/HC-SC/GC/CA@HWC, Carmen  
Berube/HC-SC/GC/CA@HWC, Jocelyn  
Kula/HC-SC/GC/CA@HWC, Stephanie  
Szick/HC-SC/GC/CA@HWC, Tacha  
Lehouillier/HC-SC/GC/CA@HWC  
Subject Re: Fw: For your approval - It's Your Health - Salvia D 

Diane,

Cathy has approved.

Bronwyn - FYI - you may proceed.

Thank you!

Kimberly Sorfleet  
Executive Assistant to the Director General / Adjointe Exécutive a la Directrice générale  
Controlled Substances & Tobacco Directorate (CSTD)  
Direction des substances contrôlées et de la lutte au tabagisme (DSCLT)  
Health Canada / Santé Canada  
Tel: (613) 946-9316 Fax: (613) 954-2288  
www.healthcanada.gc.ca / www.santecanada.gc.ca  
Government of Canada / Gouvernement du Canada  
Diane Allan/HC-SC/GC/CA

Diane Allan/HC-SC/GC/CA  
2009-06-10 10:56 AM

To Kimberly Sorfleet/HC-SC/GC/CA@HWC  
cc Tacha Lehouillier/HC-SC/GC/CA@HWC, Jocelyn  
Kula/HC-SC/GC/CA@HWC, Bronwyn  
Cline/HC-SC/GC/CA@HWC, Carmen  
Berube/HC-SC/GC/CA@HWC, Stephanie  
Szick/HC-SC/GC/CA@HWC

Subject Fw: For your approval - It's Your Health - Salvia D

Kim:

This is for DG approval, I understand that this is already at HPFBADMO approval stage. If I can impose and request that Cathy review and approve this today?

Thanks,  
Diane

Diane Allan

Director / Directrice  
Office of Controlled Substances / Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch / Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada / Santé Canada  
Tel: 613-952-2177  
Fax: 613-952-2196

----- Forwarded by Diane Allan/HC-SC/GC/CA on 2009-06-10 10:54 AM -----

**Diane Allan/HC-SC/GC/CA**

2009-06-10 10:50 AM

To Bronwyn Cline/HC-SC/GC/CA

cc Jocelyn Kula/HC-SC/GC/CA@HWC

Subject Fw: For your approval - It's Your Health - Salvia D

Approved, the docket will be going to DGO this morning.

Diane Allan

Director / Directrice  
Office of Controlled Substances / Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch / Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada / Santé Canada  
Tel: 613-952-2177  
Fax: 613-952-2196

----- Forwarded by Diane Allan/HC-SC/GC/CA on 2009-06-10 10:49 AM -----

**Ronald  
Denault/HC-SC/GC/CA**

2009-06-08 07:50 AM

To Jocelyn Kula/HC-SC/GC/CA

cc "Diane Allan" <diane\_allan@hc-sc.gc.ca>

Subject Fw: For your approval - It's Your Health - Salvia D



Hi jocelyn  
I missed this email a while a go  
Please check from point of view if everything is correct  
Thank you  
Ronald  
Bronwyn Cline

----- Original Message -----

**From:** Bronwyn Cline  
**Sent:** 2009-06-07 10:48 PM EDT  
**To:** Ronald Denault  
**Cc:** Carmen Berube; Christine Roush  
**Subject:** Re: For your approval - It's Your Health - Salvia D

Hello Ronald,

Were you able to review the It's Your Health article below? Or should it go to Diane Allen for approval now?

Thanks,

Bronwyn Cline  
Communications Officer | Agente des communications

613-941-2511 | facsimile / télécopieur 613-948-8085  
bronwyn\_cline@hc-sc.gc.ca  
Health Canada | 269 Laurier Ave Ottawa ON K1A 0K9  
Santé Canada | 269 ave Laurier Ottawa ON K1A 0K9  
Government of Canada | Gouvernement du Canada  
Bronwyn Cline/HC-SC/GC/CA



Bronwyn  
Cline/HC-SC/GC/CA  
2009-05-27 11:15 AM

To Ronald Denault/HC-SC/GC/CA  
cc Carmen Berube/HC-SC/GC/CA@HWC, Christine  
Roush/HC-SC/GC/CA@HWC  
Subject For your approval - It's Your Health - Salvia D

Hello Ronald,

Could I please get your approval of this for Tuesday, June 2? We're aiming to have this completely approved by June 12.



Apps Slip DG&ADM HECS Salvia May2009.wpd IYH - Salvia divinatorum - Draft Seven (May 27, 2009).wpd

Thank you,

Bronwyn Cline  
Communications Officer | Agente des communications

613-941-2511 | facsimile / télécopieur 613-948-8085  
bronwyn\_cline@hc-sc.gc.ca  
Health Canada | 269 Laurier Ave Ottawa ON K1A 0K9



Santé Canada | 269 ave Laurier Ottawa ON K1A 0K9  
Government of Canada | Gouvernement du Canada

### Past Year Use of Salvia Divinorum

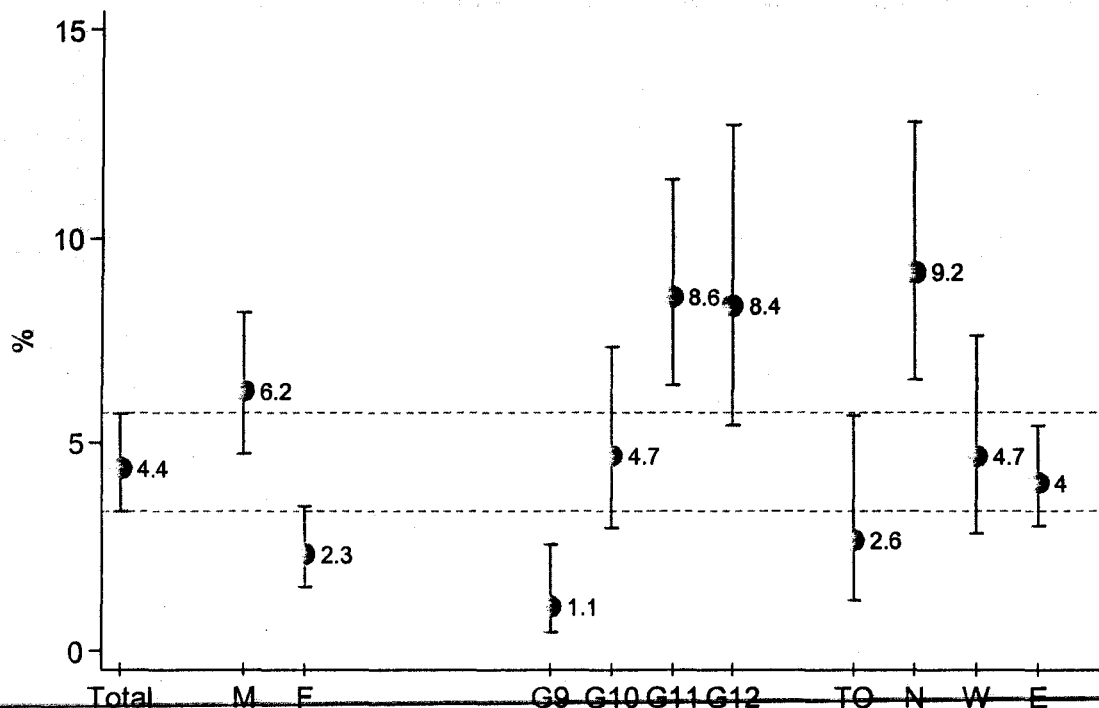
(Figure 3.6.8)

Salvia divinorum is a legal plant, which can be purchased online or in "head shops," that causes hallucinations and delusions. This drug can be ingested by chewing the fresh leaves, drinking their extracted juices, or smoking the dried leaves. For the first time in 2009, students were asked about their use of this drug with the question: "In the last 12 months, how often did you use salvia divinorum (also known as 'sally-D', 'magic mint', 'sadi')?"

2009: Grades 7 to 12


- Among all students in 2009, 4.4% (range: 3.3%-5.7%) report using salvia divinorum at least once in the past year. This percentage represents about 42,600 students in Ontario.
- Males (6.2%) are significantly more likely than females (2.3%) to use salvia divinorum.
- There is significant grade variation, with salvia use most likely among 11<sup>th</sup>-graders (8.6%) and 12<sup>th</sup>-graders (8.4%).
- There is significant regional variation, with students in the North (9.2%) most likely to use salvia.

Figure 3.6.8  
Past Year Salvia Divinorum Use by Sex, Grade and Region, 2009 OSDUHS



Vertical bars represent 95% confidence intervals; horizontal bar represents 95% CI for total estimate; estimates for grade 7 and grade 8 were suppressed

Jay Khosla/HC-SC/GC/CA  
2009-06-22 02:31 PM

To Jocelyn Kula/HC-SC/GC/CA@HWC  
cc Cheryl Tremblay/HC-SC/GC/CA@HWC, Diane  
Allan/HC-SC/GC/CA@HWC, Stephanie  
Szick/HC-SC/GC/CA@HWC, Tacha  
bcc  
Subject Re: Paul's comment on Salvia IYH 

Thanks. Based on this, I think a plainly worded explanation on why standard text is not being used would be helpful so let's tackle it from that perspective. Also, a few lines addressing other questions and a comment on the issue of approvals should assist in putting it to rest.


Could you please craft a response to this effect for Diane's review and we'll go from there.

Thanks much.

Jay Khosla  
Associate Director General /Directeur générale associé  
Controlled Substances & Tobacco Directorate (CSTD)  
Direction des substances contrôlées et de la lutte au tabagisme (DSCLT)  
Health Canada / Santé Canada  
Tel: (613) 952-4064 / Fax: (613) 954-2288  
E-mail/courriel :  
[Jay\\_Khosla@hc-sc.gc.ca](mailto:Jay_Khosla@hc-sc.gc.ca)  
Website/Site web:  
[www.hc-sc.gc.ca](http://www.hc-sc.gc.ca)  
Jocelyn Kula/HC-SC/GC/CA



Jocelyn Kula/HC-SC/GC/CA  
2009-06-22 01:34 PM

To Jay Khosla/HC-SC/GC/CA@HWC  
cc Diane Allan/HC-SC/GC/CA@HWC, Stephanie  
Szick/HC-SC/GC/CA@HWC, Tacha  
Lehouillier/HC-SC/GC/CA@HWC, Cheryl  
Tremblay/HC-SC/GC/CA@HWC  
Subject Re: Paul's comment on Salvia IYH 

We can look at the wording but I am not sure the standard lines on drug prevention really work here because they are really oriented around illicit drugs (which are regulated as controlled substances) and the whole point of doing this IYH is that salvia is not yet regulated as a controlled substance and the preliminary findings of our scheduling assessment are that it does not warrant these types of controls. Hence the language about not knowing very much about how it acts on the brain and the body, and that we don't recommend that people use it....

Cheryl (analyst responsible) is away today but we will get something back to DGO as soon as possible. That said, if Paul really wants changes, we are going to have to go all the way back through approvals in HPFB as this IYH has been a co-production if you will, and it is my understanding from Comms that Meena has already signed off.

JK

2) re: the Status in Other Countries section - is that normal to include this in an IYH article?  
Adding...  
As written, it seems to generate more questions than provide answers.

Thanks,

Stephanie Szick  
Controlled Substances & Tobacco Directorate (CSTD)  
Direction des substances contrôlées et de la lutte au tabagisme (DSCLT)  
Health Canada / Santé Canada  
Tel / Tél: (613) 952-3367

----- Forwarded by Stephanie Szick/HC-SC/GC/CA on 2009-06-22 11:20 AM -----

**Hayden**  
Lansdell/HC-SC/GC/CA  
2009-06-22 11:03 AM  
To Jay Khosla/HC-SC/GC/CA@HWC  
cc Stephanie Szick/HC-SC/GC/CA@HWC  
Subject Fw: scan

PG has questions on this IYH. Can you please get Diane to take a look. An email response is all that is necessary at this point in time.

Hayden

----- Forwarded by Hayden Lansdell/HC-SC/GC/CA on 2009-06-22 10:58 AM -----



**Julie**  
Paquette/HC-SC/GC/CA  
2009-06-22 10:52 AM  
To Hayden Lansdell/HC-SC/GC/CA@HWC  
cc  
Subject scan



salvia divinorum.pdf

Julie Paquette  
Executive Assistant to the Director / Adjointe exécutive à la directrice  
Health Canada / Santé Canada  
Assistant Deputy Minister's Office / Bureau de la sous-ministre adjointe  
HECSB / DGSESC  
Tel: 613-946-6710  
Fax: 613-946-6666

Jay - this is the revised version of the lines around drug prohibition in the states in other countries that normal in an It's your Health!

Salvia divinorum

The Issue

Reports suggest that Canadian teens and young adults are using a substance called Salvia divinorum (S. divinorum) for its ability to produce hallucinations. Certain Web sites are also promoting the use of S. divinorum as a "legal" alternative to street drugs.

Street names for S. divinorum include: Sally D, Lady Sally, Maria pastra, ska Maria pastora, ska pastora. diviner's sage, magic mint, puff encens special, and salvia.

Health Canada recommends that you avoid using this substance because very little is known about the damage it may cause to the body, including the brain. There is also no way to predict how it will affect you with each use.

Background

S. divinorum is a species of sage that belongs to the mint family. It is known to have psychotropic effects, which means it affects the mind and mental processes.

The leaves of this plant have been used traditionally by the Mazatec Indians in Mexico for many years. Traditional use involves chewing the leaves or using them to make a tea for medicinal purposes (e.g., to treat such conditions as headache or stomach upset), or to induce a "mystical" or hallucinogenic experience for spiritual purposes.

Products that claim to contain S. divinorum - or its main active ingredient, salvinorin A - are widely available on the Internet and are sold in various "head shops" and natural food stores. The products are sold in a number of formats, including seeds and plant cuttings for growing purposes. Fresh or dried leaves are intended to be chewed, swallowed or smoked. Liquid preparations are also available.

Risks of Using Salvia divinorum

S. divinorum's effects, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations;
- dysphoria (feeling unwell, uneasy or unhappy);
- out-of-body experiences;
- uncontrollable laughter;
- loss of consciousness;
- short-term memory loss;
- lack of physical coordination;
- slurred speech and awkward sentence patterns.

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

Happy to discuss. Paul Williams  
As written it seems to generate more questions than provide answers.

Cheryl - these are Paul's handwritten notes that I forwarded on to you via email. Pls see my note to Jay Khosla and his response. For Action ASAP pls.

JK 000339



Jocelyn Kula/HC-SC/GC/CA  
2009-06-23 01:16 PM

To Diane Allan  
cc Cheryl Tremblay/HC-SC/GC/CA@HWC  
bcc  
Subject Salvia IYH

FOR APPROVAL

Proposed reply to ADM questions re. the Salvia IYH article.



Responses to ADM Comments on Salvia IYH June 23 2009.doc

---

Jocelyn Kula  
Manager/ Gestionnaire  
Policy and Regulatory Affairs Division/ Division des politiques et affaires réglementaires  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0125 Fax: (613) 946-4224

**Response to ADM Questions Regarding the IYH article on *Salvia Divinorum*  
June 23, 2009**

**(1) Where are our standard lines around drug prevention?**

The standard lines on drug prevention were not incorporated in this IYH because the wording of those lines is oriented around illicit drugs which are already regulated as controlled substances. They do not translate well to *Salvia divinorum* in light of the fact that neither this plant nor its active ingredient are regulated as controlled substances at this time. The preliminary findings of our scheduling assessment are that information about the different factors considered, e.g., the potential for abuse and risk of addiction associated with the substance, the extent of actual abuse of the substance in Canada and internationally and the overall risk to public health and safety posed by the substance, is either missing or anecdotal in nature and thus, the controls imposed by the CDSA are likely not warranted. It is because of these preliminary findings that this IYH was contemplated. *Salvia Divinorum* continues to attract moderate media attention and it was thought that it would be beneficial to have information available on the internet that would better inform the general public about the issue, i.e., health effects and what they can do to safe guard their own health. In this regard, the language used in the article is focused on the fact that Health Canada does not know very much about how it acts on the brain and the body and thus does not recommend that people use it.

**Is it normal to include information with respect to the status in other countries in an IYH article? (as written it seems to generate more questions than provide answers)**

The information regarding the status of *Salvia divinorum* and its active ingredient salvinorin A in other countries was included as it pertains to one of the factors that Health Canada considers when assessing whether to add a substance to one of the schedules to the CDSA, i.e., international requirements and trends in controlling the substance. This information could however be removed from the document without disrupting the flow of the article if there are concerns with its inclusion. The content of the article has however already been approved by HPFB and so we would need to go back to them for approval if this type of revision were to be made.

June 23, 2009

## **Response to Paul's Questions Regarding the IYH article on *Salvia Divinorum***

### **(1) Where are our standard lines around drug prevention?**

The standard lines on drug prevention were not incorporated in this IYH because the wording of those lines is oriented around illicit drugs which are already regulated as controlled substances. They do not translate well to *Salvia divinorum* in light of the fact that neither this plant nor its active ingredient are regulated as controlled substances at this time. The preliminary findings of our scheduling assessment are that information about the different factors considered, e.g., the potential for abuse and risk of addiction associated with the substance, the extent of actual abuse of the substance in Canada and internationally and the overall risk to public health and safety posed by the substance, is either missing or anecdotal in nature and thus, the controls imposed by the CDSA are likely not warranted. It is because of these preliminary findings that this IYH was contemplated. *Salvia Divinorum* continues to attract moderate media attention and it was thought that it would be beneficial to have information available on the internet that would better inform the general public about the issue, i.e., health effects and what they can do to safe guard their own health. In this regard, the language used in the article is focused on the fact that Health Canada does not know very much about how it acts on the brain and the body and thus does not recommend that people use it.

### **Is it normal to include information with respect to the status in other countries in an IYH article? (as written it seems to generate more questions than provide answers)**


The information regarding the status of *Salvia divinorum* and its active ingredient salvinorin A in other countries was included as it pertains to one of the factors that Health Canada considers when assessing whether to add a substance to one of the schedules to the CDSA, i.e., international requirements and trends in controlling the substance. This information could however be removed from the document without disrupting the flow of the article if there are concerns with its inclusion. The content of the article has however already been approved by HPFB and so we would need to go back to them for approval if this type of revision were to be made.

June 23, 2009





Cheryl  
Tremblay/HC-SC/GC/CA  
2009-06-23 02:38 PM

To Bronwyn Cline/HC-SC/GC/CA@HWC  
cc Christine Roush/HC-SC/GC/CA@HWC, Brooke  
Bryce/HC-SC/GC/CA@HWC, Jocelyn  
Kula/HC-SC/GC/CA@HWC  
bcc Cheryl Tremblay/HC-SC/GC/CA  
Subject Re: Salvia D media lines 

Hi Bronwyn,

Here are CSTD's comments on media lines for Salvia Divinorum.



Salvia ML v.7 April 2009\_CSTD Comments re IYH.doc

Let me know if you have any questions,  
Thanks,

Cheryl Tremblay  
Policy and Regulatory Affairs Division / Division des politiques et affaires réglementaires  
Office of Controlled Substances / Bureau des substances contrôlées  
Controlled Substances and Tobacco Directorate / Direction des substances contrôlées et de la lutte au  
tabagisme  
Healthy Environments and Consumer Safety Branch / Direction générale de la santé environnementale et  
de la sécurité consommateurs  
Health Canada / Santé Canada  
Tel: (613) 954-6527 Fax: (613) 946-4224  
Bronwyn Cline/HC-SC/GC/CA



Bronwyn Cline/HC-SC/GC/CA

2009-06-16 03:33 PM

To Cheryl Tremblay/HC-SC/GC/CA@HWC  
cc  
Subject Salvia D media lines

Hi Cheryl,

Can you please make sure to cc Christine Roush and Brooke Bryce when you send me your comments on  
the Salvia D lines?

FYI, the IYH on Salvia is currently with the HECS ADM.

Thanks,

Bronwyn Cline  
Communications Officer | Agente des communications

613-941-2511 | facsimile / télécopieur 613-948-8085  
bronwyn\_cline@hc-sc.gc.ca  
Health Canada | 269 Laurier Ave Ottawa ON K1A 0K9  
Santé Canada | 269 ave Laurier Ottawa ON K1A 0K9  
Government of Canada | Gouvernement du Canada

DRAFT  
April 7, 2009

### Media Lines Regulatory Control of *Salvia Divinorum*

#### Issue

Since 2006, Health Canada has noted ongoing media interest regarding the availability of *Salvia divinorum* on the Canadian market. Health Canada has also received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum*, particularly given reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties.

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#### Key Messages:

- Health Canada continues to collect and consider information about *Salvia divinorum* and its active ingredient, salvinorin A, from both national and international sources in order to determine what, if any, regulatory controls are needed.
- While the media have reported that use of *Salvia divinorum* is on the rise in certain parts of the country, Health Canada does not currently have statistics on its use across the Canadian population.
- Health Canada is taking steps to address this lack of data. Questions regarding the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey. A general open-ended question about the use of other substances was also been included in the 2008 Canadian Alcohol and Drug Use Monitoring Survey.

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Deleted: and Health

#### Supplementary Messages:

##### *On the classification of *Salvia divinorum*:*

- In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA).
- *Salvia divinorum* is not listed under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these conventions.
- Several countries (Australia, Belgium, Denmark, Sweden, Italy, Spain, Finland and South Korea) have placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Although some individual U.S. states have implemented laws

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restricting its use, sale and/or distribution, *Salvia divinorum* and salvinorin A are not federally regulated under the *Controlled Substances Act* in the United States.

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- *Salvia divinorum* meets the definition of a natural health product under the *Natural Health Product Regulations* (NHPR). This means that *Salvia* products that are not in compliance with the NHPR may be subject to compliance and enforcement actions.

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- As of January 2009, Health Canada had not issued any Natural Product Numbers (NPN) or Drug Identification Numbers – Homeopathic Medicine (DIN-HM) for *Salvia divinorum* products.

**If asked for specifics on when the survey data will be available:**

- Data from the Canadian Alcohol and Drug Use Monitoring Survey will be available in summer 2009, while the results of the Youth Smoking Survey and the Canadian Alcohol and Drug Use Monitoring Survey likely will not be available until 2010.

Deleted: Ontario Student

Deleted: and Health

**Questions and Answers**

**Q1 – If Health Canada is aware of *Salvia divinorum*'s ill-effects, why isn't it illegal?**

A1 – Very few controlled scientific studies of the physical and psychotropic effects of *Salvia divinorum* on humans have been carried out, and using these studies to predict the potential for addiction and abuse associated with *Salvia divinorum* is difficult. More controlled systematic research in this area is needed.

Health Canada has only received a limited number of communications regarding *Salvia divinorum* from law enforcement agencies, and none of these has advised that the use of *Salvia divinorum* poses any particular threat to public safety.

**Q2 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?**

A2 – The *Natural Health Product Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *Salvia divinorum*.

**Q3 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A3 – *Salvia divinorum* products that are not in compliance with the *Natural Health Product Regulations* and/or are found to pose a risk to the health of Canadians may be subject to compliance and enforcement action by Health Canada. An import target for products containing *Salvia divinorum* has already been placed with Canada Border Services Agency.

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**Q4 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum*. What does that involve and what stage is it at?**

A4 - Health Canada considers several factors in determining whether scheduling a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in regulatory status;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

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Health Canada has only anecdotal information about the last three of the above-mentioned factors, and thus is not yet convinced that the controls imposed by the CDSA are an appropriate strategy for managing the risks associated with the use of *Salvia divinorum*. The survey results from the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey will help fill some of the information gaps. The data, however, will not likely be available until 2010. In the interim, Health Canada will continue to collect and consider information regarding *Salvia divinorum* as it becomes available.

Deleted: , however,

**Q5 – Didn't an internal report from Health Canada's Marketed Health Products Directorate recommend that *Salvia divinorum* be scheduled under the CDSA? Why has that recommendation not been acted upon?**

A5 – See A4

**Q6 – What is the significance of the adverse reaction reports that Health Canada has received with respect to the use of *Salvia divinorum*?**

A6 – Health Canada has received four domestic adverse reaction reports related to the use of *Salvia divinorum* as a hallucinogen through the Canada Vigilance database. The number of reports and the nature of reactions reported are not adequate to characterize the risk to the general population. These data cannot be used to determine incidence of use in the general population, as Health Canada does not have any information about the number of individuals using or who have used *Salvia divinorum*.

**Background**

*Salvia divinorum* is a species of sage belonging to the mint family that is chewed or smoked in order to induce its psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are often described as unpleasant.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. While no validated data exist regarding usage in Canada, data from a 2006 National Survey on Drug Use and Health Report, published by the U.S. Substance Abuse and Mental Health Services Administration has estimated that:

- 1.8 million persons aged 12 or older have used *Salvia divinorum* at least once in their lifetime, and approximately 750,000 did so in the past year.
- Use was more common among young adults (18 to 25 years old) as opposed to older adults (>26 years of age).
- Young adults were three times more likely than youths aged 12 to 17 to have used *Salvia divinorum* in the past year.
- Use was more common in males than females.

*Salvia divinorum* is widely advertised and promoted on the Internet and sold in various "head shops" and natural food stores as a "legal" alternative to street drugs.

While some users have reported that the psychotropic effects of *Salvia divinorum* resemble those induced by other hallucinogens, such as LSD and phencyclidine, the overall experience appears to be quite unique.

**Deleted:** *Salvia divinorum* does not appear to cause the euphoria often associated with other psychoactive drugs, so many people who try it do not repeat the experience.

**Prepared by:** Cheryl Tremblay, Policy and Regulatory Affairs Division, DSCSD  
Stephanie Mitchell, Communications Advisor (HECSB)  
Darrin Denne, Communications Officer (HPFB)

**Reviewed by:** Mano Murty (MHPD – March 11, 2009)

**Approved by :**  
Approved

Andrew Adams, Director, OCS, DSCSD (March 1<sup>st</sup>, 2009)  
Nancy Richards, Director, Bureau of Policy and Regulatory Affairs, NHPD (January 23, 2009)  
Duc Vu, Director, Marketed Biologics, Biotechnology and Natural Health Products Bureau, MHPD (February 3, 2009)

Approved	Cathy Sabiston, DG, TDD, HECS (April 7, 2009)
Approved	Chris Turner, DG, MHPD (March 13, 2009)
Approved	Michelle Boudreau, DG, NHPD (March 19, 2009)
Approved	Sharon Mullins, A/DG, HPFBI (April 3, 2009)
Approved	Ken Polk, Communications Executive, HPFB (April 3, 2009)
Approved	Kathleen Malone, Senior Media Relations, PACCB (April 7, 2009)
Pending	Warren Braun, Director, Strategic Communications, PACCB
Pending	Peter Yendall, Director, Public Affairs, PACCB
Pending	Paul Glover, ADM, HECSB
Pending	Meena Ballantyne, ADM, HPFB
Pending	Anne Lamar, ADM, PACCB
Pending	DMO
Pending	MO
Pending	PCO



Cheryl  
Tremblay/HC-SC/GC/CA  
2009-06-24 09:28 AM

To Bronwyn Cline/HC-SC/GC/CA@HWC  
cc "Sue Lumsden" <lumsden@xplornet.com>, Lisa MacKay/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC  
bcc Cheryl Tremblay/HC-SC/GC/CA  
Subject [REDACTED]

Hi Bronwyn,

After taking a closer look at the media lines for *Salvia divinorum* we would like to propose that the following revision be made to the IYH on *Salvia* ( 2nd paragraph under Minimizing Your Risk on page 2) There was some back and forth regarding the inclusion of this statement during the development of the document however the inclusion of "under certain conditions of use" is simply not true in that it implies that *Salvia divinorum* has to be sold or used a certain way to be considered an NHP.

"Also, remember that just because a drug is plant-based or "natural," it does not mean it is safe. ~~Under certain conditions of use,~~ *Salvia divinorum* meets the definition of a "natural health product" (NHP) under Health Canada's *Natural Health Products Regulations* . However, no NHPs containing this substance have been approved for sale in Canada. This means that products claiming to contain *S. divinorum* have not been reviewed by Health Canada for safety, efficacy or quality. As such, they may be counterfeit or contain other ingredients that pose risks to health, and consumers should heed the "buyer beware" principle."

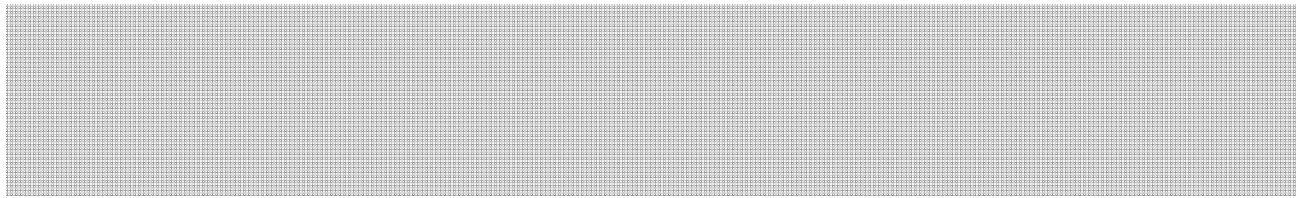
Thanks,  
Cheryl

Simon  
Carvalho/HC-SC/GC/CA  
2007-09-05 01:50 PM

To Jenny McLaughlin/HC-SC/GC/CA@HWC  
cc Philip Waddington/HC-SC/GC/CA@HWC, Nancy Richards/HC-SC/GC/CA@HWC  
Subject [REDACTED]

Jenny,





Simon

**Solicitor-Client Privilege/Protected**

This message is intended for the use of the individual or entity to which it is addressed and may contain information that is privileged or confidential and exempt from disclosure under applicable law. Unauthorized disclosure, copying or re-transmission is prohibited. Modification of the transmission is prohibited. If you have received this transmission in error, please notify me immediately by sending me a return e-mail copy. Then, delete the original message. Thank you.

Jenny McLaughlin/HC-SC/GC/CA

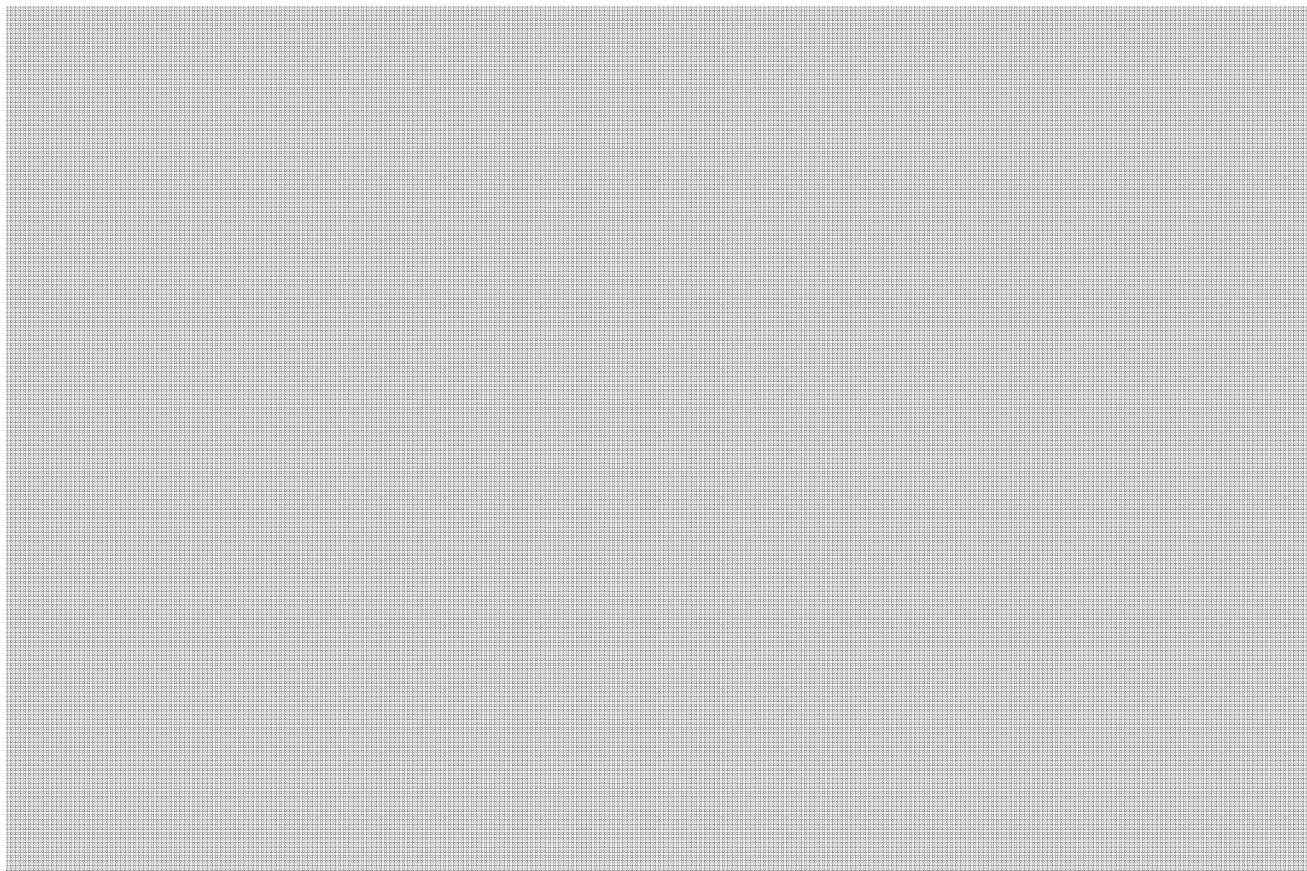


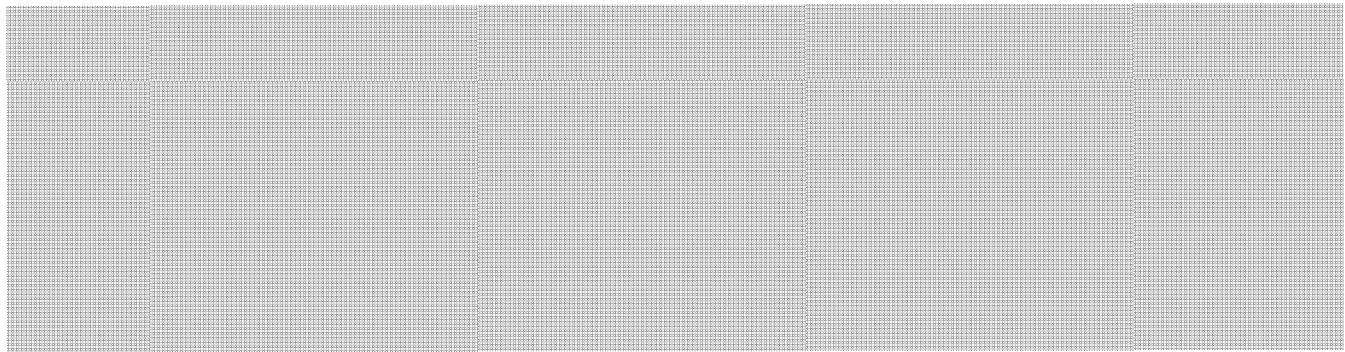
Jenny  
McLaughlin/HC-SC/GC/CA  
2007-09-05 10:22 AM

To Simon Carvalho/HC-SC/GC/CA@HWC  
cc Christine Zaczynski/HC-SC/GC/CA@HWC

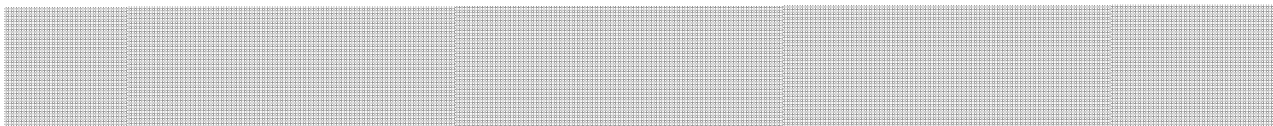
Subject

Hi Simon,





Reference Documents:




Thanks,  
Jenny

Stephanie Lessard/HC-SC/GC/CA



Stephanie  
Lessard/HC-SC/GC/CA  
2008-11-03 11:46 AM

To Cheryl Tremblay/HC-SC/GC/CA@HWC  
cc  
Subject 

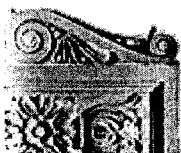
Hi Cheryl,




Thanks again,  
Stephanie

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Stephanie Lessard, MSc  
Head Health Risk Assessment Unit/ Chef, Unité d'évaluation des risques pour la santé  
Bureau of Clinical Trials and Health Science/ Bureau des essais cliniques et des sciences de la santé  
Natural Health Products Directorate/ Direction générale des produits de santé naturels  
2936 Baseline Rd, Tower A, A.L. 3302D/ 2936 chemin Baseline, indice de l'adresse 3302D  
(613) 946-0681  
Cheryl Tremblay/HC-SC/GC/CA



Cheryl  
Tremblay/HC-SC/GC/CA  
2008-11-03 11:38 AM

To Stephanie Lessard/HC-SC/GC/CA@HWC  
cc  
Subject Re: Fw: 





Hi Stephanie,

Any updates on NHPD's comments on the media lines?

Thanks,

Cheryl Tremblay  
Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Drug Strategy and Controlled Substances Directorate  
Health Canada  
Tel: (613) 954-6527  
Fax: (613) 946-4224  
Stephanie Lessard/HC-SC/GC/CA



Stephanie  
Lessard/HC-SC/GC/CA  
2008-10-29 09:19 AM

To Cheryl Tremblay/HC-SC/GC/CA@HWC

cc Jocelyn Kula/HC-SC/GC/CA@HWC

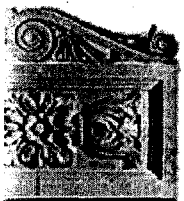
Subject Re: Fw: Reminder: Revised Media Lines for Salvia Divinorum

Thanks Cheryl. I really appreciate that.

Stephanie

---

Stephanie Lessard, MSc  
Head Health Risk Assessment Unit/ Chef, Unité d'évaluation des risques pour la santé  
Bureau of Clinical Trials and Health Science/ Bureau des essais cliniques et des sciences de la santé  
Natural Health Products Directorate/ Direction générale des produits de santé naturels  
2936 Baseline Rd, Tower A, A.L. 3302D/ 2936 chemin Baseline, indice de l'adresse 3302D  
(613) 946-0681  
Cheryl Tremblay/HC-SC/GC/CA



Cheryl  
Tremblay/HC-SC/GC/CA  
2008-10-29 08:07 AM

To Stephanie Lessard/HC-SC/GC/CA@HWC

cc Jocelyn Kula/HC-SC/GC/CA@HWC

Subject Re: Fw: Reminder: Revised Media Lines for Salvia Divinorum

Hi Stephanie,


By all means take a couple more days to ensure that everyone at NHPD that needs to look at it has seen it. Just a reminder, we are only reviewing at the working level at this point in time. Senior management (DG) level approvals will be coordinated by communications.

Thanks,

Cheryl Tremblay  
Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Drug Strategy and Controlled Substances Directorate  
Health Canada  
Tel: (613) 954-6527  
Fax: (613) 946-4224  
Stephanie Lessard/HC-SC/GC/CA



Stephanie  
Lessard/HC-SC/GC/CA  
2008-10-28 04:41 PM

To Cheryl Tremblay/HC-SC/GC/CA@HWC, Kyra  
Paterson/HC-SC/GC/CA@HWC  
cc Helmi Hussien/HC-SC/GC/CA@HWC  
Subject Re: Fw: Reminder: Revised Media Lines for Salvia Divinorum  




DRAFT - Media Lines Oct 20 2008\_NHPD.wpd

Hi Cheryl,

I've had the chance to look over these media lines, and I don't have much in the way of comment (please see my comments in blue in the attached document).

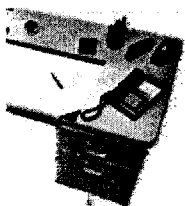
I just wanted to let you know that Robin is away on French training, and only forwarded this to me yesterday. As a result I haven't had the chance to ensure that all the appropriate people at NHPD have had the chance to provide comment.

**Kyra:** I think you were involved in this issue at some point. Do you have any comments, or know of anyone else that may need to be consulted?

Thanks,  
Stephanie

---

Stephanie Lessard, MSc  
Head Health Risk Assessment Unit/ Chef, Unité d'évaluation des risques pour la santé  
Bureau of Clinical Trials and Health Science/ Bureau des essais cliniques et des sciences de la santé  
Natural Health Products Directorate/ Direction générale des produits de santé naturels  
2936 Baseline Rd, Tower A, A.L. 3302D/ 2936 chemin Baseline, indice de l'adresse 3302D  
(613) 946-0681  
Robin Marles/HC-SC/GC/CA



Robin Marles/HC-SC/GC/CA  
2008-10-27 09:41 AM

To stephanie\_lessard@hc-sc.gc.ca  
cc  
Subject Fw: Reminder: Revised Media Lines for Salvia Divinorum

-----  
Sent from my BlackBerry Wireless Handheld  
Cheryl Tremblay

----- Original Message -----

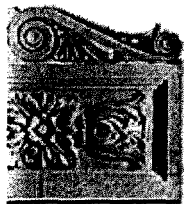
**From:** Cheryl Tremblay  
**Sent:** 2008-10-27 09:30 AM EDT  
**To:** Duc Vu; Jenna Griffiths; Michelle Gillespie; Robin Marles  
**Subject:** Reminder: Revised Media Lines for Salvia Divinorum

Good Morning,

Just a friendly reminder to submit any comments on the media lines on *Salvia divinorum* by EOB tomorrow.

Thank you,  
Have a great day!

Cheryl Tremblay  
Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Drug Strategy and Controlled Substances Directorate  
Health Canada  
Tel: (613) 954-6527  
Fax: (613) 946-4224  
Cheryl Tremblay/HC-SC/GC/CA



Cheryl  
Tremblay/HC-SC/GC/CA  
2008-10-20 02:13 PM

To Barbara Benning/HC-SC/GC/CA@HWC, Duc Vu/HC-SC/GC/CA@HWC, Michelle Gillespie/HC-SC/GC/CA@HWC, Robin Marles/HC-SC/GC/CA@HWC, Jenna Griffiths/HC-SC/GC/CA@HWC  
cc Jocelyn Kula/HC-SC/GC/CA@HWC, Andrew Adams/HC-SC/GC/CA@HWC, Gary Condran/HC-SC/GC/CA@HWC  
Subject Revised Media Lines for Salvia Divinorum

Good Afternoon,

Further to inter-branch meetings between HPFB (NHPD, MHPD, HPFBI) and HECSB (DSCSD), held in May 2007, September of 2007, and September 2008 regarding *Salvia divinorum*, DSCSD is working to update and finalize the media lines on this substance.

Please find attached, a copy of the revised media lines for *Salvia divinorum* for your review and comments. Please forward any comments to me by Tuesday, October 28, 2008.

HECSB Communications will coordinate senior management approvals once we have received and considered all working level input.



DRAFT - Media Lines Oct 20 2008.wpd

Thank you,

Cheryl Tremblay  
Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Drug Strategy and Controlled Substances Directorate  
Health Canada  
Tel: (613) 954-6527  
Fax: (613) 946-4224

s.19(1)

"Sue Lumsden" [REDACTED]



"Sue Lumsden"

2009-05-27 10:07 AM

To "Lisa MacKay" <Lisa\_MacKay@hc-sc.gc.ca>

cc "Valerie Hurry" <Valerie\_Hurry@hc-sc.gc.ca>, Brittany Sauvé <brittany\_sauve@hc-sc.gc.ca>, "Cheryl Tremblay" <Cheryl\_Tremblay@hc-sc.gc.ca>, "Jocelyn Kula" <jocelyn\_kula@hc-sc.gc.ca>, "Mano Murty" <Mano\_Murty@hc-sc.gc.ca>, <Robert\_Leitch@hc-sc.gc.ca>, "Robin Marles" <robin\_marles@hc-sc.gc.ca>

Subject IYH on Salvia divinorum - Ready for the formal approvals process

Good morning Lisa,

I've attached Draft Seven of the IYH on Salvia divinorum and am requesting that you start it through the formal approvals process.

The following Program Contacts all gave a thumbs up for Draft Six to go into formal approvals: Jocelyn Kula, Cheryl Tremblay and Brittany Sauvé (HECS-B), Robin Marles and Valerie Hurry (NHPD), and Robert Leitch and Mano Murty (MHPD).

The only differences between Draft Six and Seven are as follows:

- highlighter and strikethrough marking changes to text in Draft Six were removed for Draft Seven, as all changes were agreed upon by the Program Contacts
- at the suggestion of Brittany Sauvé, a reference (and link) to a provincial survey (Ontario) asking questions about Salvia use was replaced with a reference (and link) to a national survey that is asking



Cheryl  
Tremblay/HC-SC/GC/CA  
2009-07-30 03:26 PM

To John Stevenson/HC-SC/GC/CA@HWC  
cc Jocelyn Kula/HC-SC/GC/CA@HWC  
Subject Re: Fw: New Content for CTUMS 2010 Wave 1 / Examiner le  
contenu de la phase 1 de l'ESUTC de l'année 2010

Hi John,

Further to our conversation this afternoon, PRAD would like to submit the following topics for your consideration for the 2010 Wave 1 CTUMS. I've attached some reference documents to give up a quick update on these substances, however, please do not disseminate as these media lines have not made their way through formal approvals.

Salvia Divinorum



ORS News Piece on Salvia ENG.ppt Salvia ML v.7 April 2009\_CSTD Comments re IYH.doc

Spice



Spice media lines 1412 July 30 2009\_Diane Approved.doc

Thanks,

Cheryl Tremblay  
Policy and Regulatory Affairs Division / Division des politiques et affaires réglementaires  
Office of Controlled Substances / Bureau des substances contrôlées  
Controlled Substances and Tobacco Directorate / Direction des substances contrôlées et de la lutte au  
tabagisme  
Healthy Environments and Consumer Safety Branch / Direction générale de la santé environnementale et  
de la sécurité consommateurs  
Health Canada / Santé Canada  
Tel: (613) 954-6527 Fax: (613) 946-4224  
Jocelyn Kula/HC-SC/GC/CA

— Forwarded by Diane Allan/HC-SC/GC/CA on 2009-07-21 12:19 PM —

John  
Stevenson/HC-SC/GC/CA  
2009-07-21 10:45 AM

To CSTD-Directors  
cc Cathy A Sabiston/HC-SC/GC/CA@HWC  
Subject Fw: New Content for CTUMS 2010 Wave 1 / Examiner le  
contenu de la phase 1 de l'ESUTC de l'année 2010

Hello,

We are starting to review the content for the CTUMS 2010 Wave 1 (February - June). Please find attached the 2009 Wave 2 questionnaire for your information. If you have any surveillance ideas that you would like to have considered for 2010 Wave 1, please send them by noon August 12, 2009 to John

Stevenson, Survey Methodologist, Office of Research, Surveillance and Evaluation, at  
john\_stevenson@hc-sc.gc.ca or at 613-948-2627 if you have additional questions.

Thank you for your input,

---

Bonjour,

Nous commençons à examiner le contenu de la phase 1 de l'ESUTC de l'année 2010 (février - juin).  
Veuillez trouver ci-joint le questionnaire de la Phase 2 de l'année 2009 pour votre information. Si vous  
avez des idées de surveillance que vous aimeriez considérer pour la phase 1 de l'année 2010, veuillez  
envoyer vos commentaires d'ici midi, le 12 août 2009 à John Stevenson, Enquêteur de la méthodologie,  
Bureau de la recherche, de la surveillance et de l'évaluation, à john\_stevenson@hc-sc.gc.ca ou au  
613-948-2627 si vous avez des questions supplémentaires.

Merci pour vos commentaires,




CTUMS\_wave2\_2009\_F.doc



CTUMS\_wave2\_2009\_E.doc



**Cheryl  
Tremblay/HC-SC/GC/CA**  
2009-08-17 10:58 AM

**To** John Stevenson/HC-SC/GC/CA@HWC  
**cc**  
**bcc**  
**Subject** Re: Fw: New Content for CTUMS 2010 Wave 1 / Examiner le  
contenu de la phase 1 de l'ESUTC de l'année 2010 


Hi John,

Sorry for the late reply....just got back from holidays.

That's correct.... and thanks : )

**Cheryl Tremblay**  
**Policy and Regulatory Affairs Division / Division des politiques et affaires réglementaires**  
**Office of Controlled Substances / Bureau des substances contrôlées**  
**Controlled Substances and Tobacco Directorate / Direction des substances contrôlées et de la lutte au**  
**tabagisme**  
**Healthy Environments and Consumer Safety Branch / Direction générale de la santé environnementale et**  
**de la sécurité consommateurs**  
**Health Canada / Santé Canada**  
**Tel: (613) 954-6527 Fax: (613) 946-4224**  
**John Stevenson/HC-SC/GC/CA**

**John  
Stevenson/HC-SC/GC/CA**  
2009-07-31 09:21 AM

**To** Cheryl Tremblay/HC-SC/GC/CA@HWC  
**cc** Jocelyn Kula/HC-SC/GC/CA@HWC  
**Subject** Re: Fw: New Content for CTUMS 2010 Wave 1 / Examiner le  
contenu de la phase 1 de l'ESUTC de l'année 2010 

Cheryl,

So if I have it correct, you are looking for additional questions on:

1. Salvia Divinorum; and
2. "Spice"?

I will put in for consideration Ever Use (lifetime) and Past 30-day Use as we do with all of the tobacco products on the CTUMS.

Thanks,

**John Stevenson**  
**Survey Methodologist and Research Analyst**  
**Controlled Substances and Tobacco Directorate**  
**Healthy Environments and Consumer Safety Branch**  
**Health Canada**  
**Phone: (613) 948-2627**  
**Fax: (613) 954-2292**  
**Email: john\_stevenson@hc-sc.gc.ca**  
**Cheryl Tremblay/HC-SC/GC/CA**



Suzanna  
Keller/HC-SC/GC/CA  
2009-08-25 02:46 PM

To Cheryl Tremblay/HC-SC/GC/CA@HWC  
cc  
bcc

Subject Fw: New CTUMS Content Requests for 2010 Wave 1

Hi Cheryl,

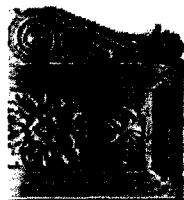
There is a salvia question on the Youth Smoking Survey and, we believe both salvia and spice are covered by CADUMS. At this time, we won't be adding questions about these substances to CTUMS, which is primarily a tobacco-use monitoring survey.

Kind regards,  
Suzanna

Suzanna Keller  
Epidemiologist / Épidémiologiste  
Controlled Substances and Tobacco Directorate, HECS  
Direction des substances contrôlées et de la lutte au tabagisme, DGSESC

Room A712 / Pièce A712  
123 Slater, Ottawa, ON  
K1A 0K9  
AL 3507B/ IA 3507B  
tel: (613) 948-7536  
fax: (613) 954-2292  
suzanna\_keller@hc-sc.gc.ca

— Forwarded by John Stevenson/HC-SC/GC/CA on 2009-08-05 10:40 AM —



Cheryl  
Tremblay/HC-SC/GC/CA  
2009-07-30 03:26 PM

To John Stevenson/HC-SC/GC/CA@HWC  
cc Jocelyn Kula/HC-SC/GC/CA@HWC  
Subject Re: Fw: New Content for CTUMS 2010 Wave 1 / Examiner le contenu de la phase 1 de l'ESUTC de l'année 2010

Hi John,

Further to our conversation this afternoon, PRAD would like to submit the following topics for your consideration for the 2010 Wave 1 CTUMS. I've attached some reference documents to give up a quick update on these substances, however, **please do not disseminate** as these media lines have not made their way through formal approvals.

Salvia Divinorum



ORS News Piece on Salvia ENG.ppt Salvia ML v.7 April 2009\_CSTD Comments re IYH.doc

Spice





Spice media lines 1412 July 30 2009\_Diane Approved.doc

Thanks,

Cheryl Tremblay  
Policy and Regulatory Affairs Division / Division des politiques et affaires réglementaires  
Office of Controlled Substances / Bureau des substances contrôlées  
Controlled Substances and Tobacco Directorate / Direction des substances contrôlées et de la lutte au  
tabagisme  
Healthy Environments and Consumer Safety Branch / Direction générale de la santé environnementale et  
de la sécurité consommateurs  
Health Canada / Santé Canada  
Tel: (613) 954-6527 Fax: (613) 946-4224  
Jocelyn Kula/HC-SC/GC/CA

----- Forwarded by Diane Allan/HC-SC/GC/CA on 2009-07-21 12:19 PM -----

John  
Stevenson/HC-SC/GC/CA  
2009-07-21 10:45 AM

To CSTD-Directors  
cc Cathy A Sabiston/HC-SC/GC/CA@HWC

Subject Fw: New Content for CTUMS 2010 Wave 1 / Examiner le  
contenu de la phase 1 de l'ESUTC de l'année 2010

Hello,

We are starting to review the content for the CTUMS 2010 Wave 1 (February - June). Please find attached the 2009 Wave 2 questionnaire for your information. If you have any surveillance ideas that you would like to have considered for 2010 Wave 1, please send them by noon August 12, 2009 to John Stevenson, Survey Methodologist, Office of Research, Surveillance and Evaluation, at john\_stevenson@hc-sc.gc.ca or at 613-948-2627 if you have additional questions.

Thank you for your input,

---

Bonjour,

Nous commençons à examiner le contenu de la phase 1 de l'ESUTC de l'année 2010 (février - juin). Veuillez trouver ci-joint le questionnaire de la Phase 2 de l'année 2009 pour votre information. Si vous avez des idées de surveillance que vous aimeriez considérer pour la phase 1 de l'année 2010, veuillez envoyer vos commentaires d'ici midi, le 12 août 2009 à John Stevenson, Enquêteur de la méthodologie, Bureau de la recherche, de la surveillance et de l'évaluation, à john\_stevenson@hc-sc.gc.ca ou au 613-948-2627 si vous avez des questions supplémentaires.

Merci pour vos commentaires,



CTUMS\_wave2\_2009\_F.doc CTUMS\_wave2\_2009\_E.doc



Bronwyn Cline/HC-SC/GC/CA  
2009-08-31 10:09 AM

To Cheryl Tremblay/HC-SC/GC/CA@HWC  
cc  
bcc  
Subject Re: Salvia D media lines

The bilat hasn't happened yet. Karen says hopefully this week.

Bronwyn Cline  
Communications Officer | Agente des communications

613-941-2511 | facsimile / télécopieur 613-948-8085  
bronwyn\_cline@hc-sc.gc.ca  
Health Canada | 269 Laurier Ave Ottawa ON K1A 0K9  
Santé Canada | 269 ave Laurier Ottawa ON K1A 0K9  
Government of Canada | Gouvernement du Canada  
Bronwyn Cline/HC-SC/GC/CA



Bronwyn Cline/HC-SC/GC/CA  
2009-08-31 09:56 AM

To Cheryl Tremblay/HC-SC/GC/CA  
cc  
Subject Re: Salvia D media lines

Hello again,

Knew I was forgetting something...went back through my emails, and around August 17th, Karen said that Paul wanted to discuss this IYH with Cathy at a bilat. I'll send Karen an email to see if that bilat happened before Cathy left.

Thanks,

Bronwyn Cline  
Communications Officer | Agente des communications

613-941-2511 | facsimile / télécopieur 613-948-8085  
bronwyn\_cline@hc-sc.gc.ca  
Health Canada | 269 Laurier Ave Ottawa ON K1A 0K9  
Santé Canada | 269 ave Laurier Ottawa ON K1A 0K9  
Government of Canada | Gouvernement du Canada  
Bronwyn Cline/HC-SC/GC/CA



Bronwyn Cline/HC-SC/GC/CA  
2009-08-31 09:50 AM

To Cheryl Tremblay/HC-SC/GC/CA  
cc  
Subject Re: Salvia D media lines

Hi Cheryl,

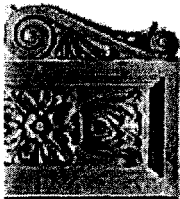
I haven't done anything with the media lines, because I wanted to wait until Paul had signed off on the article so I would know if further changes needed to be made.

As for the article, Jay Khosla's email with responses to Paul's comments got lost for about a month, and it's now back with Paul's advisor. I'll follow-up on that the article this morning.

Thanks,

Bronwyn Cline  
Communications Officer | Agente des communications

613-941-2511 | facsimile / télécopieur 613-948-8085  
bronwyn\_cline@hc-sc.gc.ca  
Health Canada | 269 Laurier Ave Ottawa ON K1A 0K9  
Santé Canada | 269 ave Laurier Ottawa ON K1A 0K9  
Government of Canada | Gouvernement du Canada  
Cheryl Tremblay/HC-SC/GC/CA



Cheryl  
Tremblay/HC-SC/GC/CA  
2009-08-31 09:48 AM

To Bronwyn Cline/HC-SC/GC/CA@HWC

cc

Subject Re: Salvia D media lines 

Morning Bronwyn,

Any news on what stage the media lines on Salvia are at? We provided the comments attached below on June 23rd.

Anything new on the IYH on Salvia? We responded to some of the ADMs comments on June 23rd as well. Are they going up for formal approvals together?

Reason I ask is that CBSA is asking for some info on whether HC regulates it and we would like to provide them with a few lines.

Thanks,

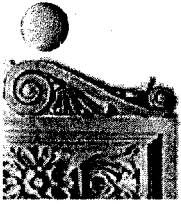
Cheryl Tremblay  
Policy and Regulatory Affairs Division / Division des politiques et affaires réglementaires  
Office of Controlled Substances / Bureau des substances contrôlées  
Controlled Substances and Tobacco Directorate / Direction des substances contrôlées et de la lutte au tabagisme  
Healthy Environments and Consumer Safety Branch / Direction générale de la santé environnementale et de la sécurité consommateurs  
Health Canada / Santé Canada  
Tel: (613) 954-6527 Fax: (613) 946-4224  
Cheryl Tremblay/HC-SC/GC/CA




Cheryl  
Tremblay/HC-SC/GC/CA  
2009-06-23 02:38 PM

To Bronwyn Cline/HC-SC/GC/CA@HWC

cc Christine Roush/HC-SC/GC/CA@HWC, Brooke  
Bryce/HC-SC/GC/CA@HWC, Jocelyn



Kula/HC-SC/GC/CA@HWC  
Subject Re: Salvia D media lines 

Hi Bronwyn,

Here are CSTD's comments on media lines for Salvia Divinorum.



Salvia ML v.7 April 2009\_CSTD Comments re IYH.doc

Let me know if you have any questions,  
Thanks,

**Cheryl Tremblay**  
Policy and Regulatory Affairs Division / Division des politiques et affaires réglementaires  
Office of Controlled Substances / Bureau des substances contrôlées  
Controlled Substances and Tobacco Directorate / Direction des substances contrôlées et de la lutte au  
tabagisme  
Healthy Environments and Consumer Safety Branch / Direction générale de la santé environnementale et  
de la sécurité consommateurs  
Health Canada / Santé Canada  
Tel: (613) 954-6527 Fax: (613) 946-4224  
Bronwyn Cline/HC-SC/GC/CA



**Bronwyn  
Cline/HC-SC/GC/CA**  
2009-06-16 03:33 PM

To Cheryl Tremblay/HC-SC/GC/CA@HWC  
cc

Subject Salvia D media lines

Hi Cheryl,

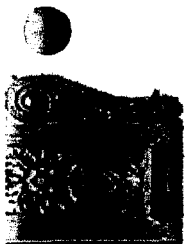
Can you please make sure to cc Christine Roush and Brooke Bryce when you send me your comments on  
the Salvia D lines?

FYI, the IYH on Salvia is currently with the HECS ADM.

Thanks,

**Bronwyn Cline**  
Communications Officer | Agente des communications

613-941-2511 | facsimile / télécopieur 613-948-8085  
bronwyn\_cline@hc-sc.gc.ca  
Health Canada | 269 Laurier Ave Ottawa ON K1A 0K9  
Santé Canada | 269 ave Laurier Ottawa ON K1A 0K9  
Government of Canada | Gouvernement du Canada



**Cheryl  
Tremblay/HC-SC/GC/CA**  
2009-08-31 02:21 PM

To Cheryl Tremblay/HC-SC/GC/CA@HWC  
cc  
bcc  
Subject Fw: Status of Salvia

Hi Mark,

Sorry for the late reply, I just wanted to verify the status of the media lines before forwarding along. I've attached the most recent version. They have not been approved by ADMO yet as they are waiting for the approval on the It's Your Health article on Salvia first to see if any changes to that document need to be reflected in the media lines. Paul and Cathy are supposed to discuss the IYH article and their next bilat when she returns from holidays. So... I wouldn't send them the whole doc, maybe just select a few additional lines to add context?




Salvia ML v.7 April 2009\_CSTD Comments re IYH.doc

Let me know if you have any questions,  
Thanks,  
Cheryl  
Jocelyn Kula/HC-SC/GC/CA



**Jocelyn Kula/HC-SC/GC/CA**  
2009-08-31 09:38 AM

To Mark Kozlowski/HC-SC/GC/CA@HWC  
cc "Cheryl Tremblay" <Cheryl\_Tremblay@hc-sc.gc.ca>  
Subject Re: Status of Salvia 

Pls speak to Cheryl as she can provide a copy of the latest media lines...it is considered to be an NHP....  
JK

Sent by blackberry

Jocelyn Kula  
Manager/ Gestionnaire  
Policy and Regulatory Affairs Division/ Division des politiques et affaires reglementaires  
Mark Kozlowski

----- Original Message -----

**From:** Mark Kozlowski  
**Sent:** 2009-08-31 09:26 AM EDT  
**To:** Jocelyn Kula  
**Subject:** Fw: Status of Salvia

Jocelyn,

Anything I can provide to CBSA? I know not controlled under CDSA, but wondering if you have anything additional?

MK

----- Forwarded by Mark Kozlowski/HC-SC/GC/CA on 2009-08-31 09:25 AM -----



"Bothwell, John"  
<John.Bothwell@cbsa-asfc.g  
c.ca>

2009-08-31 09:03 AM

To "Mark Kozlowski" <Mark\_Kozlowski@hc-sc.gc.ca>

cc

Subject Status of Salvia

Hi Mark

We are seeing more and more Salvia at our ports of entry in pipes or in small quantities on persons.  
Would you be able to tell me if Salvia is regulated by Health Canada in any way?

Thanks

John

**John Bothwell**  
Senior Intelligence Officer  
Organized Crime and Contraband Intelligence  
Intelligence Directorate  
Canada Border Services Agency  
11th floor  
300 Slater Street  
Ottawa, Ontario  
K1A 0L8

613.954.7600 work  
613.293.5061 cell  
john.bothwell@cbsa-asfc.gc.ca

DRAFT  
April 7, 2009

## Media Lines Regulatory Control of *Salvia Divinorum*

### Issue

Since 2006, Health Canada has noted ongoing media interest regarding the availability of *Salvia divinorum* on the Canadian market. Health Canada has also received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum*, particularly given reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties.

Deleted: observed a steady increase in the amount of

### Key Messages:

- Health Canada continues to collect and consider information about *Salvia divinorum* and its active ingredient, salvinorin A, from both national and international sources in order to determine what, if any, regulatory controls are needed.
- While the media have reported that use of *Salvia divinorum* is on the rise in certain parts of the country, Health Canada does not currently have statistics on its use across the Canadian population.
- Health Canada is taking steps to address this lack of data. Questions regarding the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey. A general open-ended question about the use of other substances was also included in the 2008 Canadian Alcohol and Drug Use Monitoring Survey.

Deleted: relevant

Deleted: S

Deleted: Ontario Student

Deleted: and Health

### Supplementary Messages:

#### *On the classification of *Salvia divinorum*:*

- In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA).
- *Salvia divinorum* is not listed under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these conventions.
- Several countries (Australia, Belgium, Denmark, Sweden, Italy, Spain, Finland and South Korea) have placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Although some individual U.S. states have implemented laws

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restricting its use, sale and/or distribution, *Salvia divinorum* and salvinorin A are not federally regulated under the *Controlled Substances Act* in the United States.

Deleted: is

- *Salvia divinorum* meets the definition of a natural health product under the *Natural Health Product Regulations* (NHPR). This means that *Salvia* products that are not in compliance with the NHPR may be subject to compliance and enforcement actions.
- As of January 2009, Health Canada had not issued any Natural Product Numbers (NPN) or Drug Identification Numbers – Homeopathic Medicine (DIN-HM) for *Salvia divinorum* products.

Deleted: , when associated with health claims, could

***If asked for specifics on when the survey data will be available:***

- Data from the Canadian Alcohol and Drug Use Monitoring Survey will be available in summer 2009, while the results of the Youth Smoking Survey and the Canadian Alcohol and Drug Use Monitoring Survey likely will not be available until 2010.

Deleted: Ontario Student

Deleted: and Health

**Questions and Answers**

**Q1 – If Health Canada is aware of *Salvia divinorum*'s ill-effects, why isn't it illegal?**

A1 – Very few controlled scientific studies of the physical and psychotropic effects of *Salvia divinorum* on humans have been carried out, and using these studies to predict the potential for addiction and abuse associated with *Salvia divinorum* is difficult. More controlled systematic research in this area is needed.

Health Canada has only received a limited number of communications regarding *Salvia divinorum* from law enforcement agencies, and none of these has advised that the use of *Salvia divinorum* poses any particular threat to public safety.

**Q2 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?**

A2 – The *Natural Health Product Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *Salvia divinorum*.

**Q3 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A3 – *Salvia divinorum* products that are not in compliance with the *Natural Health Product Regulations* and/or are found to pose a risk to the health of Canadians may be subject to compliance and enforcement action by Health Canada. An import target for products containing *Salvia divinorum* has already been placed with Canada Border Services Agency.

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**Q4 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum*. What does that involve and what stage is it at?**

A4 - Health Canada considers several factors in determining whether scheduling a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in regulatory status;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

**Deleted:** control  
**Deleted:** and scheduling  
**Deleted:** scheduled  
**Deleted:** A  
**Deleted:** liability  
**Deleted:** potential of  
**Deleted:** and misuse

Health Canada has only anecdotal information about the last three of the above-mentioned factors, and thus is not yet convinced that the controls imposed by the CDSA are an appropriate strategy for managing the risks associated with the use of *Salvia divinorum*. The survey results from the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey will help fill some of the information gaps. The data, however, will not likely be available until 2010. In the interim, Health Canada will continue to collect and consider information regarding *Salvia divinorum* as it becomes available.

**Deleted:** , however,

**Q5 – Didn't an internal report from Health Canada's Marketed Health Products Directorate recommend that *Salvia divinorum* be scheduled under the CDSA? Why has that recommendation not been acted upon?**

A5 – See A4

**Q6 – What is the significance of the adverse reaction reports that Health Canada has received with respect to the use of *Salvia divinorum*?**

A6 – Health Canada has received four domestic adverse reaction reports related to the use of *Salvia divinorum* as a hallucinogen through the Canada Vigilance database. The number of reports and the nature of reactions reported are not adequate to characterize the risk to the general population. These data cannot be used to determine incidence of use in the general population, as Health Canada does not have any information about the number of individuals using or who have used *Salvia divinorum*.

**Background**

*Salvia divinorum* is a species of sage belonging to the mint family that is chewed or smoked in order to induce its psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are often described as unpleasant.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. While no validated data exist regarding usage in Canada, data from a 2006 National Survey on Drug Use and Health Report, published by the U.S.

Substance Abuse and Mental Health Services Administration has estimated that:

- 1.8 million persons aged 12 or older have used *Salvia divinorum* at least once in their lifetime, and approximately 750,000 did so in the past year.
- Use was more common among young adults (18 to 25 years old) as opposed to older adults (>26 years of age).
- Young adults were three times more likely than youths aged 12 to 17 to have used *Salvia divinorum* in the past year.
- Use was more common in males than females.

*Salvia divinorum* is widely advertised and promoted on the Internet and sold in various "head shops" and natural food stores as a "legal" alternative to street drugs.

While some users have reported that the psychotropic effects of *Salvia divinorum* resemble those induced by other hallucinogens, such as LSD and phencyclidine, the overall experience appears to be quite unique.

**Deleted:** *Salvia divinorum* does not appear to cause the euphoria often associated with other psychoactive drugs, so many people who try it do not repeat the experience.

**Prepared by:** Cheryl Tremblay, Policy and Regulatory Affairs Division, DSCSD  
Stephanie Mitchell, Communications Advisor (HECSB)  
Darrin Denne, Communications Officer (HPFB)

**Reviewed by:** Mano Murty (MHPD – March 11, 2009)

**Approved by :**  
Approved

Andrew Adams, Director, OCS, DSCSD (March 1<sup>st</sup>, 2009)  
Nancy Richards, Director, Bureau of Policy and Regulatory Affairs, NHPD (January 23, 2009)  
Duc Vu, Director, Marketed Biologics, Biotechnology and Natural Health Products Bureau, MHPD (February 3, 2009)

Approved	Cathy Sabiston, DG, TDD, HECS (April 7, 2009)
Approved	Chris Turner, DG, MHPD (March 13, 2009)
Approved	Michelle Boudreau, DG, NHPD (March 19, 2009)
Approved	Sharon Mullins, A/DG, HPFBI (April 3, 2009)
Approved	Ken Polk, Communications Executive, HPFB (April 3, 2009)
Approved	Kathleen Malone, Senior Media Relations, PACCB (April 7, 2009)
Pending	Warren Braun, Director, Strategic Communications, PACCB
Pending	Peter Yendall, Director, Public Affairs, PACCB

Pending	Paul Glover, ADM, HECSB
Pending	Meena Ballantyne, ADM, HPFB
Pending	Anne Lamar, ADM, PACCB

Pending	DMO
Pending	MO
Pending	PCO

*Denis  
Cameron*

**QUESTION PERIOD NOTE**  
**NOTE POUR LA PÉRIODE DE**  
**QUESTIONS**

Date:	September 8, 2009
Classification :	HECS PROTECTED - SESC PROTÉGÉ

**SUBJECT - SUJET**

English:

**DRUGS - SALVIA DIVINORUM**

Français:

**DROGUES - SALVIA DIVINORUM**

**SYNOPSIS - SOMMAIRE**

English:

Since 2006, Health Canada has noted ongoing media interest regarding the availability of Salvia divinorum on the Canadian market. Health Canada has also received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of Salvia divinorum, particularly given reports from scientific and media sources suggesting that Salvia divinorum is being used by adolescents and young adults specifically for its hallucinogenic properties.

**ANTICIPATED QUESTION - QUESTION PRÉVUE**

English:

What is Health Canada doing to protect Canadians from the potential adverse effects associated with the use of Salvia divinorum?

Français:

Quelles mesures Santé Canada prend-il pour protéger les Canadiens contre les effets indésirables possibles liés à l'utilisation de la Salvia divinorum?

English:

Health Canada continues to collect and consider information about *Salvia divinorum* and its active ingredient, salvinorin A, from both national and international sources in order to determine what, if any, regulatory controls are needed.

Scientific info

Health Canada does not currently have statistics on the use of *Salvia divinorum* across the Canadian population. Health Canada is taking steps to address this lack of data by including questions regarding the use of *Salvia divinorum* to the 2008-2009 Youth Smoking Survey and to the 2009 Canadian Alcohol and Drug Use Monitoring Survey.

The results from these surveys, ~~which will not likely be available until 2010~~, <sup>to</sup> will help fill some of the information gaps and will assist Health Canada in determining the most appropriate strategy to manage the risks associated with the use of *Salvia divinorum*.

In the meantime, He is preparing a

Français:

~~IVH~~ ~~est~~ ~~inséparables~~ ~~matériaux~~

## BACKGROUND - CONTEXTE

English:

*Salvia divinorum* is a species of sage which belongs to the mint family, and which is found in the form of dried leaves, extract and plant cuttings. Also known as "diviner's sage", the plant is known to induce illusions and hallucinations when chewed or smoked. The leaves of this plant have been used traditionally by the Mazatec Indians in Mexico for many years. Traditional use involves chewing the leaves or using them to make a tea for medicinal purposes (e.g., to treat such conditions as headache or stomach upset), or to induce a "mystical" or hallucinogenic experience for spiritual purposes.

The main active ingredient of *Salvia divinorum* is salvinorin A. Salvinorin A is a highly efficacious *kappa*-opioid receptor agonist, and as such, this substance has been used to investigate the pharmacological contribution of this opioid system to the etiology of depression, dementia, bipolar disorder and schizophrenia.

*Salvia divinorum* is widely touted as a "legal" alternative to street drugs on the Internet, and has also been reported to be one of the most prevalently marketed herbal dietary supplements available for use as an alternative to illicit drugs of abuse among adolescents and young adults. While very little is known about how and where *Salvia divinorum* is sold in Canada, it is suspected that it is mainly purchased over the Internet and/or bought at head shops, ~~and~~ alternative life style stores, etc.

#### Regulatory Control of *Salvia divinorum*

In Canada neither the herb, *Salvia divinorum*, nor its main active ingredient salvinorin A, are regulated in any Schedule to the *Controlled Drugs and Substances Act* (CDSA).

*Salvia divinorum* does meet the definition of a "natural health product" (NHP) under the *Natural Health Product Regulations* (NHPR), which means that products that are not in compliance with the NHPR may be subject to compliance and enforcement actions, however, Health Canada has not approved any NHPs containing this substance for sale in Canada and it does not appear to be sold as a "health product."

*Salvia divinorum* is not listed under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these conventions.

Several countries (Australia, Belgium, Denmark, Sweden, Italy, Spain, Finland and South Korea) have placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Although some individual U.S. states have implemented laws restricting its use, sale and/or distribution, *Salvia divinorum* and salvinorin A are not federally regulated under the *Controlled Substances Act* in the United States.


#### Current Situation in Canada

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention in 2002. In 2004, Health Canada received four domestic adverse reaction reports related to the use of *Salvia divinorum* as a hallucinogen through the Canada Vigilance database, however, the number of reports and the nature of reactions reported are not adequate to characterize the risk to the general population. These data cannot be used to determine incidence of use in the general population, as Health Canada does not have any information about the number of individuals using or who have used *Salvia divinorum*.

*Salvia divinorum* could <sup>potentially</sup> also be scheduled under the CDSA. In contemplating whether to add a substance to one of the schedules to the CDSA, Health Canada considers a range of factors including, the potential for abuse and risk of addiction associated with the substance, the extent of actual abuse of the substance in Canada and internationally, the overall risk to public health and safety posed by the substance, etc. In the case of *Salvia divinorum*, information about these factors is either missing or anecdotal in nature. For example, very few controlled scientific studies of the physical and psychotropic effects of *Salvia divinorum* on humans have been carried out, and using these studies to predict the potential for addiction and abuse associated with *Salvia divinorum* is difficult. More controlled systematic research in this area is needed.

Health Canada is taking steps to address the lack of data regarding the use of and/or extent of abuse involving *Salvia divinorum*. Questions regarding the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. A general open-ended question about the use of other substances has also been included in the 2008 Canadian Alcohol and Drug Use Monitoring Survey. These survey results will not however be available until 2010.

In the interim, Health Canada has placed *Salvia divinorum* on its list of substances of concern and will continue to collect and consider information about *Salvia divinorum* and its active ingredient, salvinin A, from both national and international sources in order to determine what, if any, regulatory controls are needed.

ATTACHMENTS / PIÈCE(S)-JOINTE(S)
 Salvia ML v.7 April 2009_CSTD Comments re IYH.doc

Contact/Personne ressource : Cheryl Tremblay/HC-SC/GC/CA	Tel. no./No de tél. 613-954-6527	Approved by/ Approuvé par	Tel. no./No. de tél.
	Mobile/ Cellulaire:	Title/ Titre:	Mobile/ Cellulaire:
Alternate/ Secondaire:	Telephone/ Téléphone:		
	Mobile/ Cellulaire:		

Date Prepared/Préparé le : 2009-09-08

Prepared by/Préparé par : Cheryl Tremblay Phone/ No de tél. : 613-954-6527

Office/Bureau : Office of Controlled Substances

Date Contact Signed/  
Signature de la personne  
ressource :

Contact Signed - Signé

D.G. Verification/  
Vérification par le D.E. :

Cathy Sabiston

D.G. Approved / Approuvé D.É.

Date D.G. Verified/  
Date vérifié par le D.E. :

Programme : Controlled Substances and Tobacco Directorate

ADM Approved/ Approbation  
par le SMA : Paul Glover, ADM (HECS/SESC)  
(946-6701)

Branch/ Direction générale : HECS/SESC

Department/ Ministère : Health Canada / Santé Canada

s.19(1)



Cathy A  
Sabiston/HC-SC/GC/CA  
2009-10-04 05:21 PM

To Christine Roush/HC-SC/GC/CA@HWC  
cc Kimberly Sorfleet/HC-SC/GC/CA@HWC, Stephanie Szick/HC-SC/GC/CA@HWC, Katie Greenwood/HC-SC/GC/CA@HWC, Diane  
bcc  
Subject Re: URGENT: Interview request: For input/approval: [REDACTED] - CBC Radio Toronto - Salvia divinorum [REDACTED]

Approved. Thx. Cas  
Christine Roush

----- Original Message -----

**From:** Christine Roush  
**Sent:** 2009-10-04 11:17 AM EDT  
**To:** Cathy A Sabiston  
**Cc:** Kimberly Sorfleet; Stephanie Szick; Katie Greenwood; Diane Allan; Nicole Prentice; Cheryl Tremblay; Tacha Lehouillier; Bronwyn Cline; Jennifer Peddle  
**Subject:** Fw: URGENT: Interview request: For input/approval: Kimberly Gale - CBC Radio Toronto - Salvia divinorum  
Cathy,

For your re-approval: HPFB's Natural Health Products Div proposed several changes to the responses. The most important change is that *S. divinorum* is not regulated as an NHP - it could meet the definition of an NHP when associated with health claims.

These responses have been approved by Dr. Robin Marles, Director, and Michelle Boudreau, DG, NHPD.

Diane Allan reviewed again and approved, making additional changes to Q.1. We were too late to meet the reporter's deadline of 5PM Friday. CBC will be running a story on Monday at 7:30am. However, reporter expects to be running a followup story on Salvia, so we would like to obtain approval of these lines for Monday.

Q1 - How is *Salvia divinorum* classified in Canada?

A1 - In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, Salvinorin A, are controlled under the *Controlled Drugs and Substances Act* (CDSA).

*Salvia divinorum* is not listed under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these conventions.

*Salvia divinorum*, when associated with health claims, could meet the definition of a natural health product under the *Natural Health Product Regulations* (NHPR). This means that *Salvia* products that are being sold as NHPs that are not in compliance with the NHPR, may be subject to compliance and enforcement actions.

As of January 2009, Health Canada had not issued any Natural Product Numbers (NPN) or Drug Identification Numbers - Homeopathic Medicine (DIN-HM) for *Salvia divinorum* products

Q2 - Is it regulated (or are there plans to regulate it)?

Christine  
Roush/HC-SC/GC/CA  
2009-10-04 11:17 AM

s.19(1)  
To Cathy A Sabiston/HC-SC/GC/CA@HWC  
cc Kimberly Sorfleet/HC-SC/GC/CA@HWC, Stephanie  
Szick/HC-SC/GC/CA@HWC, Katie  
Greenwood/HC-SC/GC/CA@HWC, Diane  
bcc  
Subject Fw: URGENT: Interview request: For input/approval:  
[REDACTED] - CBC Radio Toronto - Salvia divinorum

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Q1 - How is *Salvia divinorum* classified in Canada?

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*Salvia divinorum* is not listed under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these conventions.

*Salvia divinorum*, when associated with health claims, could meet the definition of a natural health product under the *Natural Health Product Regulations* (NHPR). This means that *Salvia* products that are being sold as NHPs that are not in compliance with the NHPR, may be subject to compliance and enforcement actions.

As of January 2009, Health Canada had not issued any Natural Product Numbers (NPN) or Drug Identification Numbers – Homeopathic Medicine (DIN-HM) for *Salvia divinorum* products

Q2 - Is it regulated (or are there plans to regulate it)?

A2 - *Salvia divinorum*, when associated with health claims, could meet the definition of a natural health product under the NHPR. In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA). *Salvia divinorum* is not listed under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these conventions.

Health Canada continues to collect relevant information about *Salvia Divinorum* and its active



ingredient, Salvinorin A, from both national and international sources in order to determine what, if any, regulatory controls are needed.

Q3 - How much research has been done on the effects of salvia (what is known about its properties etc.)?

A3- While the media have reported that use of *Salvia divinorum* is on the rise in certain parts of the country, Health Canada does not currently have statistics on its use across the Canadian population.

Health Canada is taking steps to address this lack of data. Questions regarding the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey. A general open-ended question about the use of other substances was also included in the 2008 Canadian Alcohol and Drug Use Monitoring Survey.

~~Very few controlled scientific studies of the physical and psychotropic effects of *Salvia divinorum* on humans have been carried out, and using these studies to predict the potential for addiction and abuse associated with *Salvia divinorum* is difficult. More controlled systematic research in this area is needed.~~

~~Health Canada continues to collect and consider information about *Salvia divinorum* and its active ingredient, salvinorin A, from both national and international sources in order to determine what, if any, regulatory controls are needed.~~

Q4 - Are there concerns that anyone could access it ? (it's under glass counter at corner stores and in most head shops here in Toronto).

A4 - In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA). Health Canada is aware of some of the effects associated with the use of *Salvia divinorum* and continues to collect and consider information about *Salvia divinorum* and its active ingredient, salvinorin A, from both national and international sources in order to determine what, if any, regulatory controls are needed.

Very few controlled scientific studies of the physical and psychotropic effects of *Salvia divinorum* on humans have been carried out, and using these studies to predict the potential for addiction and abuse associated with *Salvia divinorum* is difficult. More controlled systematic research in this area is needed.

Health Canada has only received a limited number of communications regarding *Salvia divinorum* from law enforcement agencies, and none of these has advised that the use of *Salvia divinorum* poses any threat to public safety.

Q5 - What would it take to get regulated ? (ie: kids uploading videos to You Tube of their "bad trips" on salvia).

A5 - Health Canada considers several factors in determining whether scheduling a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in regulatory status;

- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

In the case of *Salvia divinorum*, information about these factors is either missing or anecdotal in nature. For example, very few controlled scientific studies of the physical and psychotropic effects of *Salvia divinorum* on humans have been carried out, and using these studies to predict the potential for addiction and abuse associated with *Salvia divinorum* is difficult. More controlled systematic research in this area is needed. Health Canada is taking steps to address the lack of data regarding the use of and/or extent of abuse involving *Salvia divinorum*. Questions regarding the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. A general open-ended question about the use of other substances has also been included in the 2008 Canadian Alcohol and Drug Use Monitoring Survey. The data, however, will not likely be available until 2010. In the interim, Health Canada will continue to collect and consider information regarding *Salvia divinorum* as it becomes available.

Christine Roush  
Senior Communications Advisor/

Diane Allan/HC-SC/GC/CA  
2009-10-02 09:12 PM

To Christine Roush/HC-SC/GC/CA@HWC  
cc "Katie Greenwood" <Katie\_Greenwood@hc-sc.gc.ca>  
Subject Re: Fw: URGENT: Interview request: For input/approval:  
[REDACTED] - CBC Radio Toronto - Salvia divinorum [img alt="document icon"]

Christine - here is what I propose - I removed the third paragraph under A1 - the rest is fine, approved.

Q1 - How is *Salvia divinorum* classified in Canada?

A1 - In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, Salvinorin A, are controlled under the *Controlled Drugs and Substances Act* (CDSA).

*Salvia divinorum* is not listed under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these conventions.

*Salvia divinorum*, when associated with health claims, could meet the definition of a natural health product under the *Natural Health Product Regulations* (NHPR). This means that *Salvia* products that are being sold as NHPs are not in compliance with the NHPR may be subject to compliance and enforcement actions.

As of January 2009, Health Canada had not issued any Natural Product Numbers (NPN) or Drug Identification Numbers – Homeopathic Medicine (DIN-HM) for *Salvia divinorum* products

Diane Allan

Director / Directrice  
Office of Controlled Substances / Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch / Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada / Santé Canada  
Tel: 613-952-2177  
Fax: 613-946-4224

Christine Roush/HC-SC/GC/CA

Christine  
Roush/HC-SC/GC/CA  
2009-10-02 08:37 PM

To Diane Allan/HC-SC/GC/CA@HWC  
cc "Katie Greenwood" <Katie\_Greenwood@hc-sc.gc.ca>  
Subject Re: Fw: URGENT: Interview request: For input/approval:  
[REDACTED] - CBC Radio Toronto - Salvia divinorum

No, HPFB's comments are in red. Our original lines were in blue.

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
Health Canada/Santé Canada  
Tel/Tél : (613) 954-0712/Cell: (613) 219-7194  
Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca

Diane Allan/HC-SC/GC/CA

Diane Allan/HC-SC/GC/CA  
2009-10-02 06:32 PM

To Christine Roush/HC-SC/GC/CA@HWC  
cc "Katie Greenwood" <Katie\_Greenwood@hc-sc.gc.ca>  
Subject Re: Fw: URGENT: Interview request: For input/approval:  
[REDACTED] CBC Radio Toronto - Salvia divinorum

What colour are they in - Blue?

Diane Allan

Director / Directrice  
Office of Controlled Substances / Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch / Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada / Santé Canada  
Tel: 613-952-2177  
Fax: 613-946-4224

Christine Roush/HC-SC/GC/CA

Christine  
Roush/HC-SC/GC/CA  
2009-10-02 06:29 PM

To "Katie Greenwood" <Katie\_Greenwood@hc-sc.gc.ca>  
cc "Diane Allan" <diane\_allan@hc-sc.gc.ca>

Subject Fw: URGENT: Interview request: For input/approval:  
[REDACTED] CBC Radio Toronto - Salvia divinorum

Katie - pls let me know if you agree with HPFB's changes.  
Jennifer Peddle

----- Original Message -----

**From:** Jennifer Peddle  
**Sent:** 2009-10-02 05:58 PM EDT  
**To:** Nicole Prentice; Christine Roush  
**Cc:** Gary Holub  
**Subject:** Re: URGENT: Interview request: For input/approval: [REDACTED]  
- CBC Radio Toronto - Salvia divinorum

Hi,  
NHPD has proposed several changes to the responses. The most important change is that *S. divinorum* is not regulated as an NHP - it could meet the definition of an NHP when associated with health claims.

These responses have been approved by Dr. Robin Marles, Director, and Michelle Boudreau, DG, NHPD.

Q1 - How is *Salvia divinorum* classified in Canada?

Q2 - Is it regulated (or are there plans to regulate it)?

A2 - *Salvia divinorum*, when associated with health claims, could meet the definition of a natural health product under the NHPR. In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA). *Salvia divinorum* is not listed under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these conventions.

Health Canada continues to collect relevant information about *Salvia Divinorum* and its active

ingredient, Salvinorin A, from both national and international sources in order to determine what, if any, regulatory controls are needed.

Q3 - How much research has been done on the effects of salvia (what is known about its properties etc.)?

A3- While the media have reported that use of *Salvia divinorum* is on the rise in certain parts of the country, Health Canada does not currently have statistics on its use across the Canadian population.

Health Canada is taking steps to address this lack of data. Questions regarding the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey. A general open-ended question about the use of other substances was also included in the 2008 Canadian Alcohol and Drug Use Monitoring Survey.

~~Very few controlled scientific studies of the physical and psychotropic effects of *Salvia divinorum* on humans have been carried out, and using these studies to predict the potential for addiction and abuse associated with *Salvia divinorum* is difficult. More controlled systematic research in this area is needed.~~

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Q4 - Are there concerns that anyone could access it ? (it's under glass counter at corner stores and in most head shops here in Toronto).

A4 - In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA). Health Canada is aware of some of the effects associated with the use of *Salvia divinorum* and continues to collect and consider information about *Salvia divinorum* and its active ingredient, salvinorin A, from both national and international sources in order to determine what, if any, regulatory controls are needed.

Very few controlled scientific studies of the physical and psychotropic effects of *Salvia divinorum* on humans have been carried out, and using these studies to predict the potential for addiction and abuse associated with *Salvia divinorum* is difficult. More controlled systematic research in this area is needed.

Health Canada has only received a limited number of communications regarding *Salvia divinorum* from law enforcement agencies, and none of these has advised that the use of *Salvia divinorum* poses any threat to public safety.

Q5 - What would it take to get regulated ? (ie: kids uploading videos to You Tube of their "bad trips" on salvia).

A5 - Health Canada considers several factors in determining whether scheduling a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in regulatory status;

- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

In the case of *Salvia divinorum*, information about these factors is either missing or anecdotal in nature. For example, very few controlled scientific studies of the physical and psychotropic effects of *Salvia divinorum* on humans have been carried out, and using these studies to predict the potential for addiction and abuse associated with *Salvia divinorum* is difficult. More controlled systematic research in this area is needed. Health Canada is taking steps to address the lack of data regarding the use of and/or extent of abuse involving *Salvia divinorum*. Questions regarding the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. A general open-ended question about the use of other substances has also been included in the 2008 Canadian Alcohol and Drug Use Monitoring Survey. The data, however, will not likely be available until 2010. In the interim, Health Canada will continue to collect and consider information regarding *Salvia divinorum* as it becomes available.

Jennifer Peddle  
Senior Communications Advisor -HPFB | Conseillère principale en communications - DGPSA  
Strategic Communications Directorate | Direction des communications stratégique  
Public Affairs, Consultations and Regions Branch (PACRB) | Direction générale des affaires publiques, de la consultation et des régions (DGAPCR)  
Health Canada | Santé Canada  
613.957.8483 (office/bureau)  
613.957.8805 (fax/télécopieur)  
613.868.5835 (cell/portable)

Nicole Prentice/HC-SC/GC/CA



Nicole  
Prentice/HC-SC/GC/CA  
2009-10-02 02:14 PM

To Jennifer Peddle/HC-SC/GC/CA@HWC  
cc

Subject URGENT: Interview request: For input/approval: [REDACTED]  
[REDACTED] - CBC Radio Toronto - Salvia divinorum

Please see below.

Nicole Prentice/HC-SC/GC/CA



Nicole  
Prentice/HC-SC/GC/CA

To Ashley Lemire/HC-SC/GC/CA@HWC

2009-10-02 02:10 PM

cc

Subject Fw: Interview request: For input/approval: [REDACTED] -  
CBC Radio Toronto - Salvia divinorum

Hello,

Here is a media enquiry for Salvia which is due at COB today. This enquiry needs to go through both HECS and HPFB approvals (Director, DG, and Sr. comms exec.) Are you able to help me get HPFB approvals this afternoon, if so can you send it to the appropriate director and DG, then back to me for my DG approval then we can send it to each of our sr comms executives. I would like to have this done by 4, as I work another job tonight. Let me know. Thanks in advance.

Approved by:

Christine Roush, Sr Comms Advisor  
Diane Allan, Director, OCS  
XX, Director, XX (pending)  
Cathy Sabiston, DG, CSTD (pending)  
XX, DG, XX (pending)  
Kathleen Malone, Sr Comms Executive (pending)  
Ken Polk, Sr Comms Executive (pending)

Another request for Salvia divinorum - this one an interview request for COB Today. reporter's questions are:

Q1 - How is Salvia divinorum classified in Canada?

A1 - *Salvia divinorum* meets the definition of a natural health product under the *Natural Health Product Regulations* (NHPR). This means that Salvia products that are not in compliance with the NHPR may be subject to compliance and enforcement actions. As of January 2009, Health Canada had not issued any Natural Product Numbers (NPN) or Drug Identification Numbers – Homeopathic Medicine (DIN-HM) for *Salvia divinorum* products.

Q2 - Is it regulated (or are there plans to regulate it)?

A2 - *Salvia divinorum* meets the definition of a natural health product under the NHPR and is regulated under this set of regulations. In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA). *Salvia divinorum* is not listed under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these conventions.

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Very few controlled scientific studies of the physical and psychotropic effects of *Salvia divinorum* on humans have been carried out, and using these studies to predict the potential for addiction and abuse associated with *Salvia divinorum* is difficult. More controlled systematic research in this area is needed.

Health Canada continues to collect and consider information about *Salvia divinorum* and its active ingredient, salvinorin A, from both national and international sources in order to determine what, if any, regulatory controls are needed.

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Nicole Prentice  
Junior Communications Officer | L'Officier junior de Communications  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la  
consultation et des communications  
Health Canada | Santé Canada  
Tel: 613.941.3107  
Fax: 613.948.8085

----- Forwarded by Nicole Prentice/HC-SC/GC/CA on 2009-10-02 01:53 PM -----

**Diane Allan/HC-SC/GC/CA**

2009-10-02 01:41 PM

To "Nicole Prentice" <nicole\_prentice@hc-sc.gc.ca>  
cc "Katie Greenwood" <Katie\_Greenwood@hc-sc.gc.ca>,  
"Cheryl Tremblay" <Cheryl\_Tremblay@hc-sc.gc.ca>  
Subject Fw: Interview request: For input/approval: [REDACTED] -  
CBC Radio Toronto - Salvia divinorum

Nicole

Please note change. Approved.  
Cheryl Tremblay

----- Original Message -----

**From:** Cheryl Tremblay  
**Sent:** 2009-10-02 01:39 PM EDT  
**To:** Katie Greenwood  
**Cc:** Daniel Galarneau; Diane Allan  
**Subject:** Re: Interview request: For input/approval: [REDACTED] - CBC  
Radio Toronto - Salvia divinorum  
Good idea! see addition...

Katie Greenwood/HC-SC/GC/CA



**Katie  
Greenwood/HC-SC/GC/CA**

2009-10-02 01:35 PM

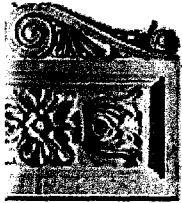
To Cheryl Tremblay/HC-SC/GC/CA@HWC  
cc Daniel Galarneau/HC-SC/GC/CA@HWC, Diane  
Allan/HC-SC/GC/CA@HWC  
Subject Re: Interview request: For input/approval: [REDACTED]  
CBC Radio Toronto - Salvia divinorum

Hi Cheryl,

Do you think in Q4 we should reiterate that it is not controlled at the beginning?

Just a thought.

Katie  
Cheryl Tremblay/HC-SC/GC/CA



Cheryl  
Tremblay/HC-SC/GC/CA  
2009-10-02 01:25 PM

To Diane Allan/HC-SC/GC/CA@HWC  
cc Daniel Galarneau/HC-SC/GC/CA@HWC, Katie  
Greenwood/HC-SC/GC/CA@HWC  
Subject Re: Interview request: For input/approval: [REDACTED]  
CBC Radio Toronto - Salvia divinorum

Hi Diane,

Please see my suggestions in purple for your review/approval...

Thanks,  
Cheryl  
Diane Allan/HC-SC/GC/CA

Diane Allan/HC-SC/GC/CA  
2009-10-02 12:45 PM

To Katie Greenwood/HC-SC/GC/CA@HWC, Cheryl  
Tremblay/HC-SC/GC/CA@HWC, Daniel  
Galarneau/HC-SC/GC/CA@HWC  
cc  
Subject Re: Interview request: For input/approval: [REDACTED]  
CBC Radio Toronto - Salvia divinorum

Cheryl. Your comments too please.  
Katie Greenwood

----- Original Message -----

**From:** Katie Greenwood  
**Sent:** 2009-10-02 12:43 PM EDT  
**To:** Cheryl Tremblay; Daniel Galarneau  
**Cc:** Diane Allan

**Subject:** Fw: Interview request: For input/approval: [REDACTED] - CBC  
Radio Toronto - Salvia divinorum

I have made a few changes below which you can choose to include or ignore. They are based on the fact that we say in the first question that Salvia is considered an NHP. Thus, it is regulated, just not under the CDSA.

----- Forwarded by Katie Greenwood/HC-SC/GC/CA on 2009-10-02 12:36 PM -----

Diane Allan/HC-SC/GC/CA  
2009-10-02 12:32 PM

To "Cheryl Tremblay" <Cheryl\_Tremblay@hc-sc.gc.ca>, "Mr.  
Daniel Galarneau" <Daniel\_Galarneau@hc-sc.gc.ca>  
cc "Katie Greenwood" <Katie\_Greenwood@hc-sc.gc.ca>  
Subject Fw: Interview request: For input/approval: [REDACTED]  
CBC Radio Toronto - Salvia divinorum

Please review.  
Nicole Prentice

----- Original Message -----

**From:** Nicole Prentice

**Sent:** 2009-10-02 12:24 PM EDT

**To:** Diane Allan; Katie Greenwood

**Cc:** Carmen Berube

**Subject:** Interview request: For input/approval: [REDACTED] - CBC Radio  
Toronto - *Salvia divinorum*

Hello,

Here is media enquiry for input/approval by 2pm as this is due at COB. Below are my suggested responses, but I still need input for Q4. Thanks in advance.

Another request for *Salvia divinorum* - this one an interview request for COB Today. reporter's questions are:

Q1 - How is *Salvia divinorum* classified in Canada?

A1 - *Salvia divinorum* meets the definition of a natural health product under the *Natural Health Product Regulations* (NHPR). This means that *Salvia* products that are not in compliance with the NHPR may be subject to compliance and enforcement actions. As of January 2009, Health Canada had not issued any Natural Product Numbers (NPN) or Drug Identification Numbers – Homeopathic Medicine (DIN-HM) for *Salvia divinorum* products.

Q2 - Is it regulated (or are there plans to regulate it)?

A2 - *Salvia divinorum* meets the definition of a natural health product under the NHPR and is regulated under this set of regulations. In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA). *Salvia divinorum* is not listed under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these conventions.

Q3 - How much research has been done on the effects of salvia (what is known about its properties etc.)?

A3- Changed the order a little...

While the media have reported that use of *Salvia divinorum* is on the rise in certain parts of the country, Health Canada does not currently have statistics on its use across the Canadian population.

Health Canada is taking steps to address this lack of data. Questions regarding the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey. A general open-ended question about the use of other substances was also included in the 2008 Canadian Alcohol and Drug Use Monitoring Survey.

Very few controlled scientific studies of the physical and psychotropic effects of *Salvia divinorum* on humans have been carried out, and using these studies to predict the potential for addiction and abuse associated with *Salvia divinorum* is difficult. More controlled systematic research in this area is needed.

Health Canada continues to collect and consider information about *Salvia divinorum* and its active ingredient, salvinorin A, from both national and international sources in order to determine what, if any, regulatory controls are needed.

Q4 - Are there concerns that anyone could access it ? (it's under glass counter at corner stores and in most head shops here in Toronto).

A4 - In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA). Health Canada is aware of some of the effects associated with the use of *Salvia divinorum* and continues to collect and consider information about *Salvia divinorum* and its active ingredient, salvinorin A, from both national and international sources in order to determine what, if any, regulatory controls are needed.

Q5 - What would it take to get regulated ? (ie: kids uploading videos to You Tube of their "bad trips" on salvia).

A5 - Health Canada considers several factors in determining whether scheduling a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in regulatory status;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

In the case of *Salvia divinorum*, information about these factors is either missing or anecdotal in nature. For example, very few controlled scientific studies of the physical and psychotropic effects of *Salvia divinorum* on humans have been carried out, and using these studies to predict the potential for addiction and abuse associated with *Salvia divinorum* is difficult. More controlled systematic research in this area is needed. ~~Health Canada has only anecdotal information about the last three of the above mentioned factors, and thus is not yet convinced that the controls imposed by the CDSA are an appropriate strategy for managing the risks associated with the use of *Salvia divinorum*. The survey results from the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey will help fill some of the information gaps.~~ Health Canada is taking steps to address the lack of data regarding the use of and/or extent of abuse involving *Salvia divinorum*. Questions regarding the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. A general open-ended question about the use of other substances has also been included in the 2008 Canadian Alcohol and Drug Use Monitoring Survey. The data, however, will not likely be available until 2010. In the interim, Health Canada will continue to collect and consider information regarding *Salvia divinorum* as it becomes available.

Nicole Prentice  
Junior Communications Officer | L'Officier junior de Communications

Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la consultation et des communications  
Health Canada | Santé Canada  
Tel: 613.941.3107  
Fax: 613.948.8085

----- Forwarded by Nicole Prentice/HC-SC/GC/CA on 2009-10-02 12:21 PM -----

Christine  
Roush/HC-SC/GC/CA  
2009-10-02 12:20 PM

To Nicole Prentice/HC-SC/GC/CA@HWC  
cc

Subject Re: URGENT Interview request: For approval: [REDACTED]  
- CBC Radio Toronto - Salvia divinorum [REDACTED]

OK - I made a few changes below. Good to go

Christine Roush  
Senior Communications Advisor/

Nicole Prentice/HC-SC/GC/CA



Nicole  
Prentice/HC-SC/GC/CA  
2009-10-02 11:15 AM

To Christine Roush/HC-SC/GC/CA@HWC  
cc

Subject URGENT Interview request: For approval: [REDACTED]  
CBC Radio Toronto - Salvia divinorum

Hello,

Below are my suggested responses. I still need input for Q4. Should I send it to OCS (kula, tremblay and greenwood) for input/approval? Does this need to go through HPFB input/approvals?

Another request for Salvia divinorum - this one an interview request for COB Today. reporter's questions are:

Q1 - How is Salvia divinorum classified in Canada?

A1 - *Salvia divinorum* meets the definition of a natural health product under the *Natural Health Product Regulations* (NHPR). This means that Salvia products that are not in compliance with the NHPR may be subject to compliance and enforcement actions. As of January 2009, Health Canada had not issued any Natural Product Numbers (NPN) or Drug Identification Numbers – Homeopathic Medicine (DIN-HM) for *Salvia divinorum* products.

Q2 - Is it regulated (or are there plans to regulate it)?

A2 - In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA). *Salvia divinorum* is not listed

under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these conventions.

Q3 - How much research has been done on the effects of salvia (what is known about its properties etc.)?

A3- Health Canada continues to collect and consider information about *Salvia divinorum* and its active ingredient, salvinorin A, from both national and international sources in order to determine what, if any, regulatory controls are needed.

While the media have reported that use of *Salvia divinorum* is on the rise in certain parts of the country, Health Canada does not currently have statistics on its use across the Canadian population.

Health Canada is taking steps to address this lack of data. Questions regarding the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey. A general open-ended question about the use of other substances was also included in the 2008 Canadian Alcohol and Drug Use Monitoring Survey.

Q4 - Are there concerns that anyone could access it ? (it's under glass counter at corner stores and in most head shops here in Toronto).

A4 -

Q5 - What would it take to get regulated ? (ie: kids uploading videos to You Tube of their "bad trips" on salvia).

A5 - Health Canada considers several factors in determining whether scheduling a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in regulatory status;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

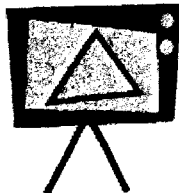
Health Canada has only anecdotal information about the last three of the above-mentioned factors, and thus is not yet convinced that the controls imposed by the CDSA are an appropriate strategy for managing the risks associated with the use of *Salvia divinorum*. The survey results from the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey will help fill some of the information gaps. The data, however, will not likely be available until 2010. In the interim, Health Canada will continue to collect and consider information regarding *Salvia divinorum* as it becomes available.

COB Friday Today

Nicole Prentice  
Junior Communications Officer | L'Officier junior de Communications

Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la consultation et des communications  
Health Canada | Santé Canada  
Tel: 613.941.3107  
Fax: 613.948.8085

----- Forwarded by Nicole Prentice/HC-SC/GC/CA on 2009-10-02 11:07 AM -----



Gary Holub/HC-SC/GC/CA

2009-10-02 10:58 AM

To Christine Roush/HC-SC/GC/CA@HWC, Nicole Prentice/HC-SC/GC/CA@HWC, Brooke Bryce/HC-SC/GC/CA@HWC, Bronwyn Cline/HC-SC/GC/CA@HWC

cc

Subject Interview request - [REDACTED] - CBC Radio Toronto - Salvia divinorum

Hi Christine, gang

Another request for Salvia divinorum - this one an interview request for COB Today. reporter's questions are:

- Q1 - How is Salvia divinorum classified in Canada?
- Q2 - Is it regulated (or are there plans to regulate it)?
- Q3 - How much research has been done on the effects of salvia (what is known about its properties etc.)?
- Q4 - Are there concerns that anyone could access it ? (it's under glass counter at corner stores and in most head shops here in Toronto).
- Q5 - What would it take to get regulated ? (ie: kids uploading videos to You Tube of their "bad trips" on salvia).

COB Friday Today

\*\*\*

Thanks,  
Gary

Gary Scott Holub  
Media Relations Officer | Agent des relations avec les médias  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la consultation et des communications  
Health Canada | Santé Canada  
(t) 613.954.4807  
(e) gary\_holub@hc-sc.gc.ca  
Government of Canada | Gouvernement du Canada

----- Forwarded by Gary Holub/HC-SC/GC/CA on 2009-10-02 10:57 AM -----



### Media Enquiry - Demande médiatique

Name/Nom : [REDACTED]	Media/Média : CBC Toronto
Telephone/Téléphone : [REDACTED]	Language/Langue : English-anglais
Cell Telephone/Téléphone cellulaire : [REDACTED]	Fax/Télécopieur :

s.19(1)

Email/Courriel :

Date and Time Received

Date et Heure de réception : 2009-10-02 10:41:18 AM

Date Completed

Date d'achèvement :

Subject/Objet : Controlled Substances/Substances contrôlées

Question:

Add to the Question/ajouter a la question

2009-10-02 10:41:19 AM (Gary Holub)

from CBC Toronto

Request of interview with someone to speak about Salvia- Plant -substance inst regulated in Canada and dont plan on regulating it.

This substance is banned in other countries.

psychoactive

2009-10-02 10:55:13 AM (Gary Holub)

Q1 - How is Salvia divinorum classified in Canada?

Q2 - Is it regulated (or are there plans to regulate it)?

Q3 - How much research has been done on the effects of salvia (what is known about its properties etc.)?

Q4 - Are there concerns that anyone could access it ? (it's under glass counter at corner stores and in most head shops here in Toronto).

Q5 - What would it take to get regulated ? (ie: kids uploading videos to You Tube of their "bad trips" on salvia).

COB Friday Today

Response/Réponse :

Add to the Response/ajouter a la réponse

Action Taken/Mesures prises :

Add to the Action Taken/ajouter au mesures prises

2009-10-02 10:41:56 AM (Gary Holub)

HUA TCB

2009-10-02 10:57:06 AM (Gary Holub)

Sent to Christine, Micole, Bryce, Bronwyn

Interview with spokesperson granted/Entrevue avec porte-parole accordé:  Yes-Oui  No-Non

Branch/Direction générale : HECS - Controlled Substances & Drug Analysis/DGSESC - Direction de la sécurité des substances chimiques et des produits de consommation

Spokesperson/Porte-parole :

Reporter's Deadline

Heure de tombée du journaliste :

Priority/Priorité : Regular

Telephone/Téléphone :

Story Run Date

Date de parution de l'article :

Status/Rapport de situation : Follow-up

Comment/Commentaire :

Attachments/Pièces jointes :



**Related Clippings/Coupages connexes :**

**Media Relations Officer/Agente de relations avec les médias : Gary Holub**

**Edit History / Historique des révisions**

**Send To / Transmettre à :** Suzanne Desjardins; Stephanie Szick; Christine von Arx; Ray Edwards; Pamela Arnott; Kathleen Malone; Ken Moore; Bronwyn Cline; Christine Roush; Charles Mojsey/HC-SC/GC/CA; Peter Yendall/HC-SC/GC/CA; Jean Tessier/HC-SC/GC/CA; Josee Bellemare/HC-SC/GC/CA; Tim Vail/HC-SC/GC/CA;

**Branch Recipient:**

Suzanne Desjardins, Stephanie Szick, Christine von Arx, Ray Edwards, Pamela Arnott, Kathleen Malone, Ken Moore, Bronwyn Cline, Christine Roush

**Mail Recipients:**

CN=Charles Mojsey/OU=HC-SC/O=GC/C=CA, CN=Peter Yendall/OU=HC-SC/O=GC/C=CA, CN=Jean Tessier/OU=HC-SC/O=GC/C=CA, CN=Josee Bellemare/OU=HC-SC/O=GC/C=CA, CN=Tim Vail/OU=HC-SC/O=GC/C=CA



Nicole  
Prentice/HC-SC/GC/CA  
2009-10-05 09:09 AM

To Cheryl Tremblay/HC-SC/GC/CA@HWC  
cc Carmen Berube/HC-SC/GC/CA@HWC, "Cheryl Tremblay"  
<Cheryl\_Tremblay@hc-sc.gc.ca>, Christine  
Roush/HC-SC/GC/CA@HWC, Diane  
bcc

Subject Re: For approval: Media enquiry - [REDACTED] - CMAJ -  
Salvia Divinorum

Hi all,

Yes, this is a different request - it was just sent at the same time as the last one so may have been confusing. This one is due at COB today so if I can have your approval asap that would be great - also should this one go through HPFB approvals too?

Nicole Prentice  
Junior Communications Officer | L'Officier junior de Communications  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la consultation et des communications  
Health Canada | Santé Canada  
Tel: 613.941.3107  
Fax: 613.948.8085

Cheryl  
Tremblay/HC-SC/GC/CA  
2009-10-05 09:06  
AM

To Diane Allan/HC-SC/GC/CA@HWC  
cc Carmen Berube/HC-SC/GC/CA@HWC, "Cheryl Tremblay" <Cheryl\_Tremblay@hc-sc.gc.ca>, Christine  
Roush/HC-SC/GC/CA@HWC, Katie Greenwood/HC-SC/GC/CA@HWC, Nicole  
Prentice/HC-SC/GC/CA@HWC  
Subject Re: For approval: Media enquiry - [REDACTED] - CMAJ - Salvia Divinorum [Link](#)

I believe this is a new request...Nicole?

Diane  
Allan/HC-SC/GC/CA  
2009-10-05 09:01 AM

To Nicole Prentice/HC-SC/GC/CA@HWC, Katie Greenwood/HC-SC/GC/CA@HWC  
cc Carmen Berube/HC-SC/GC/CA@HWC, Christine Roush/HC-SC/GC/CA@HWC, "Cheryl Tremblay"  
<Cheryl\_Tremblay@hc-sc.gc.ca>  
Subject Re: For approval: Media enquiry - [REDACTED] - CMAJ - Salvia Divinorum [Link](#)

s.19(1)

Nicole. Please contact Cheryl. These were all approved over the weekend via Christine Roush.

I am confused by your request.

----- Original Message -----

**From:** Nicole Prentice

**Sent:** 2009-10-05 08:38 AM EDT

**To:** Diane Allan; Katie Greenwood

**Cc:** Carmen Berube; Christine Roush

**Subject:** Fw: For approval: Media enquiry - [REDACTED] - CMAJ - Salvia

Divinorum

Hello,

How is this media enquiry coming along? Can I get approval asap?

Thanks.

Nicole Prentice

Junior Communications Officer | L'Officier junior de Communications

Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la  
consultation et des communications

Health Canada | Santé Canada

Tel: 613.941.3107

Fax: 613.948.8085

----- Forwarded by Nicole Prentice/HC-SC/GC/CA on 2009-10-05 08:32 AM -----

Nicole Prentice/HC-SC/GC/CA

2009-10-02 12:27 PM

To Diane Allan/HC-SC/GC/CA, Katie Greenwood/HC-SC/GC/CA

cc Carmen Berube/HC-SC/GC/CA@HWC, Christine Roush/HC-SC/GC/CA@HWC

Subject For approval: Media enquiry - [REDACTED] - CMAJ - Salvia Divinorum

Hello,

Here is yet another media enquiry for your approval by COB today. Thanks.

CMAJ has an interest in Salvia divinorum, a tropical member of the Mint family. It's called a "legal high".  
It's increasingly being banned in the U.S.

Q1 - I was hoping you could get me a comment from Health Canada about Salvia. If it's being looked at. If  
it will be banned?

000393

A1 - *Salvia Divinorum* is a species of sage which belongs to the mint family. It is found in the form of dried leaves, extract and plant cuttings. *Salvia Divinorum*, also known as "diviner's sage", is chewed or smoked and can induce illusions and hallucinations. It is known to have psychotropic effects, which means it affects the mind and mental processes.

Health Canada continues to collect relevant information about *Salvia divinorum* and its active ingredient, Salvinorin A, from both national and international sources in order to determine what, if any, regulatory controls are needed. In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, Salvinorin A, are controlled under the *Controlled Drugs and Substances Act* (CDSA). *Salvia divinorum* is not listed under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these conventions.

A regulatory amendment is necessary to add a substance to one of the Schedules of the Controlled Drugs and Substances Act. This process may take 12 to 18 months once the requirement to schedule a substance has been identified; however, where a substance presents grave harm to the public, extraordinary measures may be taken to control a substance in a more timely manner.

Several countries (Australia, Belgium, Denmark, Sweden, Italy, Spain, Finland and South Korea) have placed controls on the import and/or sale of *Salvia divinorum*. Although some individual U.S. states have implemented laws restricting its use, sale and/or distribution, *Salvia divinorum* is not federally regulated under the *Controlled Substances Act* in the United States.

While the media have reported that use of *Salvia divinorum* is on the rise in certain parts of the country, Health Canada does not currently have statistics on its use across the Canadian population. Health Canada is taking steps to address this lack of data. Questions regarding the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. A general open-ended question about the use of other substances was also included in the 2008 Canadian Alcohol and Drug Use Monitoring Survey.

*Salvia divinorum*, when associated with health claims, could meet the definition of a natural health product under the *Natural Health Product Regulations* (NHPR). This means that *Salvia* products that are not in compliance with the NHPR may be subject to compliance and enforcement actions. As of January 2009, Health Canada had not issued any Natural Product Numbers (NPN) or Drug Identification Numbers - Homeopathic Medicine (DIN-HM) for *Salvia divinorum* products.

Q2 - Is it a big deal or not at all? (ie. Are there serious health concerns?)

A2 - *Salvia Divinorum*'s mechanism of action is still not fully understood. Although long-term effects have not yet been observed, *Salvia Divinorum* has been known to cause hallucinations, out-of-body experiences, unconsciousness and short-term memory loss. There is, consequently, a potential for accidents occurring while the user is under the influence of the substance.

The plant's effects are short acting. We are not aware at this time of any cases of dependency to *Salvia Divinorum* having been reported. Nevertheless, Health Canada will continue to monitor *Salvia Divinorum*. Should evidence arise that suggests a significant risk to public health and safety, Health Canada will take action accordingly, which could include adding *Salvia Divinorum* to one of the schedules under the Controlled Drugs and Substances Act. (Yes, Health Canada, essentially through the Drug Strategy and Controlled Substances Program, has the authority to schedule *Salvia D* under the CDSA)

Health Canada recommends that you avoid using this substance because very little is known about the damage it may cause to the body, including the brain. There is also no way to predict how it will affect you

with each use.

### **Risks of Using *Salvia divinorum***

*S. divinorum's* effects, which vary from person to person, are often described as unpleasant and may include the following: hallucinations; dysphoria (feeling unwell, uneasy or unhappy); out-of-body experiences; uncontrollable laughter; loss of consciousness; short-term memory loss; lack of physical coordination; slurred speech and awkward sentence patterns.

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as: the potency of the product; how much is used; the purity of the product (it may be mixed with other substances); how it is taken (e.g., chewed, swallowed or smoked); the user's mood and expectations.

**Deadline : Monday COB**

**Nicole Prentice**

Junior Communications Officer | L'Officier junior de Communications  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la  
consultation et des communications  
Health Canada | Santé Canada  
Tel: 613.941.3107  
Fax: 613.948.8085

----- Forwarded by Nicole Prentice/HC-SC/GC/CA on 2009-10-02 12:25 PM -----

Nicole Prentice/HC-SC/GC/CA

2009-10-02 11:18 AM

To Christine Roush/HC-SC/GC/CA

cc

Subject Fw: Media enquiry - [REDACTED] - CMAJ - Salvia Divinorum

Please see additions in red. I have added them from the IYH article and the media lines. Let me know what should be taken out etc.

**Nicole Prentice**

Junior Communications Officer | L'Officier junior de Communications  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la  
consultation et des communications  
Health Canada | Santé Canada  
Tel: 613.941.3107  
Fax: 613.948.8085

----- Forwarded by Nicole Prentice/HC-SC/GC/CA on 2009-10-02 10:54 AM -----

Christine Roush/HC-SC/GC/CA

2009-10-02 10:05 AM

To Nicole Prentice/HC-SC/GC/CA@HWC

cc

Subject Re: Fw: Media enquiry - [REDACTED] - CMAJ - Salvia Divinorum [Link](#)

There is a It's Your Health article that has been going around for comments for awhile now - you should take a look at the latest draft of this and use the latest wording in it. I don't think it has been approved yet - it is one of these projects that keeps going back and forth to the various groups for approval. You may therefore need to seek approval from other areas too. I will try and locate the latest article and give you the contact persons to follow up with to obtain the very latest article. The CMAJ is a pretty big, well respected medical journal so we have to treat this inquiry with a lot of attention.

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
Health Canada/Santé Canada  
Tel/Tél : (613) 954-0712/Cell: (613) 219-7194  
Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca

Nicole Prentice/HC-SC/GC/CA

2009-10-02 10:02 AM

To Christine Roush/HC-SC/GC/CA@HWC

cc

Subject Fw: Media enquiry - [REDACTED] - CMAJ - Salvia Divinorum

Hello,

I have pulled responses for this enquiry. There is lots of info so please let me know what you want taken out before I push this through approvals...also will this enquiry have to go through HPFB approvals?

CMAJ has an interest in Salvia divinorum, a tropical member of the Mint family. It's called a "legal high". It's increasingly being banned in the U.S.

Q1 - I was hoping you could get me a comment from Health Canada about Salvia. If it's being looked at. If it will be banned?

A1 - Salvia Divinorum is a species of sage which belongs to the mint family. It is found in the form of dried leaves, extract and plant cuttings. Salvia Divinorum, also known as "diviner's sage", is chewed or smoked

and can induce illusions and hallucinations. It is known to have psychotropic effects, which means it affects the mind and mental processes.

Health Canada continues to collect relevant information about *Salvia divinorum* and its active ingredient, Salvinorin A, from both national and international sources in order to determine what, if any, regulatory controls are needed. In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, Salvinorin A, are controlled under the *Controlled Drugs and Substances Act* (CDSA). *Salvia divinorum* is not listed under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these conventions.

A regulatory amendment is necessary to add a substance to one of the Schedules of the Controlled Drugs and Substances Act. This process may take 12 to 18 months once the requirement to schedule a substance has been identified; however, where a substance presents grave harm to the public, extraordinary measures may be taken to control a substance in a more timely manner.

Several countries (Australia, Belgium, Denmark, Sweden, Italy, Spain, Finland and South Korea) have placed controls on the import and/or sale of *Salvia divinorum*. Although some individual U.S. states have implemented laws restricting its use, sale and/or distribution, *Salvia divinorum* is not federally regulated under the *Controlled Substances Act* in the United States.

While the media have reported that use of *Salvia divinorum* is on the rise in certain parts of the country, Health Canada does not currently have statistics on its use across the Canadian population. Health Canada is taking steps to address this lack of data. Questions regarding the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. A general open-ended question about the use of other substances was also included in the 2008 Canadian Alcohol and Drug Use Monitoring Survey.

*Salvia divinorum*, when associated with health claims, could meet the definition of a natural health product under the *Natural Health Product Regulations* (NHPR). This means that Salvia products that are not in compliance with the NHPR may be subject to compliance and enforcement actions. As of January 2009, Health Canada had not issued any Natural Product Numbers (NPN) or Drug Identification Numbers - Homeopathic Medicine (DIN-HM) for *Salvia divinorum* products.

Q2 - Is it a big deal or not at all? (ie. Are there serious health concerns?)

A2 - *Salvia Divinorum*'s mechanism of action is still not fully understood. Although long-term effects have not yet been observed, *Salvia Divinorum* has been known to cause hallucinations, out-of-body experiences, unconsciousness and short-term memory loss. There is, consequently, a potential for accidents occurring while the user is under the influence of the substance.

The plant's effects are short acting. We are not aware at this time of any cases of dependency to *Salvia Divinorum* having been reported. Nevertheless, Health Canada will continue to monitor *Salvia Divinorum*. Should evidence arise that suggests a significant risk to public health and safety, Health Canada will take action accordingly, which could include adding *Salvia Divinorum* to one of the schedules under the Controlled Drugs and Substances Act. (Yes, Health Canada, essentially through the Drug Strategy and Controlled Substances Program, has the authority to schedule *Salvia D* under the CDSA)

Health Canada recommends that you avoid using this substance because very little is known about the damage it may cause to the body, including the brain. There is also no way to predict how it will affect you with each use.

s.19(1)

**Risks of Using *Salvia divinorum***

*S. divinorum*'s effects, which vary from person to person, are often described as unpleasant and may include the following: hallucinations; dysphoria (feeling unwell, uneasy or unhappy); out-of-body experiences; uncontrollable laughter; loss of consciousness; short-term memory loss; lack of physical coordination; slurred speech and awkward sentence patterns.

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as: the potency of the product; how much is used; the purity of the product (it may be mixed with other substances); how it is taken (e.g., chewed, swallowed or smoked); the user's mood and expectations.

Deadline : Monday COB

Nicole Prentice

Junior Communications Officer | L'Officier junior de Communications

Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la consultation et des communications

Health Canada | Santé Canada

Tel: 613.941.3107

Fax: 613.948.8085

----- Forwarded by Nicole Prentice/HC-SC/GC/CA on 2009-10-02 09:46 AM -----

Gary

Holub/HC-SC/GC/C

A

To Christine Roush/HC-SC/GC/CA@HWC, Brooke Bryce/HC-SC/GC/CA@HWC, Bronwyn Cline/HC-SC/GC/CA@HWC, Nicole Prentice/HC-SC/GC/CA@HWC

cc

2009-10-01 01:56 PM

Subj Media enquiry - [REDACTED] - CMAJ - Salvia Divinorum  
ect

Hi team,

CMAJ has an interest in *Salvia divinorum*, a tropical member of the Mint family. It's called a "legal high". It's increasingly being banned in the U.S.

I pulled up some old media lines that may/may not be helpful.

Reporter's Qs:

Q1 - I was hoping you could get me a comment from Health Canada about *Salvia*. If it's being looked at. If it will be banned?

Q2 - Is it a big deal or not at all? (ie. Are there serious health concerns?)

Deadline : Monday COB



\*\*\*

Thanks,  
Gary

Media lines (June 2009) [Link](#)

**Q10: What is the difference between the CADUMS and the Canadian Addiction Survey of 2004 (CAS)?**

**A10.** Selected comparisons with the results from the Canadian Addiction Survey of 2004 will be available, due to similarities in questions and methodology with CADUMS. It is important to point out, however, that data collection for the CAS took place from **December 2003 to March 2004**, while CADUMS interviews were conducted from **April 2008 to December 2008**. Hence, some of the differences in results may be due to seasonal variations (such as an increase of the use of alcohol and drugs) rather than year-to-year differences in behaviours or outcomes. In addition, unlike the CAS, the CADUMS did not examine lifetime prevalence of illicit drug use because priority was given to describing the current alcohol and illicit drug use situation in Canada. Also, unlike its predecessor, CADUMS included questions about use and abuse of pharmaceuticals and expanded the hallucinogens question to include Salvia Divinorum and magic mushrooms.

**Q16. Will there be any changes to the 2009 CADUMS?**

**A16.** CADUMS is continuing in 2009 with some revisions. In 2008, the CADUMS did not examine lifetime prevalence of illicit drug use because priority was given to describing the current alcohol and illicit drug use situation in Canada. In 2009, changes to the questionnaire will entail the inclusion of questions looking at lifetime prevalence, in addition to past 12 month, of illicit drug use. In addition, in 2009 the use of Salvia Divinorum will no longer be examined within the scope of the question on hallucinogens, but instead will be examined on its own in a new question. Other changes to the questionnaire include the addition of questions on the perceived risks of substance use as well as reasons for not using; a question examining type of drivers licence; and a question on any involvement in a motor vehicle accident/collision, regardless of alcohol or drug use.

Gary Scott Holub  
Media Relations Officer | Agent des relations avec les médias  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la  
consultation et des communications  
Health Canada | Santé Canada  
(t) 613.954.4807  
(e) gary\_holub@hc-sc.gc.ca  
Government of Canada | Gouvernement du Canada

----- Forwarded by Gary Holub/HC-SC/GC/CA on 2009-10-01 01:52 PM -----



### Media Enquiry - Demande médiatique

Name/Nom : [REDACTED]	Media/Média : Canadian Medical Association Journal
Telephone/Téléphone [REDACTED]	Language/Langue : English-anglais
Cell Telephone/Téléphone cellulaire :	Fax/Télécopieur :
Email/Courriel : [REDACTED]	
Date and Time Received Date et Heure de réception : 2009-10-01 10:28:02 AM	Date Completed Date d'achèvement :

**Subject/Objet :** Controlled Substances/Substances contrôlées

2009-10-01 10:28:03 AM (Gary Holub)

Article for CMAJ about Salvia divinorum, a tropical member of the Mint family. It's called a "legal high". It's increasingly being banned in the U.S.

Q1 - I was hoping you could get me a comment from Health Canada about Salvia. If it's being looked at. If it will be banned?

Q2 - Is it a big deal or not at all? (ie. Are there serious health concerns?)

Deadline : Monday COB

2009-10-01 10:28:04 AM (Gary Holub)

Media lines (June 2009) [Link](#)

**Q10:** What is the difference between the CADUMS and the Canadian Addiction Survey of 2004 (CAS)?

**A10.** Selected comparisons with the results from the Canadian Addiction Survey of 2004 will be available, due to similarities in questions and methodology with CADUMS. It is important to point out, however, that data collection for the CAS took place from December 2003 to March 2004, while CADUMS interviews were conducted from April 2008 to December 2008. Hence, some of the differences in results may be due to seasonal variations (such as an increase of the use of alcohol and drugs) rather than year-to-year differences in behaviours

or outcomes. In addition, unlike the CAS, the CADUMS did not examine lifetime prevalence of illicit drug use because priority was given to describing the current alcohol and illicit drug use situation in Canada. Also, unlike its predecessor, CADUMS included questions about use and abuse of pharmaceuticals and expanded the hallucinogens question to include Salvia Divinorum and magic mushrooms.

**Q16. Will there be any changes to the 2009 CADUMS?**

**A16.** CADUMS is continuing in 2009 with some revisions. In 2008, the CADUMS did not examine lifetime prevalence of illicit drug use because priority was given to describing the current alcohol and illicit drug use situation in Canada. In 2009, changes to the questionnaire will entail the inclusion of questions looking at lifetime prevalence, in addition to past 12 month, of illicit drug use. In addition, in 2009 the use of Salvia Divinorum will no longer be examined within the scope of the question on hallucinogens, but instead will be examined on its own in a new question. Other changes to the questionnaire include the addition of questions on the perceived risks of substance use as well as reasons for not using; a question examining type of drivers licence; and a question on any involvement in a motor vehicle accident/collision, regardless of alcohol or drug use.

2009-10-01 10:29:12 AM (Gary Holub)

Sent Qs, with proposed media lines, to Christine roush, Nicole, Brooke, Bronwyn

Interview with spokesperson granted/Entrevue avec porte-parole accordé:

Branch/Direction générale : HECS - Controlled Substances & Drug Analysis/DGSESC - Direction de la sécurité des substances chimiques et des produits de consommation

Spokesperson/Porte-parole :

Reporter's Deadline

Heure de tombée du journaliste :

Priority/Priorité : Regular

Telephone/Téléphone :

Story Run Date

Date de parution de l'article :

Status/Rapport de situation : Follow-up



Media Relations Officer/Agente de relations avec les médias : Gary Holub

Gary Holub/HC-SC/GC/CA

2009-10-01 10:42:27 AM EDT

Gary Holub/HC-SC/GC/CA

2009-10-01 01:51:46 PM EDT

Send To / Transmettre à : Suzanne Desjardins; Stephanie Szick; Christine von Arx; Ray Edwards; Pamela Arnott; Kathleen Malone; Ken Moore; Bronwyn Cline; Christine Roush; Charles Mojsey/HC-SC/GC/CA; Peter Yendall/HC-SC/GC/CA; Jean Tessier/HC-SC/GC/CA; Josee Bellemare/HC-SC/GC/CA; Tim Vail/HC-SC/GC/CA;

**Branch Recipient:**

Suzanne Desjardins, Stephanie Szick, Christine von Arx, Ray Edwards, Pamela Arnott, Kathleen Malone, Ken Moore, Bronwyn Cline, Christine Roush

**Mail Recipients:**

CN=Charles Mojsey/OU=HC-SC/O=GC/C=CA, CN=Peter Yendall/OU=HC-SC/O=GC/C=CA, CN=Jean

Tessier/OU=HC-SC/O=GC/C=CA, CN=Josee Bellemare/OU=HC-SC/O=GC/C=CA, CN=Tim Vail/OU=HC-SC/O=GC/C=CA



Cheryl  
Tremblay/HC-SC/GC/CA  
2009-10-05 09:40 AM

To Nicole Prentice/HC-SC/GC/CA@HWC  
cc Carmen Berube/HC-SC/GC/CA@HWC, Christine Roush/HC-SC/GC/CA@HWC, Diane Allan/HC-SC/GC/CA@HWC, Katie  
bcc  
Subject Re: For approval: Media enquiry - [REDACTED] - CMAJ - Salvia Divinorum

Hi Nicole,

Proposed changes in red...

Q1 - I was hoping you could get me a comment from Health Canada about Salvia. If it's being looked at. If it will be banned?

A1 - *Salvia Divinorum* is a species of sage which belongs to the mint family. It is found in the form of dried leaves, extract and plant cuttings. *Salvia Divinorum*, also known as "diviner's sage", is chewed or smoked and can in order to induce illusions and hallucinations. It is known to have its psychotropic effects, which means it affects the mind and mental processes.

~~Health Canada continues to collect relevant information about *Salvia divinorum* and its active ingredient, S salvinorin A, from both national and international sources in order to determine what, if any, regulatory controls are needed.~~

In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, Ssalvinorin A, are controlled under the *Controlled Drugs and Substances Act* (CDSA). *Salvia divinorum* is not listed under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these conventions. ~~*Salvia divinorum*, when associated with health claims, could~~ does however meet the definition of a natural health product under the *Natural Health Product Regulations* (NHPR). This means that Salvia products that are not in compliance with the NHPR may be subject to compliance and enforcement actions. As of January 2009, Health Canada had not issued any Natural Product Numbers (NPN) or Drug Identification Numbers - Homeopathic Medicine (DIN-HM) for *Salvia divinorum* products.

Several countries (Australia, Belgium, Denmark, Sweden, Italy, Spain, Finland and South Korea) have placed controls on the import and/or sale of *Salvia divinorum*. Although some individual U.S. states have implemented laws restricting its use, sale and/or distribution, *Salvia divinorum* is not federally regulated under the *Controlled Substances Act* in the United States.

~~A regulatory amendment is necessary to add a substance to one of the Schedules of the *Controlled Drugs and Substances Act*. This process may take 12 to 18 months once the requirement to schedule a substance has been identified; however, where a substance presents grave harm to the public, extraordinary measures may be taken to control a substance in a more timely manner.~~

Health Canada considers several factors in determining whether scheduling a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in regulatory status;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

In the case of *Salvia divinorum*, information about these factors is either missing or anecdotal in nature. For example, very few controlled scientific studies of the physical and psychotropic effects of *Salvia divinorum* on humans have been carried out, and using these studies to predict the potential for addiction and abuse associated with *Salvia divinorum* is difficult. More controlled systematic research in this area is needed. Health Canada is taking steps to address the lack of data regarding the use of and/or extent of abuse involving *Salvia divinorum*. Questions regarding the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. A general open-ended question about the use of other substances has also been included in the 2008 Canadian Alcohol and Drug Use Monitoring Survey. The data, however, will not likely be available until 2010. In the interim, Health Canada will continue to collect and consider information regarding *Salvia divinorum* as it becomes available.

~~While the media have reported that use of *Salvia divinorum* is on the rise in certain parts of the country, Health Canada does not currently have statistics on its use across the Canadian population. Health Canada is taking steps to address this lack of data. Questions regarding the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. A general open-ended question about the use of other substances was also been included in the 2008 Canadian Alcohol and Drug Use Monitoring Survey.~~

~~*Salvia divinorum*, when associated with health claims, could meet the definition of a natural health product under the *Natural Health Product Regulations* (NHPR). This means that *Salvia* products that are not in compliance with the NHPR may be subject to compliance and enforcement actions. As of January 2009, Health Canada had not issued any Natural Product Numbers (NPN) or Drug Identification Numbers - Homeopathic Medicine (DIN-HM) for *Salvia divinorum* products.~~

Health Canada continues to collect relevant information about *Salvia divinorum* and its active ingredient, <sup>Salv</sup>salvinorin A, from both national and international sources in order to determine what, if any, regulatory controls are needed.

Q2 - Is it a big deal or not at all? (ie. Are there serious health concerns?)

A2 - Health Canada is aware of some of the effects associated with the use of *Salvia divinorum* including hallucinations, out-of-body experiences, unconsciousness and short-term memory loss. <sup>shakes (?)</sup>

Very few controlled scientific studies of the physical and psychotropic effects of *Salvia divinorum* on humans have been carried out, and using these studies to predict the potential for addiction and abuse associated with *Salvia divinorum* is difficult. More controlled systematic research in this area is needed.

Health Canada has only received a limited number of communications regarding *Salvia divinorum* from law enforcement agencies, and none of these has advised that the use of *Salvia divinorum* poses any threat to public safety.

~~*Salvia Divinorum's* mechanism of action is still not fully understood. Although long-term effects have not yet been observed, *Salvia Divinorum* has been known to cause hallucinations, out-of-body experiences, unconsciousness and short-term memory loss. There is, consequently, a potential for accidents occurring while the user is under the influence of the substance.~~

~~The plant's effects are short acting. We are not aware at this time of any cases of dependency to *Salvia Divinorum* having been reported. Nevertheless, Health Canada will continue to monitor *Salvia Divinorum*. Should evidence arise that suggests a significant risk to public health and safety, Health Canada will take action accordingly, which could include adding *Salvia Divinorum* to one of the schedules under the *Controlled Drugs and Substances Act*. (Yes, Health Canada, essentially through the *Drug Strategy and Controlled Substances Program*, has the authority to schedule *Salvia D* under the *CDSA*.)~~

That being said,

Health Canada recommends that ~~you avoid using~~ the use of this substance be avoided because very little is known about the damage it may cause to the body, including the brain. There is also no way to predict how it will affect ~~you~~ an individual with each use.

### Risks of Using *Salvia divinorum*

*S. alvia divinorum's* effects, which vary from person to person, are often described as unpleasant and may include the following: hallucinations; dysphoria (i.e., feeling unwell, uneasy or unhappy); out-of-body experiences; uncontrollable laughter; loss of consciousness; short-term memory loss; lack of physical coordination; slurred speech and awkward sentence patterns.

There is no way to predict what effect this substance may have on ~~you~~ individuals. In addition, the effects may differ from one use to the next, depending on factors such as: the potency of the product; how much is used; the purity of the product (it may be mixed with other substances); how it is taken (e.g., chewed, swallowed or smoked); and the user's mood and expectations.

Health Canada continues to collect relevant information about *Salvia divinorum* and its active ingredient, salvinin A, from both national and international sources in order to determine what, if any, regulatory controls are needed.


Nicole Prentice/HC-SC/GC/CA



Nicole  
Prentice/HC-SC/GC/CA  
2009-10-05 09:09 AM

To Cheryl Tremblay/HC-SC/GC/CA@HWC

cc Carmen Berube/HC-SC/GC/CA@HWC, "Cheryl Tremblay"  
<Cheryl\_Tremblay@hc-sc.gc.ca>, Christine  
Roush/HC-SC/GC/CA@HWC, Diane  
Allan/HC-SC/GC/CA@HWC, Katie  
Greenwood/HC-SC/GC/CA@HWC

Subject Re: For approval: Media enquiry - [REDACTED] - CMAJ -  
Salvia Divinorum 

Hi all,

Yes, this is a different request - it was just sent at the same time as the last one so may have been confusing. This one is due at COB today so if I can have your approval asap that would be great - also should this one go through HPFB approvals too?

Nicole Prentice  
Junior Communications Officer | L'Officier junior de Communications  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la  
consultation et des communications  
Health Canada | Santé Canada  
Tel: 613.941.3107  
Fax: 613.948.8085



Nicole  
Prentice/HC-SC/GC/CA  
2009-10-05 12:01 PM

To Cheryl Tremblay/HC-SC/GC/CA@HWC  
cc Bronwyn Cline/HC-SC/GC/CA@HWC, Carmen  
Berube/HC-SC/GC/CA@HWC, Diane  
Allan/HC-SC/GC/CA@HWC

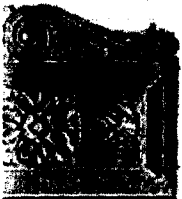
bcc

Subject Re: Urgent: MEDIA REQUEST - Étude sur le Salvia  
(Radio-Canada Toronto)

I spoke with media relations and they were not able to get any more information on this study from the reporter. They want to know if you have a way to search the call number given below.

Nicole Prentice  
Junior Communications Officer | L'Officier junior de Communications  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la  
consultation et des communications  
Health Canada | Santé Canada  
Tel: 613.941.3107  
Fax: 613.948.8085

Cheryl Tremblay/HC-SC/GC/CA



Cheryl  
Tremblay/HC-SC/GC/CA  
2009-10-05 11:57 AM

To Nicole Prentice/HC-SC/GC/CA@HWC  
cc Bronwyn Cline/HC-SC/GC/CA@HWC, Carmen  
Berube/HC-SC/GC/CA@HWC, Diane  
Allan/HC-SC/GC/CA@HWC  
Subject Re: Urgent: MEDIA REQUEST - Étude sur le Salvia  
(Radio-Canada Toronto)

Hi Nicole,

Here is everything with the exception of Q1. As discussed, not sure what study they are referring to???

Thanks,  
Cheryl  
Nicole Prentice/HC-SC/GC/CA



Nicole  
Prentice/HC-SC/GC/CA  
2009-10-05 11:06 AM

To Diane Allan/HC-SC/GC/CA@HWC  
cc Carmen Berube/HC-SC/GC/CA@HWC, Bronwyn  
Cline/HC-SC/GC/CA@HWC, Cheryl  
Tremblay/HC-SC/GC/CA@HWC  
Subject Urgent: MEDIA REQUEST - Étude sur le Salvia  
(Radio-Canada Toronto)

Nicole Prentice/HC-SC/GC/CA

Hello,



Christine 954-6789  
Geston

Below is yet another media enquiry on saliva for input/approval by noon if possible as this is due at 3 today.

Approved by:

HECS

Diane Allan, Director, OCS, CSTD (pending)  
Suzanne Desjardins, Director, ODARS, CSTD (Q4 only - pending)  
Cathy A. Sabiston, DG, CSTD (pending)  
Kathleen Malone, Senior Communications Executive, HECSB (pending)  
Paul Glover, HECS ADM (pending)

HPFB

Dr. Robin Marles, Director, NHPD (pending)  
Michelle Boudreau, DG, NHPD (pending)  
Ken Polk, Communications Executive, HPFB (pending)  
XX, ADM, HPFB (pending)

**Entrevue:** Le journaliste aimerait parler à un porte-parole (pré-enregistré) - mettre une voix sur les conclusions de l'étude et la position de Santé Canada.

*Ask if Jocelyn is available for interview/if program recommends doing it.*

**Échéance:** Aujourd'hui (15:00)

*Ask MRO for more time - need to coordinate with HPFB*

Q1 - Est-ce possible d'avoir une copie de l'étude? (l'étude devait se terminer à la fin mars 2009 - appel d'offre 1000096933)?

A1 - ?

Q2 - Intéressé à savoir la position de Santé Canada. Est-ce qu'on considère changer le placement/classification de ce produit dû au fait qu'il contient des caractéristiques hallucinogènes?

A2-- In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA). *Salvia divinorum* is not listed under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these conventions.

~~Under certain conditions of use, (OR Under certain conditions of use,)~~ *Salvia divinorum* does however meet(s) the definition of a natural health product under the Natural Health Product Regulations (NHPR). This means that *Salvia* products that are not in compliance with the NHPR may be subject to compliance and enforcement actions. As of January 2009, Health Canada had not issued any Natural Product Numbers (NPN) or Drug Identification Numbers - Homeopathic Medicine (DIN-HM) for *Salvia divinorum* products.

~~As of January 2009, Health Canada had not issued any Natural Product Numbers (NPN) or Drug Identification Numbers - Homeopathic Medicine (DIN-HM) for *Salvia divinorum* products.~~

Health Canada continues to collect relevant information about *Salvia divinorum* and its active ingredient, Salvinorin A, from both national and international sources in order to determine what, if any, regulatory controls are needed.

s.19(1)



Nicole  
Prentice/HC-SC/GC/CA  
2009-10-05 03:01 PM

To Cheryl Tremblay/HC-SC/GC/CA@HWC  
cc  
bcc

Subject Fw: URGENT: Interview request: For input/approval:  
[REDACTED] CBC Radio Toronto - Salvia divinorum

Here is the first one that was due last Friday.

Nicole Prentice  
Junior Communications Officer | L'Officier junior de Communications  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la  
consultation et des communications  
Health Canada | Santé Canada  
Tel: 613.941.3107  
Fax: 613.948.8085

— Forwarded by Nicole Prentice/HC-SC/GC/CA on 2009-10-05 03:00 PM —



Nicole  
Prentice/HC-SC/GC/CA  
2009-10-05 02:02 PM

To Gary Holub/HC-SC/GC/CA, Christelle Legault/HC-SC/GC/CA  
cc Bronwyn Cline/HC-SC/GC/CA@HWC, Christine  
Roush/HC-SC/GC/CA@HWC

Subject Fw: URGENT: Interview request: For input/approval:  
[REDACTED] - CBC Radio Toronto - Salvia divinorum

Hello again,

We have another media response fully approved. Sorry for delay!

Approved by:  
Christine Roush, Sr Comms Advisor  
Diane Allan, Director, OCS  
Dr. Robin Marles, Director, NHPD  
Cathy Sabiston, DG, CSTD  
Michelle Boudreau, DG, NHPD  
Kathleen Malone, Sr Comms Executive  
Paul Glover, ADM, HECS  
Siddika Mathani, A/ADM, HPFB ADMO

Q1 - How is *Salvia divinorum* classified in Canada?

A1 - In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, Salvinorin A, are controlled under the *Controlled Drugs and Substances Act* (CDSA).

*Salvia divinorum* is not listed under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these conventions.

*Salvia divinorum* , when associated with health claims, could meet the definition of a natural

health product under the *Natural Health Product Regulations* (NHPR). This means that *Salvia* products that are being sold as NHPs that are not in compliance with the NHPR, may be subject to compliance and enforcement actions.

As of January 2009, Health Canada had not issued any Natural Product Numbers (NPN) or Drug Identification Numbers – Homeopathic Medicine (DIN-HM) for *Salvia divinorum* products.

Q2 - Is it regulated (or are there plans to regulate it)?

A2 - *Salvia divinorum* , when associated with health claims, could meet the definition of a natural health product under the NHPR. In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA). *Salvia divinorum* is not listed under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these conventions.

Health Canada continues to collect relevant information about *Salvia Divinorum* and its active ingredient, Salvinorin A, from both national and international sources in order to determine what, if any, regulatory controls are needed.

Q3 - How much research has been done on the effects of salvia (what is known about its properties etc.)?

A3- Health Canada does not currently have statistics on its use across the Canadian population. Health Canada is taking steps to address this lack of data. Questions regarding the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey. A general open-ended question about the use of other substances was also included in the 2008 Canadian Alcohol and Drug Use Monitoring Survey.

Q4 - Are there concerns that anyone could access it ? (it's under glass counter at corner stores and in most head shops here in Toronto).

A4 - In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA). Health Canada is aware of some of the effects associated with the use of *Salvia divinorum* and continues to collect and consider information about *Salvia divinorum* and its active ingredient, salvinorin A, from both national and international sources in order to determine what, if any, regulatory controls are needed.

Very few controlled scientific studies of the physical and psychotropic effects of *Salvia divinorum* on humans have been carried out, and using these studies to predict the potential for addiction and abuse associated with *Salvia divinorum* is difficult. More controlled systematic research in this area is needed.

Health Canada has only received a limited number of communications regarding *Salvia divinorum* from law enforcement agencies, and none of these has advised that the use of *Salvia divinorum* poses any threat to public safety.

Q5 - What would it take to get regulated ? (ie: kids uploading videos to You Tube of their "bad trips" on

s.19(1)

salvia).

A5 - Health Canada considers several factors in determining whether scheduling a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in regulatory status;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

In the case of *Salvia divinorum*, information about these factors is either missing or anecdotal in nature. For example, very few controlled scientific studies of the physical and psychotropic effects of *Salvia divinorum* on humans have been carried out, and using these studies to predict the potential for addiction and abuse associated with *Salvia divinorum* is difficult. More controlled systematic research in this area is needed. Health Canada is taking steps to address the lack of data regarding the use of and/or extent of abuse involving *Salvia divinorum*. Questions regarding the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. A general open-ended question about the use of other substances has also been included in the 2008 Canadian Alcohol and Drug Use Monitoring Survey. The data, however, will not likely be available until 2010. In the interim, Health Canada will continue to collect and consider information regarding *Salvia divinorum* as it becomes available.

Nicole Prentice  
Junior Communications Officer | L'Officier junior de Communications  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la consultation et des communications  
Health Canada | Santé Canada  
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----- Forwarded by Nicole Prentice/HC-SC/GC/CA on 2009-10-05 01:59 PM -----



Jennifer  
Peddle/HC-SC/GC/CA  
2009-10-05 01:54 PM

To Nicole Prentice/HC-SC/GC/CA@HWC  
cc

Subject Fw: URGENT: Interview request: For input/approval:  
[REDACTED] - CBC Radio Toronto - Salvia divinorum

Hi Nicole,  
HPFB ADMO has approved (Siddika Mathani, A/ADM)

Jennifer Peddle  
Senior Communications Advisor -HPFB | Conseillère principale en communications - DGPSA  
Strategic Communications Directorate | Direction des communications stratégique  
Public Affairs, Consultations and Regions Branch (PACRB) | Direction générale des affaires publiques, de

s.19(1)

la consultation et des régions (DGAPCR)  
Health Canada | Santé Canada  
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613.957.8805 (fax/télécopieur)  
613.868.5835 (cell/portable)

----- Forwarded by Jennifer Peddle/HC-SC/GC/CA on 2009-10-05 01:54 PM -----



**Jennifer-Anne  
McNeill/HC-SC/GC/CA**  
2009-10-05 01:53 PM

To Jennifer Peddle/HC-SC/GC/CA@HWC  
cc Ken Polk/HC-SC/GC/CA@HWC

Subject Re: Fw: URGENT: Interview request: For input/approval:  
CBC Radio Toronto - Salvia divinorum

Siddika has approved. sorry it took so long.

---

Jennifer-Anne McNeill  
Senior Advisor to the Executive Director, Issues Management/ Conseillère principale à la Directrice  
exécutive, Gestion des questions d'intérêt  
ADMO/BSMA  
Health Canada  
Health Products and Food Branch (HPFB) / Direction générale des produits de santé et des aliments  
(DGPSA)  
Phone: (613) 941-9094 / Fax: (613) 957-3954  
e-mail: jennifer-anne\_mcneill@hc-sc.gc.ca

Jennifer Peddle/HC-SC/GC/CA



**Jennifer  
Peddle/HC-SC/GC/CA**  
2009-10-05 11:02 AM

To Jennifer-Anne McNeill/HC-SC/GC/CA@HWC  
cc Ken Polk/HC-SC/GC/CA@HWC

Subject Fw: URGENT: Interview request: For input/approval:  
Toronto - Salvia divinorum

Hi Jenn-Anne,  
We have received a media inquiry from \_\_\_\_\_ on Salvia Divinorum. HECS has the  
lead on the response, and NHPD has provided input, which was approved by Robin Marles and Michelle  
Boudreau. HECS ADMO has requested that we share the responses with HPFB ADMO for approval.  
The deadline is quite urgent. We would need ADMO approval by Noon today.

Thanks,  
Jennifer Peddle  
Senior Communications Advisor -HPFB | Conseillere principale en communications - DGPSA  
Strategic Communications Directorate | Direction des communications stratégique  
Public Affairs, Consultations and Regions Branch (PACRB) | Direction générale des affaires publiques, de  
la consultation et des régions (DGAPCR)  
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----- Forwarded by Jennifer Peddle/HC-SC/GC/CA on 2009-10-05 11:00 AM -----



Nicole  
Prentice/HC-SC/GC/CA  
2009-10-05 10:56 AM

To Jennifer Peddle/HC-SC/GC/CA@HWC  
cc Bronwyn Cline/HC-SC/GC/CA@HWC, Christine Roush/HC-SC/GC/CA@HWC  
Subject URGENT: Interview request: For input/approval: [REDACTED]  
[REDACTED] CBC Radio Toronto - Salvia divinorum

Hello again,

This is back to you now. Our ADM has asked that we obtain HPFB ADM approval - can you pass this along for us Thanks.

Approved by:  
Christine Roush, Sr Comms Advisor  
Diane Allan, Director, OCS  
Dr. Robin Marles, Director, NHPD  
Cathy Sabiston, DG, CSTD  
Michelle Boudreau, DG, NHPD  
Kathleen Malone, Sr Comms Executive  
Paul Glover, ADM, HECS  
XX, ADM, HPFB (pending)

Q1 - How is *Salvia divinorum* classified in Canada?

A1 - In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, Salvinorin A, are controlled under the *Controlled Drugs and Substances Act* (CDSA).

*Salvia divinorum* is not listed under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these conventions.

*Salvia divinorum*, when associated with health claims, could meet the definition of a natural health product under the *Natural Health Product Regulations* (NHPR). This means that *Salvia* products that are being sold as NHPs that are not in compliance with the NHPR, may be subject to compliance and enforcement actions.

As of January 2009, Health Canada had not issued any Natural Product Numbers (NPN) or Drug Identification Numbers – Homeopathic Medicine (DIN-HM) for *Salvia divinorum* products.

Q2 - Is it regulated (or are there plans to regulate it)?

A2 - *Salvia divinorum*, when associated with health claims, could meet the definition of a natural health product under the NHPR. In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA). *Salvia divinorum* is not listed under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these conventions.

Health Canada continues to collect relevant information about *Salvia Divinorum* and its active ingredient, Salvinorin A, from both national and international sources in order to determine what, if any, regulatory controls are needed.

Q3 - How much research has been done on the effects of salvia (what is known about its properties etc.)?

A3- Health Canada does not currently have statistics on its use across the Canadian population. Health Canada is taking steps to address this lack of data. Questions regarding the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey. A general open-ended question about the use of other substances was also included in the 2008 Canadian Alcohol and Drug Use Monitoring Survey.

Q4 - Are there concerns that anyone could access it ? (it's under glass counter at corner stores and in most head shops here in Toronto).

A4 - In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA). Health Canada is aware of some of the effects associated with the use of *Salvia divinorum* and continues to collect and consider information about *Salvia divinorum* and its active ingredient, salvinorin A, from both national and international sources in order to determine what, if any, regulatory controls are needed.

Very few controlled scientific studies of the physical and psychotropic effects of *Salvia divinorum* on humans have been carried out, and using these studies to predict the potential for addiction and abuse associated with *Salvia divinorum* is difficult. More controlled systematic research in this area is needed.

Health Canada has only received a limited number of communications regarding *Salvia divinorum* from law enforcement agencies, and none of these has advised that the use of *Salvia divinorum* poses any threat to public safety.

Q5 - What would it take to get regulated ? (ie: kids uploading videos to You Tube of their "bad trips" on salvia).

A5 - Health Canada considers several factors in determining whether scheduling a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in regulatory status;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

In the case of *Salvia divinorum*, information about these factors is either missing or anecdotal in nature. For example, very few controlled scientific studies of the physical and psychotropic

effects of *Salvia divinorum* on humans have been carried out, and using these studies to predict the potential for addiction and abuse associated with *Salvia divinorum* is difficult. More controlled systematic research in this area is needed. Health Canada is taking steps to address the lack of data regarding the use of and/or extent of abuse involving *Salvia divinorum*. Questions regarding the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. A general open-ended question about the use of other substances has also been included in the 2008 Canadian Alcohol and Drug Use Monitoring Survey. The data, however, will not likely be available until 2010. In the interim, Health Canada will continue to collect and consider information regarding *Salvia divinorum* as it becomes available.

Nicole Prentice

Junior Communications Officer | L'Officier junior de Communications

Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la consultation et des communications

Health Canada | Santé Canada

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Fax: 613.948.8085





Nicole  
Prentice/HC-SC/GC/CA

2009-10-06 08:20 AM

To Cheryl Tremblay/HC-SC/GC/CA@HWC

cc

bcc

Subject Fw: Urgent: For input/approval: MEDIA REQUEST - Étude  
sur le Salvia (Radio-Canada Toronto)

FYI

Nicole Prentice

Junior Communications Officer | L'Officier junior de Communications

Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la  
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— Forwarded by Nicole Prentice/HC-SC/GC/CA on 2009-10-06 08:20 AM —



Bronwyn Cline/HC-SC/GC/CA

2009-10-05 05:48 PM

To Gary Holub/HC-SC/GC/CA@HWC, Christelle  
Legault/HC-SC/GC/CA@HWC

cc Christine Roush/HC-SC/GC/CA@HWC, Nicole  
Prentice/HC-SC/GC/CA@HWC

Subject Urgent: For input/approval: MEDIA REQUEST - Étude sur le  
Salvia (Radio-Canada Toronto)

Approved by:

Diane Allan, Director, OCS, CSTD (Q2 & Q3)

Suzanne Desjardins, Director, ODARS, CSTD (Q1 & Q4)

Lindsey Blaney, Director Policy, NHPD, HPFB

Cathy A. Sabiston, DG, CSTD

Kathleen Malone, Senior Communications Executive, HECSB

Paul Glover, HECS ADM

**Q1 - Est-ce possible d'avoir une copie de l'étude? (l'étude devait se terminer à la fin mars 2009 - appel  
d'offre 1000096933)?**

A1 - Health Canada has not conducted its own studies on *Salvia divinorum*, however the department  
continues to collect and consider information about *Salvia divinorum* and its active ingredient, salvinorin A,  
from both national and international sources in order to determine what, if any, regulatory controls are  
needed.

**Q2 - Intéressé à savoir la position de Santé Canada. Est-ce qu'on considère changer le  
placement/classification de ce produit dû au fait qu'il contient des caractéristiques hallucinogènes?**

A2- In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated  
under the *Controlled Drugs and Substances Act* (CDSA). *Salvia divinorum* is not listed under the United  
Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of  
the countries (including Canada) that are signatories to these conventions.

Under certain conditions of use *Salvia divinorum* may meet the definition of a "natural health product"  
(NHP) under Health Canada's *Natural Health Products Regulations* (NHPR), but no NHPs containing this

substance have been approved for sale in Canada. This means products that contain *S. divinorum* have not been reviewed by Health Canada for safety, efficacy or quality. Salvia products that are being sold as NHPs that are not in compliance with the NHPR, may be subject to compliance and enforcement actions.

Health Canada continues to collect relevant information about *Salvia divinorum* and its active ingredient, Salvinorin A, from both national and international sources in order to determine what, if any, regulatory controls are needed.

**Q3 - Est-ce que Santé Canada peut élaborer sur le Salvia et ces caractéristiques?**

A3- *Salvia divinorum* is a species of sage which belongs to the mint family. It is found in the form of dried leaves, extract and plant cuttings. *Salvia divinorum*, also known as "diviner's sage", is chewed or smoked in order to induce its psychotropic effects, which means it affects the mind and mental processes. Health Canada is aware of some of the effects associated with the use of *Salvia divinorum* including hallucinations, out-of-body experiences, unconsciousness and short-term memory loss.

There is no way to predict what effect this substance may have from one individual to the next. In addition, the effects may differ from one use to the next, depending on factors such as: the potency of the product; how much is used; the purity of the product (it may be mixed with other substances); how it is taken (e.g., chewed, swallowed or smoked); and the user's mood and expectations.

**4 - Combien de gens utilisent cette substance?**

A4. Health Canada does not currently have statistics on its use across the Canadian population.

Health Canada is taking steps to address the lack of data regarding the use of and/or extent of abuse involving *Salvia divinorum*. Questions regarding the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. In addition, questions regarding the use of *Salvia divinorum* in the general population have also been included in the 2009 Canadian Alcohol and Drug Use Monitoring Survey. The data, however, will not likely be available until 2010. In the interim, Health Canada will continue to collect and consider information regarding *Salvia divinorum* as it becomes available.

Bronwyn Cline  
Communications Officer | Agente des communications

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bronwyn\_cline@hc-sc.gc.ca  
Health Canada | 269 Laurier Ave Ottawa ON K1A 0K9  
Santé Canada | 269 ave Laurier Ottawa ON K1A 0K9  
Government of Canada | Gouvernement du Canada

s.19(1)



Nicole  
Prentice/HC-SC/GC/CA  
2009-10-06 08:20 AM

To Cheryl Tremblay/HC-SC/GC/CA@HWC  
cc  
bcc  
Subject Fw: Media enquiry - [REDACTED] - CMAJ - Salvia Divinorum

FYI

Nicole Prentice  
Junior Communications Officer | L'Officier junior de Communications  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la consultation et des communications  
Health Canada | Santé Canada  
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Fax: 613.948.8085

— Forwarded by Nicole Prentice/HC-SC/GC/CA on 2009-10-06 08:20 AM —



Bronwyn Cline/HC-SC/GC/CA

2009-10-05 05:49 PM

To Gary Holub/HC-SC/GC/CA@HWC, Christelle Legault/HC-SC/GC/CA@HWC  
cc Christine Roush/HC-SC/GC/CA@HWC, Nicole Prentice/HC-SC/GC/CA@HWC  
Subject Media enquiry - [REDACTED] - CMAJ - Salvia Divinorum

Approved by:

Diane Allan, Director, OCS  
Lindsey Blaney, Director, Policy, NHPD  
Cathy Sabiston, DG, CSTD  
Kathleen Malone, Sr Comms Executive  
Paul Glover, ADM, HECS (pending)

**Q1 - I was hoping you could get me a comment from Health Canada about Salvia. If it's being looked at. If it will be banned?**

**A1 - *Salvia divinorum* is a species of sage which belongs to the mint family. It is found in the form of dried leaves, extract and plant cuttings. *Salvia divinorum*, also known as "diviner's sage", is chewed or smoked in order to induce its psychotropic effects, which means it affects the mind and mental processes.**

In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are controlled under the *Controlled Drugs and Substances Act* (CDSA). *Salvia divinorum* is not listed under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these conventions.

Under certain conditions of use *Salvia divinorum* may meet the definition of a "natural health product" (NHP) under Health Canada's *Natural Health Products Regulations* (NHPR), but no NHPs containing this substance have been approved for sale in Canada. This means products that contain *S. divinorum* have not been reviewed by Health Canada for safety, efficacy or quality. *Salvia* products that are being sold as NHPs that are not in compliance with the NHPR, may be subject to compliance and enforcement actions.

Health Canada considers several factors in determining whether scheduling a substance under the

*Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in regulatory status;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

In the case of *Salvia divinorum*, information about these factors is either missing or anecdotal in nature. Health Canada is taking steps to address the lack of data regarding the use of and/or extent of abuse involving *Salvia divinorum*. Questions regarding the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. A general open-ended question about the use of other substances has also been included in the 2008 Canadian Alcohol and Drug Use Monitoring Survey. The data, however, will not likely be available until 2010. In the interim, Health Canada will continue to collect and consider information regarding *Salvia divinorum* as it becomes available.

Health Canada continues to collect relevant information about *Salvia divinorum* and its active ingredient, salvinorin A, from both national and international sources in order to determine what, if any, regulatory controls are needed.

**Q2 - Is it a big deal or not at all? (ie. Are there serious health concerns?)**

A2 - Health Canada is aware of some of the effects associated with the use of *Salvia divinorum* including hallucinations, out-of-body experiences, unconsciousness and short-term memory loss.

Very few controlled scientific studies of the physical and psychotropic effects of *Salvia divinorum* on humans have been carried out, and using these studies to predict the potential for addiction and abuse associated with *Salvia divinorum* is difficult. More controlled systematic research in this area is needed.

Health Canada has only received a limited number of communications regarding *Salvia divinorum* from law enforcement agencies, and none of these has advised that the use of *Salvia divinorum* poses any threat to public safety.

Health Canada recommends that the use of this substance be avoided because very little is known about the damage it may cause to the body, including the brain. There is also no way to predict how it will affect an individual with each use.

#### **Risks of Using *Salvia divinorum***

There is no way to predict what effect this substance may have on individuals. In addition, the effects may differ from one use to the next, depending on factors such as: the potency of the product; how much is used; the purity of the product (it may be mixed with other substances); how it is taken (e.g., chewed, swallowed or smoked); and the user's mood and expectations.

Bronwyn Cline  
Communications Officer | Agente des communications

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bronwyn\_cline@hc-sc.gc.ca  
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Santé Canada | 269 ave Laurier Ottawa ON K1A 0K9  
Government of Canada | Gouvernement du Canada

Diane Allan/HC-SC/GC/CA  
2009-10-13 02:51 PM

To Bronwyn Cline/HC-SC/GC/CA@HWC  
cc Carmen Berube/HC-SC/GC/CA@HWC, Cheryl Tremblay/HC-SC/GC/CA@HWC, Christine Gagnon/HC-SC/GC/CA@HWC, Suzanne  
bcc

Subject Re: MEDIA REQUEST - Étude sur le Salvia (Radio-Canada Toronto)

Approved from me, yet I suspect this is more for Suzanne.

Diane Allan

Director / Directrice  
Office of Controlled Substances / Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch / Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada / Santé Canada  
Tel: 613-952-2177  
Fax: 613-946-4224

Bronwyn Cline/HC-SC/GC/CA



Bronwyn Cline/HC-SC/GC/CA

2009-10-13 01:44 PM

To Diane Allan/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC  
cc Carmen Berube/HC-SC/GC/CA@HWC, Christine Gagnon/HC-SC/GC/CA@HWC, Cheryl Tremblay/HC-SC/GC/CA@HWC  
Subject MEDIA REQUEST - Étude sur le Salvia (Radio-Canada Toronto)

Hello Diane and Suzanne,

The reporter has followed up again about Salvia D studies - suggested response from myself and HPFB below, for your input/approval. We want to try and make it as clear as possible that we haven't done any studies, but that we stay up-to-date on research done by others:

**Demande pour \*toute(s)\* étude(s) réalisée(s) par (ou pour) Santé Canada sur (uniquement ou dans un plus large contexte) la substance nommée Salvia Divinorum. Selon des commentaires faits par divers portes-paroles de Santé Canada aux médias, le ministère "étudie" les effets de cette substance depuis 2006... (Radio-Canada février 2008, Jason Bouzanis à la Presse Canadienne en avril 2007, Renée Bergeron au Journal de Québec en novembre 2006, etc...)**

**Comme je l'ai précisé au téléphone et dans mes courriels, je comprend que cette (ou ces) étude(s) ne sont pas nécessairement réalisée(s) \*per\* Santé Canada... mais parfois \*pour le compte\* du ministère. Dans les 2 cas, il me semble d'intérêt de partager avec le public les conclusions (et de possibles recommandations) concernant ce produit.**


A1 - Health Canada has not conducted or commissioned any ~~its own~~ studies on *Salvia divinorum*, however, the department continues to collect and consider information about *Salvia divinorum* and its active ingredient, salvinin A, from both national and

international sources in order to determine what, if any, regulatory controls are needed.

Bronwyn Cline  
Communications Officer | Agente des communications

613-941-2511 | facsimile / télécopieur 613-948-8085  
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Santé Canada | 269 ave Laurier Ottawa ON K1A 0K9  
Government of Canada | Gouvernement du Canada

Diane Allan/HC-SC/GC/CA  
2009-10-14 03:10 PM

To Cheryl Tremblay/HC-SC/GC/CA@HWC  
cc Daniel Galameau/HC-SC/GC/CA@HWC, Denis  
Arsenault/HC-SC/GC/CA@HWC  
bcc  
Subject Re: MEDIA REQUEST - Étude sur le Salvia (Radio-Canada  
Toronto) 

Thanks.

Cheryl Tremblay

----- Original Message -----

**From:** Cheryl Tremblay  
**Sent:** 2009-10-14 03:09 PM EDT  
**To:** Diane Allan  
**Cc:** Daniel Galarneau; Denis Arsenault  
**Subject:** Fw: MEDIA REQUEST - Étude sur le Salvia (Radio-Canada Toronto)

Hi Diane,


Daniel and Denis have approved the following.

Thanks,  
Cheryl

----- Forwarded by Cheryl Tremblay/HC-SC/GC/CA on 2009-10-14 03:06 PM -----



Cheryl  
Tremblay/HC-SC/GC/CA  
2009-10-14 01:12 PM

To Daniel Galameau/HC-SC/GC/CA, Denis  
Arsenault/HC-SC/GC/CA  
cc Cheryl Tremblay/HC-SC/GC/CA@HWC  
Subject Re: Fw: MEDIA REQUEST - Étude sur le Salvia  
(Radio-Canada Toronto) 

Looks ok to me. See changes in red regarding CADUMS info.

Diane Allan/HC-SC/GC/CA

Diane Allan/HC-SC/GC/CA  
2009-10-14 12:29 PM

To "Cheryl Tremblay" <Cheryl\_Tremblay@hc-sc.gc.ca>, "Denis  
Arsenault" <denis\_arsenault@hc-sc.gc.ca>  
cc "Mr. Daniel Galameau" <Daniel\_Galameau@hc-sc.gc.ca>  
Subject Fw: MEDIA REQUEST - Étude sur le Salvia (Radio-Canada  
Toronto)

Please review and propose changes or add response.

Thanks  
Bronwyn Cline

----- Original Message -----

**From:** Bronwyn Cline  
**Sent:** 2009-10-14 12:15 PM EDT  
**To:** Diane Allan; Suzanne Desjardins  
**Cc:** Christine Roush; Nicole Prentice  
**Subject:** MEDIA REQUEST - Étude sur le Salvia (Radio-Canada Toronto)

Hello,

Another follow-up question from Radio Canada on Salvia:

**Q6) Quelles sont les conclusions, préliminaires ou finales, à laquelle (auxquelles) Santé Canada est parvenu au cours des 3 années pendant lesquelles des analyses et de la recherche ont été effectués par le personnel du ministre sur la *Salvia divinorum*.**

**A6) Do we have any preliminary/final conclusions? If not we could say something along the lines of this, from an enquiry on Salvia on October 2, 2009:**

Health Canada has not yet reached any conclusions on *Salvia divinorum*. Health Canada continues to collect relevant information about *Salvia Divinorum* and its active ingredient, Salvinorin A, from both national and international sources in order to determine what, if any, regulatory controls are needed. Health Canada considers several factors in determining whether scheduling a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in regulatory status;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

In the case of *Salvia divinorum*, information about these factors is either missing or anecdotal in nature. For example, very few controlled scientific studies of the physical and psychotropic effects of *Salvia divinorum* on humans have been carried out, and using these studies to predict the potential for addiction and abuse associated with *Salvia divinorum* is difficult. More controlled systematic research in this area is needed.

Health Canada is taking steps to address the lack of data regarding the use of and/or extent of abuse involving *Salvia divinorum*. Questions regarding the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey. ~~Ontario Student Drug Use and Health Survey. A general open-ended question about the use of other substances has also been included in the 2008~~ [should this be 2009? yes, please see changes] ~~Canadian Alcohol and Drug Use Monitoring Survey.~~ The data, however, will not likely be available until 2010. In the interim, Health Canada will continue to collect and consider information regarding *Salvia divinorum* as it becomes available.

Bronwyn Cline  
Communications Officer | Agente des communications

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Santé Canada | 269 ave Laurier Ottawa ON K1A 0K9  
Government of Canada | Gouvernement du Canada





Bronwyn Cline/HC-SC/GC/CA  
2009-10-15 09:45 AM

To Cheryl Tremblay/HC-SC/GC/CA@HWC  
cc  
bcc

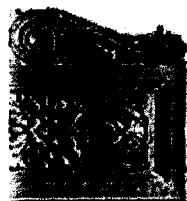
Subject Re: Salvia D media lines

I asked Hayden about it two days ago, and he said that the IYH is still in Paul's file...so no bilat yet, and no movement on the media lines.

Where are you moving on to?

Bronwyn Cline  
Communications Officer | Agente des communications

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Government of Canada | Gouvernement du Canada  
Cheryl Tremblay/HC-SC/GC/CA



Cheryl  
Tremblay/HC-SC/GC/CA  
2009-10-15 09:44 AM

To Bronwyn Cline/HC-SC/GC/CA@HWC  
cc

Subject Re: Salvia D media lines

Hi Bronwyn,

Sorry to keep bugging about this, but I will be leaving HC soon and would like to provide my colleague that will be taking over this file with an update on the status. Any update on whether Paul and Cathy discussed the IYH and Media lines on Salvia?

Thanks,  
Cheryl Tremblay  
Policy and Regulatory Affairs Division / Division des politiques et affaires réglementaires  
Office of Controlled Substances / Bureau des substances contrôlées  
Controlled Substances and Tobacco Directorate / Direction des substances contrôlées et de la lutte au tabagisme  
Healthy Environments and Consumer Safety Branch / Direction générale de la santé environnementale et de la sécurité consommateurs  
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Tel: (613) 954-6527 Fax: (613) 946-4224  
Bronwyn Cline/HC-SC/GC/CA



Bronwyn Cline/HC-SC/GC/CA  
2009-08-31 10:09 AM

To Cheryl Tremblay/HC-SC/GC/CA@HWC  
cc

Subject Re: Salvia D media lines



The bilat hasn't happened yet. Karen says hopefully this week.

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Government of Canada | Gouvernement du Canada  
Bronwyn Cline/HC-SC/GC/CA



Bronwyn  
Cline/HC-SC/GC/CA  
2009-08-31 09:56 AM

To Cheryl Tremblay/HC-SC/GC/CA  
cc

Subject Re: Salvia D media lines 

Hello again,

Knew I was forgetting something...went back through my emails, and around August 17th, Karen said that Paul wanted to discuss this IYH with Cathy at a bilat. I'll send Karen an email to see if that bilat happened before Cathy left.

Thanks,

Bronwyn Cline  
Communications Officer | Agente des communications

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Government of Canada | Gouvernement du Canada  
Bronwyn Cline/HC-SC/GC/CA



Bronwyn  
Cline/HC-SC/GC/CA  
2009-08-31 09:50 AM

To Cheryl Tremblay/HC-SC/GC/CA  
cc

Subject Re: Salvia D media lines 

Hi Cheryl,

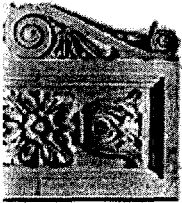
I haven't done anything with the media lines, because I wanted to wait until Paul had signed off on the article so I would know if further changes needed to be made.

As for the article, Jay Khosla's email with responses to Paul's comments got lost for about a month, and it's now back with Paul's advisor. I'll follow-up on that the article this morning.

Thanks,

Bronwyn Cline  
Communications Officer | Agente des communications

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Government of Canada | Gouvernement du Canada  
Cheryl Tremblay/HC-SC/GC/CA



Cheryl  
Tremblay/HC-SC/GC/CA  
2009-08-31 09:48 AM

To Bronwyn Cline/HC-SC/GC/CA@HWC  
cc

Subject Re: Salvia D media lines 

Morning Bronwyn,

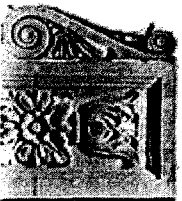
Any news on what stage the media lines on Salvia are at? We provided the comments attached below on June 23rd.

Anything new on the IYH on Salvia? We responded to some of the ADMs comments on June 23rd as well. Are they going up for formal approvals together?

Reason I ask is that CBSA is asking for some info on whether HC regulates it and we would like to provide them with a few lines.


Thanks,

Cheryl Tremblay  
Policy and Regulatory Affairs Division / Division des politiques et affaires réglementaires  
Office of Controlled Substances / Bureau des substances contrôlées  
Controlled Substances and Tobacco Directorate / Direction des substances contrôlées et de la lutte au tabagisme  
Healthy Environments and Consumer Safety Branch / Direction générale de la santé environnementale et de la sécurité des consommateurs  
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Cheryl Tremblay/HC-SC/GC/CA



Cheryl  
Tremblay/HC-SC/GC/CA  
2009-06-23 02:38 PM

To Bronwyn Cline/HC-SC/GC/CA@HWC  
cc Christine Roush/HC-SC/GC/CA@HWC, Brooke  
Bryce/HC-SC/GC/CA@HWC, Jocelyn  
Kula/HC-SC/GC/CA@HWC

Subject Re: Salvia D media lines 

Hi Bronwyn,

Here are CSTD's comments on media lines for Salvia Divinorum.



Salvia ML v.7 April 2009\_CSTD Comments re IYH.doc

Let me know if you have any questions,  
Thanks,

**Cheryl Tremblay**  
Policy and Regulatory Affairs Division / Division des politiques et affaires réglementaires  
Office of Controlled Substances / Bureau des substances contrôlées  
Controlled Substances and Tobacco Directorate / Direction des substances contrôlées et de la lutte au  
tabagisme  
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de la sécurité des consommateurs  
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Bronwyn Cline/HC-SC/GC/CA



**Bronwyn  
Cline/HC-SC/GC/CA**  
2009-06-16 03:33 PM

To Cheryl Tremblay/HC-SC/GC/CA@HWC  
cc

Subject Salvia D media lines

Hi Cheryl,

Can you please make sure to cc Christine Roush and Brooke Bryce when you send me your comments on  
the Salvia D lines?

FYI, the IYH on Salvia is currently with the HECS ADM.

Thanks,

**Bronwyn Cline**  
Communications Officer | Agente des communications

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Government of Canada | Gouvernement du Canada



Brittany Sauvé/HC-SC/GC/CA

2009-10-16 10:47 AM

To Cheryl Tremblay/HC-SC/GC/CA@HWC

cc

bcc

Subject Fw: CMAJ: Researchers fear "Magic Mint" ban could slow studies

FYI

— Forwarded by Brittany Sauvé/HC-SC/GC/CA on 2009-10-16 10:47 AM —



Suzanne Desjardins/HC-SC/GC/CA

2009-10-13 12:13 PM

To HECSB\_DSCS\_ORB/BRS\_SASC\_DGSESC

cc

Subject Fw: CMAJ: Researchers fear "Magic Mint" ban could slow studies

— Forwarded by Suzanne Desjardins/HC-SC/GC/CA on 2009-10-13 12:13 PM —

HC\_Media\_SC/HC-SC/GC/C

A

Sent by: Nicolas Frate

2009-10-13 11:27 AM

To

cc

Subject CMAJ: Researchers fear "Magic Mint" ban could slow studies

October 13, 2009

### Researchers fear "Magic Mint" ban could slow studies

Source: Canadian Medical Association Journal (online / early release)

Salvia divinorum can beam you to Mars. It can eradicate gravity. It can show you things that will make you howl with laughter and things that will make you scream in fear. But it only does these things in your head — and only for about 15 minutes.

Millions of people have embarked on short-haul head trips after smoking Salvia divinorum, a plant from the mint family. Thousands have posted their hallucinogenic journeys on YouTube. In one video, viewed some two million times, a young woman says her mouth is falling off.

Some lawmakers believe Salvia divinorum, a.k.a. "Diviner's Sage," is dangerous. About a dozen countries have banned it, including Australia and Belgium. Selling it in parts of the United States will also earn you a fine and jail time. But it's legal in Canada. In some Canadian cities, a shop selling bonges is likely to have a cardboard sign in the window that says "Salvia sold here."

Though many politicians have the plant on their not-in-my-jurisdiction lists, there is no scientific data to suggest the plant's active ingredient, Salvinorin A, has any long-term effects. Some researchers studying the plant — which may prove useful in treating mental illness — are worried that bans may make their work more difficult. They say the herb doesn't appear to be addictive or toxic. Hospital emergency rooms aren't reporting major problems with patients suffering "bad trips" from Salvia divinorum. Nor have police made much noise about the herb.

"Health Canada has only received a limited number of communications regarding *Salvia divinorum* from law enforcement agencies, and none of these has advised that the use of *Salvia divinorum* poses any threat to public safety," Health Canada spokesman Gary Holub writes in an email.

Holub notes, however, that Health Canada is attempting to learn how many Canadians are using *Salvia divinorum*. It included questions about the plant in the 2008–2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. Health Canada is also collecting data about the herb, from national and international sources, to determine if it should be regulated.

"Very few controlled scientific studies of the physical and psychotropic effects of *Salvia divinorum* on humans have been carried out, and using these studies to predict the potential for addiction and abuse associated with *Salvia divinorum* is difficult," writes Holub. "Health Canada recommends that the use of this substance be avoided because very little is known about the damage it may cause to the body, including the brain. There is also no way to predict how it will affect an individual with each use."

*Salvia divinorum* has been used by the Mazatecs in Oaxaca, Mexico, for centuries. Folk healers chew the leaves to produce mild hallucinations they believe provide spiritual guidance. In the early 1960s, Gordon Wasson, an American anthropologist, became the first person from a Western nation to take and write about the herb. In the early 1980s, a Mexican researcher isolated its active ingredient. But it wasn't until the 1990s that people began extracting that ingredient and adding it to fresh *Salvia divinorum* leaves.

These fortified leaves are what people buy, often over the Internet, and smoke in a bong or pipe. In the United States, about 1.8 million people have tried *Salvia divinorum*, according to the 2008 National Survey on Drug Use and Health. As with crack cocaine, the effects upon inhalation are almost instantaneous. And though short-lived, these effects are anything but mild.

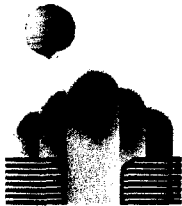
"It is the most potent naturally occurring hallucinogen," says Dr. Bryan Roth, project director of the National Institute of Mental Health Psychoactive Drugs Screening Program. "It rivals LSD [lysergic acid diethylamide] in potency."

In 2002, Roth discovered that Salvinorin A had a different chemical structure than any other hallucinogen, natural or synthetic (PNAS 2002;99: 11934–9). He also found that it didn't activate the serotonin receptor responsible for the mind-bending effects of other hallucinogens. Because of its unique properties, Salvinorin A might be a novel compound for use in therapies for diseases that distort perception, such as schizophrenia and bipolar disorder.

"What we are hoping, when we find drugs that affect human consciousness, is to use them to make better treatments for mental illness," says Roth, a professor at the University of North Carolina in Chapel Hill.

That research might prove challenging, however, if the US Food and Drug Administration outlaws *Salvia divinorum*, which Roth says is likely. Though supportive of regulating distribution, he isn't looking forward to widespread legal barriers to accessing Salvinorin A. Such laws would not only keep the herb out of the hands of teenagers hoping to visit Jupiter on purple unicorns, but also out of the labs of scientists.

"It will make subsequent studies very difficult," says Roth. "It won't make them impossible but will make it difficult to obtain for therapeutic research." — Roger Collier, CMAJ



Jocelyn Kula/HC-SC/GC/CA

2009-11-10 11:58 PM

To Brigitte Mainville/HC-SC/GC/CA@HWC

cc Cheryl Tremblay/HC-SC/GC/CA@HWC,

bcc

s.19(1)

Subject Re: salvia 

Hi Brigitte

I can confirm that Salvia is not a controlled substance under the CDSA. That said, it is considered to be a natural health product (as defined in the *Natural Health Product Regulations*) and thus products containing salvia require approval from Health Canada (and issuance of an NPN) prior to sale. That said, as many salvia products do not come into the country labelled as natural health products but rather as consumer products like incense, etc., salvia products are still available in Canada.

In the context of a country wishing to import it for use by an Olympic delegation, I have to be honest and say that it seems odd as salvia is not, as far as I know, associated with any particular therapeutic benefit (although it has been documented to have been used as a traditional medicine many years ago). This might be a situation where it would be good to obtain some more information from the delegation in question and then perhaps consult NHPD as to whether in the situation provided, it would be subject to whatever controls HPFB is expecting with respect to NHPs coming in for use by visiting athletes during the Games (if any).

Hope this helps, and am happy to discuss further. Am copying Cheryl as she is the lead on salvia at the moment, and may have more to add.

Jocelyn

---

Jocelyn Kula

Manager/ Gestionnaire

Policy and Regulatory Affairs Division/ Division des politiques et affaires réglementaires

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs

Health Canada/ Santé Canada

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Brigitte Mainville/HC-SC/GC/CA

Brigitte

Mainville/HC-SC/GC/CA

2009-11-09 04:37 PM

To Jocelyn Kula/HC-SC/GC/CA@HWC

cc

Subject salvia

Jocelyn,

I just want to know if salvia extract is ok to be imported. Is it considered controlled? (on list of products of olympic participating country)

Thank you!

Brigitte

Diane Allan/HC-SC/GC/CA  
2009-11-03 05:33 PM

To Cheryl Tremblay/HC-SC/GC/CA@HWC, Denis  
Arsenault/HC-SC/GC/CA@HWC

cc

bcc

Subject Fw: CBC-radio Vancouver - Exploring salvia divinorum - Nov  
2 2009, 7:42AM

Diane Allan

Director / Directrice

Office of Controlled Substances / Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch / Direction générale de la santé environnementale et  
de la sécurité des consommateurs

Health Canada / Santé Canada

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Fax: 613-946-4224

----- Forwarded by Diane Allan/HC-SC/GC/CA on 2009-11-03 05:33 PM -----

HC\_Media\_SC/HC-SC/GC/C

A

Sent by: Nicolas Frate

To

cc

2009-11-03 04:00 PM

Subject CBC-radio Vancouver - Exploring salvia divinorum - Nov 2  
2009, 7:42AM

STATION	CBC Radio 1 (Victoria)
DATE	Mon 02 Nov 2009
PROGRAM	On The Island
TIME	7:42 AM
REPORTER	Interview
HEADLINE	<b>Exploring salvia divinorum</b>
MEDIA LOG ID	20091102R-2528

CBC: What you're listening to there in the background is a YouTube recording of an older male team writing on the floor and experiencing intense hallucinations after smoking a drug called salvia divinorum. Short-lived and intense mild-altering experiences are typical with this drug. Some countries and some US states have banned the substance but not Canada. That may change soon however. According to a recent edition of the Canadian Medical Association Journal Health Canada is studying whether it should become a regulated drug. Michael Tymchuk sets out to find if salvia was available here in Victoria. He discovered it has been for sale in the past in some head shops although no one admits to selling it at the moment but Michael did meet someone who works in the counterculture industry who's tried the drug and here is his conversation with Ryan HENCHIES.

REPORTER: Salvia divinorum is the full name. Have you tried it?

RYAN HENCHIES: Yeah, two different occasions.

REPORTER: And what's it like?



HENCHIES: Difficult to describe and that's probably the most common description you'll get from people just 'cause one of the unique things about it is it reacts with the person who takes it very individually. There'll be common threads, for instance a sensation like you're, you're leaving your body, some people say they feel like they're dying.

REPORTER: Do you remember for yourself what it felt like?

HENCHIES: It felt as if I was like slipping away like being drawn into like a deep, like a cave or falling down a passageway - very much a lightness. It was frightening at first but as soon as I, as soon as I got used to it it became a very comforting kind of fascinating experience. You could classify it as a hallucination but it's more of like, it affects your imagination so you go within yourself and instead of like reacting to the colors on the wall you're drawing from your subconscious as the palate for the, for the, for what you see so images from your past, stuff that's important to you, issues that you need to overcome, stuff like that. It was very intense, it's a very short duration of time. Most experiences last about 25 to 45 minutes; mine was about a half an hour each.

REPORTER: Are you aware when you're stoned on it that you are actually stoned or does it seem like completely different reality?

HENCHIES: Very much a different reality. One of the, one of the key traits of it is that you're not very conscious of what's going on around you at all. One of the important traditions is to have a sitter, somebody who is not on the substance who is able to look after you. Generally what you want to do is like find a comfortable place to be, you know preferably on a couch or on a bed or somewhere where you're, you're already in a comfortable position and then you, you take it and it just hits you and it hits you very quickly so within 45 seconds you're under the full impact of the, of the substance. The sensations that you're experiencing totally overwhelm you which is why it's kind of a danger to people who are uninitiated because if you're not prepared it's very unexpected.

REPORTER: Now it used to be that you could buy it from a number of the head shops in Victoria and yet they all seem to now not carry it.

HENCHIES: Most of the main commercial suppliers are in the States so when you're trying to order it across the border it's always getting hell or impeded in some way so it, it becomes a bit of a hassle to bring it into the stores. That's one of the main reasons why it's become scarcer but the concern with it and the reason why a lot of places have stopped carrying it is because it's come to popularity very quickly and without proper education about it. It's mysterious, it's cool but it's not understood so...

REPORTER: And is it dangerous, I mean do people sometimes go over the deep end with it and do rash things?

HENCHIES: That's about the closest thing to dangerous like physically like you can't overdose it. The amount you'd have to take in for it to like seriously affect your body, you wouldn't be conscious long enough to take it, to take that much. The danger is is that the profoundness and the potency of the effect on your emotions and on your mind. People can sort of lose their way really

quickly so a person who's on it, if they're not prepared for it, if they're like at a party or just like hanging out with some friends or they're outside if people aren't prepared it's possible a person could behave dangerously, cause a fire or you know hurt themselves in some way. It's not like it drives you to do stupid things, you just won't be conscious of the actions that you're taking.

REPORTER: And your name again.

HENCHIES: Ryan HENCHIES.

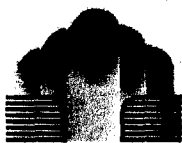
REPORTER: Thank you very much.

HENCHIES: Thanks.

CBC: Thank you Michael.

\*\*\* END OF STORY \*\*\*

Media Monitoring Unit / Unité de surveillance des médias  
Health Canada / Santé Canada



Jocelyn Kula/HC-SC/GC/CA

2009-11-27 03:13 PM

To Suzanne Desjardins/HC-SC/GC/CA@HWC

cc Brittany Sauvé/HC-SC/GC/CA@HWC, Bruna Brands/HC-SC/GC/CA@HWC, Cathy A Sabiston/HC-SC/GC/CA@HWC,

bcc

Subject Re: Fw: Salvia D - IYH

This is great Suzanne. We will pull something together and send it to you for review.  
Jocelyn

---

Jocelyn Kula

Manager/ Gestionnaire

Policy and Regulatory Affairs Division/ Division des politiques et affaires réglementaires

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs

Health Canada/ Santé Canada

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Suzanne Desjardins/HC-SC/GC/CA



Suzanne  
Desjardins/HC-SC/GC/CA

2009-11-27 03:10 PM

To Diane Allan/HC-SC/GC/CA@HWC

cc Cheryl.Tremblay@hc-sc.gc.ca, "Denis Arsenault" <denis.arsenault@hc-sc.gc.ca>, "Jocelyn Kula" <jocelyn.kula@hc-sc.gc.ca>, "Mrs. Patricia Rapold" <Patricia.Rapold@hc-sc.gc.ca>, "Stephanie Szick" <stephanie.szick@hc-sc.gc.ca>, Cathy A Sabiston/HC-SC/GC/CA@HWC, Bruna Brands, Brittany Sauvé/HC-SC/GC/CA@HWC

Subject Re: Fw: Salvia D - IYH

I believe this is an old file (several months now) and the information needs to be updated. We did not have much information in terms of health impact at the time, and we don't have much more now, but while we did not have much information on the extent of use in Canada then, there are now recent data on the prevalence of salvia that were just released in the Ontario student drug use survey (6% of students reported having used it at least once, rate higher than for ecstasy) . Bruna is preparing a short article for CMAJ with more details on it .

Salvia has been identified for discussion by our Scheduling Committee.

Suzanne

Diane Allan/HC-SC/GC/CA

Diane Allan/HC-SC/GC/CA

2009-11-27 02:41 PM

To Cheryl.Tremblay@hc-sc.gc.ca, "Suzanne Desjardins" <Suzanne.Desjardins@hc-sc.gc.ca>

cc "Jocelyn Kula" <jocelyn.kula@hc-sc.gc.ca>, "Denis Arsenault" <denis.arsenault@hc-sc.gc.ca>, "Mrs. Patricia Rapold" <Patricia.Rapold@hc-sc.gc.ca>, "Stephanie Szick"

<stephanie.szick@hc-sc.gc.ca>  
Subject Fw: Salvia D - IYH

Please help.  
Stephanie Szick

----- Original Message -----

**From:** Stephanie Szick  
**Sent:** 2009-11-27 02:29 PM EST  
**To:** Diane Allan; Patricia Rapold  
**Cc:** Jodi Brown; Kimberly Sorfleet; Arafo Talane; Carmen Berube  
**Subject:** Salvia D - IYH

Hi Diane and Patricia,

Long trail below on this. In short, the Salvia D article is with Paul for his sign-off....he would like clarity on the following:

- **Why would we do an it's your health if we say we have insufficient evidence to regulate it? i.e Why do we have enough about the health impacts yet aren't acting to regulate?**

I've attempted to reply to some of this in my email below to Cathy....

Per my email below, can your shop touch base with comms on this, as these articles are pretty much comms-led and implemented, and let us know by next week.

Clarification in an email is fine, please attach/include from comms the final rationale/proposal (with confirmation of who signed off), and the last version of the article, as well as any formal/approved media lines on the issue.


**Deadline to DGO** - next Wednesday, December 2, noon


Kim - please note for BF.

Thanks very much,

Stephanie

----- Forwarded by Stephanie Szick/HC-SC/GC/CA on 2009-11-27 02:21 PM -----

 Stephanie  
Szick/HC-SC/GC/CA  
2009-11-27 02:21 PM

To Cathy A Sabiston/HC-SC/GC/CA  
cc Jodi Brown/HC-SC/GC/CA@HWC, Kimberly  
Sorfleet/HC-SC/GC/CA@HWC  
Subject Re: Salvia D 

Hi Cathy,  
Pasted here is what was originally provided as rationale in the proposal for the Salvia D article.....keeping in mind IYH articles are comms products. I will ask Diane's shop to touch base also with comms to confirm what final approved rationale was -- the key was the both HECSB and HPFB were both *onside* with this idea - consensus. I think Paul actually approved the proposal and rationale. Comms should be able to provide more clarity.

The purpose of the article is information, including around current HC role....the dept. receives the same media Qs over and over on this issue and an IYH would be something to point reporters to, rather than the scramble to gather replies and get approvals across HECSB and HPFB. The article is just more efficient - it's approved across the two branches good to go.

**THE ISSUE** - Salvia Divinorum is a species of sage which belongs to the mint family. It is found in the form of dried leaves, extract and plant cuttings. Salvia Divinorum, also known as "diviner's sage" and/or "magic mint", is chewed or smoked and can induce illusions and hallucinations.

Salvia Divinorum continues to attract moderate media attention. It will be beneficial to have an It's Your Health article available on the internet so that the general public can be better informed about the issue, and so that reporters can refer to this article, should they have questions about the issue.

**HEALTH CANADA'S ROLE** - There are no regulations or laws prohibiting the possession, use or sale of Salvia divinorum in Canada. While many countries across the globe have prohibited Salvia, it remains legal in Canada. Health Canada is currently exploring our options for prohibiting Salvia in Canada.

**WHY IS THIS ARTICLE NEEDED AND WHY IT'S YOUR HEALTH?**- The target audience is the general public. It's Your Health is a good vehicle to use to inform individuals about Salvia because the articles are written in plain language and are easily understood by the vast majority of Canadians.

Cathy A Sabiston/HC-SC/GC/CA



Cathy A  
Sabiston/HC-SC/GC/CA  
2009-11-27 01:43 PM

To Stephanie Szick/HC-SC/GC/CA@HWC, Jodi  
Brown/HC-SC/GC/CA@HWC  
cc Kimberly Sorfleet/HC-SC/GC/CA@HWC

Subject Salvia D

Paul's question is why wld we do an it's your health if we say we have insufficient evidence to regulate it?  
le why do we have enuff about the heallth impacts yet aren't acting to regulate

Can you please ask diane to look into this - or whomever!

Cas

Diane Allan/HC-SC/GC/CA  
2009-11-27 02:48 PM

To "Cheryl Tremblay" <Cheryl.Tremblay@hc-sc.gc.ca>,  
"Suzanne Desjardins" <Suzanne.Desjardins@hc-sc.gc.ca>  
cc "Jocelyn Kula" <jocelyn.kula@hc-sc.gc.ca>, "Denis  
Arsenault" <denis.arsenault@hc-sc.gc.ca>, "Mrs. Patricia  
Rapold" <Patricia.Rapold@hc-sc.gc.ca>

bcc

Subject Fw: Salvia

More info.

Please help again.

Jodi Brown

----- Original Message -----

**From:** Jodi Brown

**Sent:** 2009-11-27 02:43 PM EST

**To:** Stephanie Szick

**Cc:** Diane Allan; Kimberly Sorfleet; Cathy A Sabiston

**Subject:** Fw:

Am not able to view attachment on BB but this apparently contains Pauls comments.

Apologies for brevity and typos...sent from handheld... Jodi/Health Canada

Hayden Lansdell

----- Original Message -----

**From:** Hayden Lansdell

**Sent:** 2009-11-27 12:31 PM EST

**To:** Jodi Brown

So the note has been sitting in Paul's bilat file for months now. That said, comments remain.



Salvia Divinorum.pdf

Jay - this document raised some questions for me -> where are our standard lines around drug prevention the states in other countries section - is that normal - in an Ilt. Year health?

## Salvia divinorum

### The Issue

Reports suggest that Canadian teens and young adults are using a substance called *Salvia divinorum* (*S. divinorum*) for its ability to produce hallucinations. Certain Web sites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs.

Street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastra, ska Maria pastora, ska pastora, diyiner's sage, magic mint, puff encens special, and salvia.

Health Canada recommends that you avoid using this substance because very little is known about the damage it may cause to the body, including the brain. There is also no way to predict how it will affect you with each use.

### Background

*S. divinorum* is a species of sage that belongs to the mint family. It is known to have psychotropic effects, which means it affects the mind and mental processes.

The leaves of this plant have been used traditionally by the Mazatec Indians in Mexico for many years. Traditional use involves chewing the leaves or using them to make a tea for medicinal purposes (e.g., to treat such conditions as headache or stomach upset), or to induce a "mystical" or hallucinogenic experience for spiritual purposes.

Products that claim to contain *S. divinorum* – or its main active ingredient, salvinorin A – are widely available on the Internet and are sold in various "head shops" and natural food stores. The products are sold in a number of formats, including seeds and plant cuttings for growing purposes. Fresh or dried leaves are intended to be chewed, swallowed or smoked. Liquid preparations are also available.

### Risks of Using *Salvia divinorum*

*S. divinorum*'s effects, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations;
- dysphoria (feeling unwell, uneasy or unhappy);
- out-of-body experiences;
- uncontrollable laughter;
- loss of consciousness;
- short-term memory loss;
- lack of physical coordination;
- slurred speech and awkward sentence patterns.

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

Happy to discuss. Paul 21-Jan-08

As written it seems to generate more questions than provide answers.

**Response to ADM Questions Regarding the IYH article on *Salvia Divinorum*  
November 27, 2009**

- (1) Why would we do an It's Your Health if we say we have insufficient evidence to regulate it? i.e. Why do we have enough about the health impacts yet aren't acting to regulate it?**

At the time that the Department elected to proceed with an It's Your Health (IYH) document on *Salvia divinorum* in 2008, information regarding the personal and societal health impacts associated with salvia, e.g., the potential for abuse and risk of addiction, the extent of actual abuse in Canada and elsewhere, overall risk to public health and safety, etc., was missing or anecdotal in nature.

A series of Health Products and Food Branch (HPFB) and Health Environments and Consumer Safety Branch (HECSB) DG-level discussions in 2007 and 2008 about this lack of data led to the conclusion that while the controls imposed by the *Controlled Drugs and Substances Act* (CDSA) were not warranted at this point in time (especially given the fact that CDSA scheduling assessments look at exactly these types of indicators), the Department still had some obligation to address the recurrent media interest and ongoing public/ law enforcement enquiries regarding this plant.

In discussions as to what type of measure might be appropriate, both branches agreed that an IYH article was an option because they aim to provide the general public with information about an issue and/or influence behaviour, which in this case, would be the reduced use of *Salvia divinorum* for its hallucinogenic properties.

Since the IYH article was completed and submitted for approval, *Salvia divinorum* has been identified for discussion by the Controlled Substances Scheduling Working Group, a new HECSB/ HPFB working group mandated to discuss substances/ issues pertaining to drug regulation of joint interest. In addition, recent data from the 2009 Ontario Student Drug Use and Health Survey shows that approximately 4.4% of all students (representing approx. 42,600 respondents) in 2009 reported using *Salvia divinorum* at least once in the past year. The Office of Drug and Alcohol Research and Surveillance, CSTD is currently preparing a short article on these findings for the Canadian Medical Association Journal. It may also be worth pointing out that should further information on the extent of abuse in Canada and/or regarding its health impacts or addictive potential come to light, there is nothing impeding Health Canada from moving to propose the inclusion of one of the Schedules to the CDSA in the future.



**Response to ADM Questions Regarding the IYH article on *Salvia Divinorum*  
November 27, 2009**

- (1) Why would we do an It's Your Health if we say we have insufficient evidence to regulate it? i.e. Why do we have enough about the health impacts yet aren't acting to regulate it?**

Several months have passed since the last draft of this Its Your Health article on *Salvia divinorum* was approved at the Director General level back in June 2009 and thus the information may require updating. While the preliminary findings we had at that time, in terms of the health impacts associated with *Salvia divinorum*, e.g., the potential for abuse and risk of addiction associated with the substance, the extent of actual abuse of the substance in Canada and internationally, and the overall risk to public health and safety posed by the substance, were (and largely remain) either missing or anecdotal in nature, recent data on the prevalence of *Salvia divinorum* was just released in the 2009 Ontario Student Drug Use and Health Survey (OSDUHS). According to the OSDUHS, approximately 4.4% of all students in 2009 reported using *Salvia divinorum* at least once in the past year, which represents about 42, 600 students in Ontario. The Office of Drug and Alcohol Research and Surveillance, CSTD is currently preparing a short article for Canadian Medical Association Journal with more details on these findings.

In light of the preliminary findings from our scheduling assessment, and the fact that the controls imposed by the *Controlled Drugs and Substances Act* (CDSA) were likely not warranted, we began to assess the effectiveness and appropriateness of a non-regulatory instrument to achieve our policy objectives. One strategy to reduce the health and safety risks associated with a substance of concern is to conduct an educational campaign that is targeted at known user groups and/or distributors. The information provided helps these individuals to make an informed decision based on the health effects of the substance and can include recommendations to mitigate its abuse and/or avoid potential risks. The publication of an IYH article was therefore contemplated to inform the general public about the issue while we continue to collect and consider information about *Salvia divinorum* and its active ingredient, salvinorin A, in order to determine what, if any, regulatory controls are needed. *Salvia divinorum* has also been identified for discussion by the Controlled Substances Scheduling Working Group (comprised of representatives from both HECSB and HPFB) the key body responsible for identifying and reviewing substances, with the exception of precursor chemicals, that are being considered for addition to one of the Schedules to the CDSA.

**Why would we do an *It's Your Health* if we say we have insufficient evidence to regulate it (i.e. why do we have enough information about the health impacts yet aren't acting to regulate)?**

#### INPUT 1

In light of the considerations and analysis above, it is recommended that neither *Salvia divinorum* nor its main active ingredient, salvinorin A, be scheduled under the CDSA at this time as they do not meet the established criteria for scheduling as follows:

- *S. divinorum* and salvinorin A are not structurally similar or even pharmacologically similar to other substances included in the schedules to the CDSA.
- The abuse liability and potential for dependence of *S. divinorum* is not known as very few controlled scientific studies of the physical and psychotropic effects of *S. divinorum* have been carried out on humans. More controlled systematic research in this area is needed.
- Effects are known to be short-lived and no long term studies of cumulative use have been conducted.
- Health Canada has only received a limited number of communications regarding *Salvia divinorum* from law enforcement agencies, and none of these have advised that the use of *Salvia divinorum* poses any particular threat to public safety.
- Prohibition under the CDSA may add unnecessary burden to policing and justice systems.
- Imprisoning individuals using or trafficking *Salvia* may aggravate an already swelling prison system.
- Evidence of a risk to public health and safety is anecdotal in nature and not quantified in any way as there is a lack of information regarding usage in Canada.

It is therefore recommended that educational materials be published in order to reduce the potential health and safety risks associated with this substance and its active ingredient.

#### INPUT 2

- Why IYH? Instrument choice (enterprise risk) change public behaviour before moving to prohibition; no incidence data outside of Ontario
- there are now recent data on the prevalence of salvia that were just released in the Ontario student drug use survey (~~6%~~ <sup>4.4%</sup> of students reported having used it at least once, rate higher than for ecstasy) . Bruna is preparing a short article for CMAJ with more details on it .



Jocelyn Kula/HC-SC/GC/CA

2009-11-27 02:49 PM

To Diane Allan/HC-SC/GC/CA@HWC

cc Cheryl.Tremblay@hc-sc.gc.ca, "Denis Arsenault"  
<denis.arsenault@hc-sc.gc.ca>, "Suzanne Desjardins"  
<Suzanne.Desjardins@hc-sc.gc.ca>

bcc

Subject Re: Fw: Salvia D - IYH

Diane,

We can certainly put a rationale together for why we started down the IYH road. This is one of those substances with a bit of history in the health portfolio.....

Suzanne- how about if we draft something and send to you for input?

Jocelyn

---

Jocelyn Kula

Manager/ Gestionnaire

Policy and Regulatory Affairs Division/ Division des politiques et affaires réglementaires

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs

Health Canada/ Santé Canada

Tel: (613) 946-0125 Fax: (613) 946-4224

Diane Allan/HC-SC/GC/CA

Diane Allan/HC-SC/GC/CA

2009-11-27 02:41 PM

To Cheryl.Tremblay@hc-sc.gc.ca, "Suzanne Desjardins"  
<Suzanne.Desjardins@hc-sc.gc.ca>

cc "Jocelyn Kula" <jocelyn.kula@hc-sc.gc.ca>, "Denis  
Arsenault" <denis.arsenault@hc-sc.gc.ca>, "Mrs. Patricia  
Rapold" <Patricia.Rapold@hc-sc.gc.ca>, "Stephanie Szick"  
<stephanie.szick@hc-sc.gc.ca>

Subject Fw: Salvia D - IYH

Please help.

Stephanie Szick

----- Original Message -----

From: Stephanie Szick

Sent: 2009-11-27 02:29 PM EST

To: Diane Allan; Patricia Rapold

Cc: Jodi Brown; Kimberly Sorfleet; Arafo Talane; Carmen Berube

Subject: Salvia D - IYH

Hi Diane and Patricia,

Long trail below on this. In short, the Salvia D article is with Paul for his sign-off....he would like clarity on the following:

- Why would we do an it's your health if we say we have insufficient evidence to regulate it? i.e Why do we have enough about the health impacts yet aren't acting to regulate?

I've attempted to reply to some of this in my email below to Cathy....

Per my email below, can your shop touch base with comms on this, as these articles are pretty much comms-led and implemented, and let us know by next week.

Clarification in an email is fine, please attach/include from comms the final rationale/proposal (with confirmation of who signed off), and the last version of the article, as well as any formal/approved media lines on the issue.

**Deadline to DGO** - next Wednesday, December 2, noon

Kim - please note for BF.


Thanks very much,

Stephanie

----- Forwarded by Stephanie Szick/HC-SC/GC/CA on 2009-11-27 02:21 PM -----



Stephanie  
Szick/HC-SC/GC/CA  
2009-11-27 02:21 PM

To Cathy A Sabiston/HC-SC/GC/CA  
cc Jodi Brown/HC-SC/GC/CA@HWC, Kimberly  
Sorfleet/HC-SC/GC/CA@HWC  
Subject Re: Salvia D 

Hi Cathy,

Pasted here is what was originally provided as rationale in the proposal for the Salvia D article.....keeping in mind IYH articles are comms products. I will ask Diane's shop to touch base also with comms to confirm what final approved rationale was -- the key was the both HECSB and HPFB were both onside with this idea - consensus. I think Paul actually approved the proposal and rationale. Comms should be able to provide more clarity.

The purpose of the article is information, including around current HC role....the dept. receives the same media Qs over and over on this issue and an IYH would be something to point reporters to, rather than the scramble to gather replies and get approvals across HECSB and HPFB. The article is just more efficient - it's approved across the two branches good to go.

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**HEALTH CANADA'S ROLE** - There are no regulations or laws prohibiting the possession, use or sale of Salvia divinorum in Canada. While many countries across the globe have prohibited Salvia, it remains legal in Canada. Health

**Canada is currently exploring our options for prohibiting Salvia in Canada.**

**WHY IS THIS ARTICLE NEEDED AND WHY IT'S YOUR HEALTH?- The target audience is the general public. It's Your Health is a good vehicle to use to inform individuals about Salvia because the articles are written in plain language and are easily understood by the vast majority of Canadians.**

Cathy A Sabiston/HC-SC/GC/CA



Cathy A  
Sabiston/HC-SC/GC/CA  
2009-11-27 01:43 PM

To Stephanie Szick/HC-SC/GC/CA@HWC, Jodi  
Brown/HC-SC/GC/CA@HWC  
cc Kimberly Sorfleet/HC-SC/GC/CA@HWC  
Subject Salvia D

Paul's question is why wld we do an it's your health if we say we have insufficient evidence to regulate it?  
le why do we have enuff about the health impacts yet aren't acting to regulate

Can you please ask Diane to look into this - or whomever!

Cas

Diane Allan/HC-SC/GC/CA  
2009-11-27 02:52 PM

To Jocelyn Kula/HC-SC/GC/CA@HWC  
cc Cheryl Tremblay/HC-SC/GC/CA@HWC, Denis  
Arsenault/HC-SC/GC/CA@HWC, Patricia  
Rapold/HC-SC/GC/CA@HWC, Suzanne  
bcc

Subject Re: Fw: Salvia

Yes likely so let's dig these up.

Jocelyn Kula

s.19(1)

----- Original Message -----

**From:** Jocelyn Kula  
**Sent:** 2009-11-27 02:51 PM EST  
**To:** Diane Allan  
**Cc:** Cheryl Tremblay; Denis Arsenault; Patricia Rapold; Suzanne Desjardins  
**Subject:** Re: Fw: Salvia

hmmm. Cheryl has gone home but I am pretty sure we responded to these comments from Paul when the IYH first went to him for approval, as I distinctly remember having a conversation with Jay Khosla about this when he was in DGO.

Jocelyn

---

Jocelyn Kula  
Manager/ Gestionnaire  
Policy and Regulatory Affairs Division/ Division des politiques et affaires réglementaires  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0125 Fax: (613) 946-4224  
Diane Allan/HC-SC/GC/CA

Diane Allan/HC-SC/GC/CA  
2009-11-27 02:48 PM

To "Cheryl Tremblay" <Cheryl.Tremblay@hc-sc.gc.ca>,  
"Suzanne Desjardins" <Suzanne.Desjardins@hc-sc.gc.ca>  
cc "Jocelyn Kula" <jocelyn.kula@hc-sc.gc.ca>, "Denis  
Arsenault" <denis.arsenault@hc-sc.gc.ca>, "Mrs. Patricia  
Rapold" <Patricia.Rapold@hc-sc.gc.ca>  
Subject Fw: Salvia

More info.

Please help again.  
Jodi Brown

----- Original Message -----

**From:** Jodi Brown  
**Sent:** 2009-11-27 02:43 PM EST  
**To:** Stephanie Szick  
**Cc:** Diane Allan; Kimberly Sorfleet; Cathy A Sabiston

**Subject:** Fw:

Am not able to view attachment on BB but this apparently contains Pauls comments.  
Apologies for brevity and typos...sent from handheld... Jodi/Health Canada  
Hayden Lansdell

----- Original Message -----

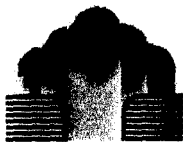
**From:** Hayden Lansdell

**Sent:** 2009-11-27 12:31 PM EST

**To:** Jodi Brown

So the note has been sitting in Paul's bilat file for months now. That said, comments remain.

[attachment "Salvia Divinorum.pdf" deleted by Diane Allan/HC-SC/GC/CA]



Jocelyn Kula/HC-SC/GC/CA  
2009-11-27 04:33 PM

To Denis Arsenault  
cc Cheryl Tremblay/HC-SC/GC/CA@HWC  
bcc  
Subject Fw: Fw:

cheryl- denis can fill you in.....

---

Jocelyn Kula  
Manager/ Gestionnaire  
Policy and Regulatory Affairs Division/ Division des politiques et affaires réglementaires  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0125 Fax: (613) 946-4224  
— Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2009-11-27 04:32 PM —



Stephanie  
Szick/HC-SC/GC/CA  
2009-11-27 04:27 PM

To Jocelyn Kula/HC-SC/GC/CA@HWC  
cc  
Subject Fw: Fw:

fyi

— Forwarded by Stephanie Szick/HC-SC/GC/CA on 2009-11-27 04:27 PM —



Stephanie  
Szick/HC-SC/GC/CA  
2009-11-27 04:13 PM

To Jodi Brown/HC-SC/GC/CA  
cc "Mrs. Cathy A Sabiston" <cathy.a.sabiston@hc-sc.gc.ca>,  
"Diane Allan" <diane.allan@hc-sc.gc.ca>, "Kimberly Sorfleet"  
<kimberly.sorfleet@hc-sc.gc.ca>  
Subject Re: Fw: [img alt="Small icon of a document with a checkmark."/>

Okay....here's the chronology of sorts.

I have the hard copy here also from my old records -- the article landed with Paul in June. He sent it to us with handwritten comments to Jay, who was acting at the time. Jay provided responses to Hayden in an email (I will send under separate cover).

Then we received here in August the hard copy of the article in PDF with Paul's comments and a cover from Paul to Cathy from Aug. in which he indicated he would like to discuss at some point, at a bilat, "not urgent."

Will leave copies of this package for both of you on your desks. This includes Jay's emails.

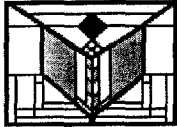
Paul's comments/Q's to Jay:

Jay -- this document raised some questions for me



1) where are our standard lines around drug prevention  
2) the status in other countries section - is that normal in an IYH article?  
Happy to discuss. Paul  
21-June-09  
As written, it seems to generate more questions than provide answers.

Jodi Brown/HC-SC/GC/CA



Jodi Brown/HC-SC/GC/CA  
2009-11-27 02:43 PM

To "Stephanie Szick" <stephanie.szick@hc-sc.gc.ca>  
cc "Diane Allan" <diane.allan@hc-sc.gc.ca>, "Kimberly Sorfleet"  
<kimberly.sorfleet@hc-sc.gc.ca>, "Mrs. Cathy A Sabiston"  
<cathy.a.sabiston@hc-sc.gc.ca>  
Subject Fw:

Am not able to view attachment on BB but this apparently contains Pauls comments.  
Apologies for brevity and typos...sent from handheld... Jodi/Health Canada  
Hayden Lansdell

----- Original Message -----

**From:** Hayden Lansdell  
**Sent:** 2009-11-27 12:31 PM EST  
**To:** Jodi Brown

So the note has been sitting in Paul's bilat file for months now. That said, comments remain.



Salvia Divinorum.pdf

## **Response to ADM Questions Regarding the IYH article on *Salvia Divinorum***

### **(1) Where are our standard lines around drug prevention?**

The standard lines on drug prevention were not incorporated in this IYH because the wording of those lines is oriented around illicit drugs which are already regulated as controlled substances. They do not translate well to *Salvia divinorum* in light of the fact that neither this plant nor its active ingredient are regulated as controlled substances at this time. The preliminary findings of our scheduling assessment are that information about the different factors considered, e.g., the potential for abuse and risk of addiction associated with the substance, the extent of actual abuse of the substance in Canada and internationally and the overall risk to public health and safety posed by the substance, is either missing or anecdotal in nature and thus, the controls imposed by the CDSA are likely not warranted. It is because of these preliminary findings that this IYH was contemplated. *Salvia Divinorum* continues to attract moderate media attention and it was thought that it would be beneficial to have information available on the internet that would better inform the general public about the issue, i.e., health effects and what they can do to safe guard their own health. In this regard, the language used in the article is focused on the fact that Health Canada does not know very much about how it acts on the brain and the body and thus does not recommend that people use it.

### **Is it normal to include information with respect to the status in other countries in an IYH article? (as written it seems to generate more questions than provide answers)**

The information regarding the status of *Salvia divinorum* and its active ingredient salvinorin A in other countries was included as it pertains to one of the factors that Health Canada considers when assessing whether to add a substance to one of the schedules to the CDSA, i.e., international requirements and trends in controlling the substance. This information could however be removed from the document without disrupting the flow of the article if there are concerns with its inclusion. The content of the article has however already been approved by HPFB and so we would need to go back to them for approval if this type of revision were to be made.

June 23, 2009

Denis  
Arsenault/HC-SC/GC/CA  
2009-11-30 11:03 AM


To Cheryl Tremblay/HC-SC/GC/CA@HWC  
cc  
bcc  
Subject Fw: IYH - Salvia D

Denis

---

Denis Arsenault  
Policy and Regulatory Affairs Division / Division des politiques et affaires réglementaires,  
Office of Controlled Substances / Bureau des substances contrôlées,  
Health Canada / Santé Canada  
Tel/Tél: (613) 957-6828  
Fax / Télécopieur : (613) 946-0125  
E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca  
— Forwarded by Denis Arsenault/HC-SC/GC/CA on 2009-11-30 11:02 AM —

Lisa MacKay/HC-SC/GC/CA  
2009-11-30 09:38 AM

To Bronwyn Cline/HC-SC/GC/CA@HWC  
cc Denis Arsenault/HC-SC/GC/CA@HWC  
Subject Re: Fw: IYH - Salvia D 

Hello,

Here is the original proposal:



Proposed Article IYH Salvia-D.wpd

FYI: the request for producing this article originally came from the drug program at HECSB. Also this article has been approved up to ADM level at HPFB.

Thank you,

Lisa Mackay  
It's Your Health Project Manager/Gestionnaire du projet Votre santé et vous  
Public Affairs Division | Division des affaires publiques  
Public Affairs, Consultation and Communications Branch/ Direction générale des affaires publiques, de la  
consultation et des communications  
Health Canada | Santé Canada  
Tel 613.954.0105  
Fax 613.952.8644  
Lisa\_Mackay@hc-sc.gc.ca

Bronwyn Cline/HC-SC/GC/CA



Bronwyn Cline/HC-SC/GC/CA

To Denis Arsenault/HC-SC/GC/CA@HWC



2009-11-27 04:47 PM

cc Lisa MacKay/HC-SC/GC/CA@HWC

Subject Fw: IYH - Salvia D

Hi Denis,

I don't have the rationale/proposal - Lisa, can you provide these? - but below are the rest of the docs you need. Jodi also has the scanned copy of the article with Paul's comments.

Thanks,

Bronwyn Cline  
Communications Officer | Agente des communications

613-941-2511 | facsimile / télécopieur 613-948-8085  
bronwyn\_cline@hc-sc.gc.ca  
Health Canada | 269 Laurier Ave Ottawa ON K1A 0K9  
Santé Canada | 269 ave Laurier Ottawa ON K1A 0K9  
Government of Canada | Gouvernement du Canada

----- Forwarded by Bronwyn Cline/HC-SC/GC/CA on 2009-11-27 04:45 PM -----



Bronwyn  
Cline/HC-SC/GC/CA  
2009-11-26 11:13 AM

To Jodi Brown/HC-SC/GC/CA

cc Diane Allan/HC-SC/GC/CA@HWC

Subject IYH - Salvia D

Hi Jodi,

I spoke to Hayden about this article, and I understand that Cathy and Paul had a bilat to discuss changes. Hayden asked me to re-send you the article, and I'm also attaching the last media lines I could find - once we know what needs to be changed in the article, we'll update the lines if necessary, and send back to ADMO as a package:



IYH - Salvia divinatorum\_8 June 29.wpd Apps Slip DG&ADM HECS Salvia May2009.wpd Salvia ML v.7 April 2009.doc

Thanks!

Bronwyn Cline  
Communications Officer | Agente des communications

613-941-2511 | facsimile / télécopieur 613-948-8085  
bronwyn\_cline@hc-sc.gc.ca  
Health Canada | 269 Laurier Ave Ottawa ON K1A 0K9  
Santé Canada | 269 ave Laurier Ottawa ON K1A 0K9  
Government of Canada | Gouvernement du Canada



Suzanne  
Desjardins/HC-SC/GC/CA  
2009-12-01 03:07 PM

To Cheryl Tremblay/HC-SC/GC/CA@HWC  
cc Denis Arsenault/HC-SC/GC/CA@HWC, Diane  
Allan/HC-SC/GC/CA@HWC, Jocelyn  
Kula/HC-SC/GC/CA@HWC  
bcc

Subject Re: Fw: Salvia D - IYH

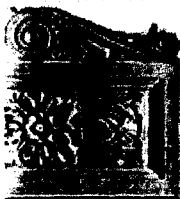
History: This message has been replied to:

Thank you Cheryl, looks excellent to me.

I only have minor suggestion on your last sentence:

It may also be worth pointing out that should further information ~~like this~~ on the extent of abuse in Canada and/or regarding its health impacts or addictive potential come to light, there is nothing impeding Health Canada from moving to propose the inclusion of one of the Schedules to the CDSA in the future.

Suzanne  
Cheryl Tremblay/HC-SC/GC/CA



Cheryl  
Tremblay/HC-SC/GC/CA  
2009-12-01 09:51 AM

To Suzanne Desjardins/HC-SC/GC/CA@HWC  
cc Diane Allan/HC-SC/GC/CA@HWC, Jocelyn  
Kula/HC-SC/GC/CA@HWC, Denis  
Arsenault/HC-SC/GC/CA@HWC  
Subject Re: Fw: Salvia D - IYH

Hi Suzanne,

Further to the emails that were circulating late last week regarding the IYH on Salvia, please find attached our response to Paul's comments concerning the rationale for the development of this article for your review and comments.

[attachment "Response to ADM Comments on Salvia IYH Dec 1 2009.doc" deleted by Suzanne Desjardins/HC-SC/GC/CA]

Thanks,  
Cheryl Tremblay  
Policy and Regulatory Affairs Division / Division des politiques et affaires réglementaires  
Office of Controlled Substances / Bureau des substances contrôlées  
Controlled Substances and Tobacco Directorate / Direction des substances contrôlées et de la lutte au tabagisme  
Healthy Environments and Consumer Safety Branch / Direction générale de la santé environnementale et de la sécurité consommateurs  
Health Canada / Santé Canada  
Tel: (613) 954-6527 Fax: (613) 946-4224  
Jocelyn Kula/HC-SC/GC/CA

Jocelyn Kula/HC-SC/GC/CA

Cheryl - comments included herein.

the. DANA  
2006/07

## Salvia divinorum

### The Issue

Recently there have been reports suggesting that Canadian teens and young adults are using a substance called *Salvia divinorum* (*S. divinorum*) for its ability to produce hallucinations. Certain Web sites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs.

Street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastra, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff encens special, and salvia.

Health Canada recommends that you avoid using this substance because very little is known about the damage it may cause to the body, including the brain. There is also no way to predict how it will affect you with each use.

### Background

*S. divinorum* is a species of sage that belongs to the mint family. It is known to have psychotropic effects, which means it affects the mind and mental processes.

The leaves of this plant have been used traditionally by the Mazatec Indians in Mexico for many years. Traditional use involves chewing the leaves or using them to make a tea for medicinal purposes (e.g., to treat such conditions as headache or stomach upset), or to induce a "mystical" or hallucinogenic experience for spiritual purposes.

for spiritual and medicinal purposes

Products that claim to contain *S. divinorum* – or its main active ingredient, salvinorin A – are widely available on the Internet and are sold in various "head shops" and natural food stores. The products are sold in a number of formats, including seeds and plant cuttings for growing purposes. Fresh or dried leaves are intended to be chewed, swallowed or smoked. Liquid preparations are also available.

to do use want to say this

### Risks of Using *Salvia divinorum*

*S. divinorum*'s effects, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations;
- dysphoria (feeling unwell, uneasy or unhappy);
- out-of-body experiences;
- uncontrollable laughter;
- loss of consciousness;
- short-term memory loss;
- lack of physical coordination;
- slurred speech and awkward sentence patterns.

to do use want to say this  
tradition  
medicinal!!

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product;
- how much is used;
- the purity of the product (it may be mixed with other substances);
- how it is taken (e.g., chewed, swallowed or smoked);
- the user's mood and expectations.

A major concern about *S. divinorum* is ~~that~~ that there have only been a few scientific studies about the way it affects the body and the brain. Scientists know which brain receptors are targeted by the active ingredient, salvinorin A, but very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or permanent damage;
- how it interacts with other substances, including other drugs, natural health products and alcohol.

The information regarding physical dependence or addiction to *S. divinorum* is unclear, although it appears the potential for either is low.

### Minimizing Your Risk

Health Canada recommends that you avoid using *S. divinorum*. Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs and other substances that distort reality. (See the "Need More Info?" section below for links to resources that can help you with this.)

Also, remember that just because a drug is plant-based or "natural," it does not mean it is safe. Under certain conditions of use, *S. divinorum* meets the definition of a "natural health product" (NHP) under Health Canada's *Natural Health Products Regulations*. However, no NHPs containing this substance have been approved for sale in Canada. This means that products claiming to contain *S. divinorum* have not been reviewed by Health Canada for safety, efficacy or quality. As such, they may be counterfeit or contain other ingredients that pose risks to health, and consumers should heed the "buyer beware" principle.

Natural health products that have been reviewed and approved by Health Canada are labelled with one of the following:

- a Natural Product Number (NPN); or
- a Drug Identification Number - Homeopathic Medicine (DIN-HM).

### The Legal Status of *Salvia divinorum*

#### In Canada

Neither *S. divinorum* nor salvinorin A is currently regulated under the *Controlled Drugs and Substances Act* (CDSA). When assessing whether to add a substance to one of the Schedules to the CDSA, Health Canada considers the following factors:

- international requirements and trends in controlling the substance;
- similarity to other substances already regulated under the CDSA;

- whether there may be legitimate uses of the substance (e.g., potential health benefits, use in manufacturing, etc.);
- the potential for abuse and the risk of addiction associated with the substance;
- the extent of actual abuse of the substance in Canada and elsewhere;
- overall risk to public health and safety posed by the substance.

In the case of *S. divinorum*, there is simply not enough information available to determine whether regulation under the CDSA is the best option to manage the potential risks. Questions about the use of *S. divinorum* have been included in the 2008-2009 Youth Smoking Survey, the 2009 Canadian Alcohol and Drug Use Monitoring Survey and the 2009 Ontario Student Drug Use and Health Survey (OSDUHS). The results from the 2009 OSDUHS were published on November 18, 2009 and indicate that among responding students in Ontario in 2009, 4.4% reported using *Salvia divinorum* at least once in the past year. Data like this, and that from the two national surveys which will be available in 2010, will help fill some of these information gaps and contribute to future decisions that Health Canada may make about this plant and its active ingredient. See the Need More Info? section below for more information on the surveys that are collecting information about *Salvia divinorum* use in Canada and for more detailed findings from the 2009 OSDUHS.

#### In Other Countries

Several countries (e.g., Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) have placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on their sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution (e.g., no sales to anyone under the age of 18).

#### **Health Canada's Role**

Health Canada continues to collect and consider information regarding *S. divinorum* and continues to consult with key stakeholders, including health officials in other countries, and law enforcement officials here at home. This will assist in determining the most appropriate strategy to manage the risks associated with the use of *S. divinorum*.

#### **Reporting Adverse Reactions**

You can report any adverse reactions to the Canada Vigilance Program by one of the following three ways:

- Report online at the MedEffect<sup>TM</sup> Canada Web site
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and either:
- Fax toll-free to 1-866-678-6789
- Mail to:       Canada Vigilance Program  
                  Health Canada



AL 0701C  
Ottawa, ON K1A 0K9

To have postage pre-paid, download the postage paid label from the MedEffect™ Canada Web site. The Canada Vigilance Reporting Form and the adverse reaction reporting guidelines may also be obtained via this Web site.

### Need More Info?

For information about the Government of Canada's Anti-Drug Strategy, go to: <http://www.nationalantidrugstrategy.gc.ca/>. The Prevention section on this site has a number of helpful resources for parents, including "Tips on Talking to Your Teenager" and "What to Do if Your Teen is Using Drugs."

Information on natural health products and the *Natural Health Products Regulations* can be found at: <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php>

For more on the surveys that are collecting information about *Salvia divinorum* use in Canada, see:

The 2008-2009 Youth Smoking Survey, at: [http://www.yss.uwaterloo.ca/yssssite\\_app/controller/index.cfm](http://www.yss.uwaterloo.ca/yssssite_app/controller/index.cfm) and

The 2009 Canadian Alcohol and Drug Use Monitoring Survey, at: <http://www.hc-sc.gc.ca/hl-vs/drug-drogues/cadums-escad-eng.php>

The 2009 Ontario Student Drug Use and Health Survey, at: <http://www.camh.net/Research/osdus.html>

### Additional Resources:

U.S. Drug Enforcement Administration: Drugs and Chemicals of Concern: *Salvia divinorum* and Salvinorin A at: [http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)

U.S. Department of Health & Human Services, National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006 at: <http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf>

For additional articles on health and safety issues go to the *It's Your Health* Web section at: <http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/index-eng.php>

<http://www.hc-sc.gc.ca/english/iyh/index.html>

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

Original:

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Catalogue#  
ISBN#

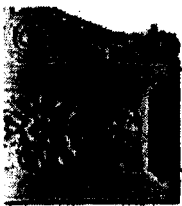
-----0-----

Writer: Sue Lumsden [lumsden@xplornet.com](mailto:lumsden@xplornet.com) 613-835-2878

Version/date: Draft Seven, May 27, 2009. Removes highlighter marking changes in Draft Six, which have been agreed to by the Program Contacts. Replaces references (and links) to the original report (and) to use of the data survey with a reference and link to the national's original Akshar and Dasa Law Monitoring Survey.

Program Contacts: (Draft One only) Debraj Nair  
HPIB-NIPD: Valerie Hurry, Robin Marles  
HPIB-MIIPD: Scott Jordan (Draft Two only), Robert Leitch, Manoj Murty

→ Salvia



Cheryl Tremblay/HC-SC/GC/CA  
2009-12-01 03:16 PM

To Diane Allan/HC-SC/GC/CA@HWC, Patricia Rapold/HC-SC/GC/CA@HWC  
cc Jocelyn Kula/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC  
bcc

Subject Re: Fw: Salvia D - IYH

Hi Diane/Patricia,

Here are the documents pertaining to the IYH on Salvia. The development of this article was initiated following a series of HPFB and HECSB DG-level discussions in 2007-2008 about the lack of data regarding Salvia and the department's obligation to address ongoing media interest and public/law enforcement enquiries. Both branches agreed that an IYH article was an option because it aims to provide the general public with information about an issue and/or influence behaviour, which in this case, would be the reduced use of *Salvia divinorum* for its hallucinogenic properties.

I spoke with Lisa Mackay (IYH Project Manager) regarding who signed off on the proposal and while we did have an opportunity to provide input on the proposal itself, she mentioned that proposals for IYH articles rarely seek formal approvals. I have attached the email from Lisa Holmes (Senior Communications Advisor, PACRB) requesting the article below. I have also attached the Approval Slips for the article itself from both HECSB and HPFB. FYI the article has been approved up to ADM level at HPFB.

**Response to ADM's Questions**



Response to ADM Comments on Salvia IYH Dec 1 2009.doc

**Final Rationale/Proposal**



Proposed Article IYH Salvia-D.wpd

**Approval Slips for Article Itself (i.e. not proposal)**



Apps Slip DG&ADM HECS Salvia May2009.wpd Apps Slip DG&ADM HPFB Salvia May2009.wpd

**Media Lines**

These are the most recent media lines on Salvia provided by comms. They have not been formally approved. We provided additional comments after the discussions that came out of the drafting of the IYH but comms was holding off on imputing our comments until they knew what needed to be changed in the IYH article, so they could update the media lines as necessary and send the IYH and media lines back to ADMO as a package. I have attached our comments on the lines below as well.



Salvia ML v.7 April 2009.doc Salvia ML v.7 April 2009\_CSTD Comments re IYH.doc

**Previous Response to Paul's Comments on the IYH**

**Why would we do an *It's Your Health* if we say we have insufficient evidence to regulate it (i.e. why do we have enough information about the health impacts yet aren't acting to regulate)?**

### **INPUT 1**

In light of the considerations and analysis above, it is recommended that neither *Salvia divinorum* nor its main active ingredient, salvinorin A, be scheduled under the CDSA at this time as they do not meet the established criteria for scheduling as follows:

- *S. divinorum* and salvinorin A are not structurally similar or even pharmacologically similar to other substances included in the schedules to the CDSA.
- The abuse liability and potential for dependence of *S. divinorum* is not known as very few controlled scientific studies of the physical and psychotropic effects of *S. divinorum* have been carried out on humans. More controlled systematic research in this area is needed.
- Effects are known to be short-lived and no long term studies of cumulative use have been conducted.
- Health Canada has only received a limited number of communications regarding *Salvia divinorum* from law enforcement agencies, and none of these have advised that the use of *Salvia divinorum* poses any particular threat to public safety.
- Prohibition under the CDSA may add unnecessary burden to policing and justice systems.
- Imprisoning individuals using or trafficking *Salvia* may aggravate an already swelling prison system.
- Evidence of a risk to public health and safety is anecdotal in nature and not quantified in any way as there is a lack of information regarding usage in Canada.

It is therefore recommended that educational materials be published in order to reduce the potential health and safety risks associated with this substance and its active ingredient.

### **INPUT 2**

- Why IYH? Instrument choice (enterprise risk) change public behaviour before moving to prohibition; no incidence data outside of Ontario
- there are now recent data on the prevalence of salvia that were just released in the Ontario student drug use survey (6% of students reported having used it at least once, rate higher than for ecstasy) . Bruna is preparing a short article for CMAJ with more details on it .

## **Its Your Health Proposed Article**

It's Your Health articles answer frequently asked questions from the general public and provide health protection advice. Each IYH article is roughly 2 pages long, with a grade 8 to 10 "readability" level. The target audience is the general public, and plain language is used whenever possible. Links to detailed technical or scientific information can be provided in the "Need More Info?" section. These publications are distributed to: doctors and their clients, teachers and students, magazine editors and their subscribers, other federal and provincial departments, private firms, Health Canada and Public Health Agency of Canada employees. This publication is also posted on Health Canada and PHACs official Web sites.

**Author and Date of Proposal** - *Lisa Holmes - October 17, 2008*

**Proposed Title** - *Salvia divinorum*

**The Issue** - *Salvia Divinorum is a species of sage which belongs to the mint family. It is found in the form of dried leaves, extract and plant cuttings. Salvia Divinorum, also known as "diviner's sage" and/or "magic mint", is chewed or smoked and can induce illusions and hallucinations.*

*Salvia Divinorum continues to attract moderate media attention. It will be beneficial to have an It's Your Health article available on the internet so that the general public can be better informed about the issue, and so that reporters can refer to this article, should they have questions about the issue.*

**Health Canada's Role** - *There are no regulations or laws prohibiting the possession, use or sale of Salvia divinorum in Canada. While many countries across the globe have prohibited Salvia, it remains legal in Canada. Health Canada is currently exploring our options for prohibiting Salvia in Canada.*

**Why is this article needed and why It's Your Health ?** - *The target audience is the general public. It's Your Health is a good vehicle to use to inform individuals about Salvia because the articles are written in plain language and are easily understood by the vast majority of Canadians.*

**Are other communications products being considered, will they be used ?** - *Media lines.*

**Is there a deadline for producing the IYH article** - *While it is not part of a larger*

*announcement, it would be beneficial to have this article produced and posted as soon as possible, as there continues to be media attention and public interest on the issue.*

**Who in the department needs to provide input and who would be the lead contact ?-** *Andrew Adams, Director, Drug Analysis Services, HECS; Ranjan Bose, Manager, Marketed Biologicals, Biotechnology and Natural Health Products Bureau, Marketed Health Products Directorate, and Dr. Helmi Hussien, A/Director, Bureau of Clinical Trials and Health Sciences, Natural Health Products Directorate, HPFB.*

**Who in the department or outside of the department should approve this article?** - *Health Canada only.*

**Is there a plan for Stakeholder involvement or dissemination when article is completed?:** *No stakeholder plan - we will refer media to this article.*

If you have any questions regarding this form please contact your Branch or Regional contact listed below:

**HECSB**  
Judy Froome  
Lisa Brinston

**HPFB**  
Blossom Leung

**PHAC**  
Julie Rivard

**ATLANTIC Region**  
Eleanor Cameron

**QUEBEC Region**  
Caroline Hares

**Ontario Region**  
Debbie Paine

**MANITOBA/SASKATCHEWAN Region**  
Adele Novak

**ALBERTA Region**  
Therese Little

**BC Region**  
Erik Bruns

**IYH Manager**  
Lisa Mackay

**IYH Publisher**  
Alastair Sinclair

**IYH Editor**  
Sally Fletcher  
Sean Upton

**FNIHB**  
Mary Hand

## *It's Your Health*

*(A Health Canada Publication)*

<b>Comments ♦ Commentaires</b>			
It's Your Health articles answer frequently asked questions from the general public and provide health protection advice. These publications are distributed to: doctors and their clients, teachers and students, magazine editors and their subscribers, other federal and provincial departments, private firms, and Health Canada employees. This publication is also posted on the Health Canada official Web site.			
<b>Subject ♦ Sujet:</b>		<b>Approval deadline Échéance d'approbation</b>	
<b>Salvia divinorum</b>		<b>June 12, 2009</b>	
<b>Branch:</b> HECSB		<b>Comm:</b> Judy Froome/Christine Roush	
<b>Coordinator:</b> Lisa Mackay 954-0105		<b>Writer:</b> Sue Lumsden	
<b>Program Contacts:</b> Jocelyn Kula, Cheryl Tremblay and Brittany Sauvé			
<b>Approvals Approbations</b>	<b>Signing Authority Autorisé par</b>	<b>Signature</b>	<b>Date</b>
1. Programme Director	Diane Allan	Email	June 10, 2009
2. Director General	Cathy A. Sabiston	Email	June 15, 2009
3. HECSB Communications Exec	Kathleen Malone	Signature	June 16, 2009
4. ADM	Paul Glover		
5. Risk Communications	Kathy Howard		
<b>Please return to ♦ Veuillez retourner à :</b> Lisa Mackay 954-0105		<b>Room ♦ Pièce:</b> 1273D BC FAX: 952-8644	

## ***It's Your Health***

***(A Health Canada/Public Health Agency Publication)***

**Comments ♦ Commentaires**

It's Your Health articles answer frequently asked questions from the general public and provide health protection and promotion advice. The articles are distributed to: doctors and their clients, teachers and students, magazine editors and their subscribers, other federal and provincial departments, private firms, and Health Canada/Public Health Agency of Canada employees. This publication is also posted on the Health Canada and Public Health Agency Web sites.

<b>Subject ♦ Sujet:</b>	<b>Approval deadline Échéance d'approbation</b>
<b>Salvia divinorum</b>	<b>June 12, 2009</b>

<b>Branch:</b> HPFB	<b>Comm Contact:</b> Blossom Leung 948-7799
<b>Coordinator:</b> Lisa Mackay 954-0105	<b>Writer:</b> Sue Lumsden

**Program Contact:** Valerie Hurry (NHPD), and Robert Leitch and Mano Murty (MHPD)

Approvals Approbations	Signing Authority Autorisé par	Signature	Date
1. Programme Director	Robin Marles	Approved	June 1, 2009
2. Programme Director	Duc Vu	Approved	June 1, 2009
3. Programme DG	Michelle Boudreau	Approved	June 1, 2009
4. Programme DG	Chris Turner	Approved	June 4, 2009
4. Communications Executive	Jennifer Peddle for Ken Polk	Approved	June 4, 2009
5. ADM	Meena Ballentyne	Approved	June 5, 2009
6. Risk/Crisis Communications	Kathy Howard		

Please return to ♦ Veuillez retourner à : Lisa Mackay 954-0105	Room ♦ Pièce: 1277D BC FAX: 952-8644
--	--

**000462**



DRAFT  
April 7, 2009

## **Media Lines Regulatory Control of *Salvia Divinorum***

### **Issue**

Since 2006, Health Canada has observed a steady increase in the amount of media interest regarding the availability of *Salvia divinorum* on the Canadian market. Health Canada has also received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum*, particularly given reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties.

### **Key Messages:**

- Health Canada continues to collect relevant information about *Salvia divinorum* and its active ingredient, Salvinorin A, from both national and international sources in order to determine what, if any, regulatory controls are needed.
- While the media have reported that use of *Salvia divinorum* is on the rise in certain parts of the country, Health Canada does not currently have statistics on its use across the Canadian population.
- Health Canada is taking steps to address this lack of data. Questions regarding the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. A general open-ended question about the use of other substances was also included in the 2008 Canadian Alcohol and Drug Use Monitoring Survey.

### **Supplementary Messages:**

#### ***On the classification of *Salvia divinorum*:***

- In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, Salvinorin A, are controlled under the *Controlled Drugs and Substances Act* (CDSA).
- *Salvia divinorum* is not listed under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these conventions.
- Several countries (Australia, Belgium, Denmark, Sweden, Italy, Spain, Finland and South Korea) have placed controls on the import and/or sale of *Salvia divinorum*. Although some individual U.S. states have implemented laws restricting its use,

sale and/or distribution, *Salvia divinorum* is not federally regulated under the *Controlled Substances Act* in the United States.

- *Salvia divinorum*, when associated with health claims, could meet the definition of a natural health product under the *Natural Health Product Regulations* (NHPR). This means that *Salvia* products that are not in compliance with the NHPR may be subject to compliance and enforcement actions.
- As of January 2009, Health Canada had not issued any Natural Product Numbers (NPN) or Drug Identification Numbers – Homeopathic Medicine (DIN-HM) for *Salvia divinorum* products.

***If asked for specifics on when the survey data will be available:***

- Data from the Canadian Alcohol and Drug Use Monitoring Survey will be available in summer 2009, while the results of the Youth Smoking Survey and the Ontario Student Drug Use and Health Survey likely will not be available until 2010.

## **Questions and Answers**

**Q1 – If Health Canada is aware of *Salvia divinorum*'s ill-effects, why isn't it illegal?**

A1 – Very few controlled scientific studies of the physical and psychotropic effects of *Salvia divinorum* on humans have been carried out, and using these studies to predict the potential for addiction and abuse associated with *Salvia divinorum* is difficult. More controlled systematic research in this area is needed.

Health Canada has only received a limited number of communications regarding *Salvia divinorum* from law enforcement agencies, and none of these has advised that the use of *Salvia divinorum* poses any particular threat to public safety.

**Q2 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?**

A2 – The *Natural Health Product Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *Salvia divinorum*.

**Q3 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A3 – *Salvia divinorum* products that are not in compliance with the *Natural Health Product Regulations* and/or are found to pose a risk to the health of Canadians may be subject to compliance and enforcement action by Health Canada. An import target for products with *Salvia divinorum* has already been placed with Canada Border Services Agency.

**Q4 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum*. What does that involve and what stage is it at?**

A4 - Health Canada considers several factors in determining whether scheduling a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in control and scheduling;
- Chemical and pharmacological similarity to other substances already scheduled under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Abuse liability and addiction potential of the substance;
- Extent of actual abuse and misuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada has only anecdotal information about the last three of the above-mentioned factors, and thus is not yet convinced that the controls imposed by the CDSA are an appropriate strategy for managing the risks associated with the use of *Salvia divinorum*.

Health Canada will, however, continue to collect and consider information regarding *Salvia divinorum* as it becomes available.

**Q5 – Didn't an internal report from Health Canada's Marketed Health Products Directorate recommend that *Salvia divinorum* be scheduled under the CDSA? Why has that recommendation not been acted upon?**

A5 – See A4

**Q6 – What is the significance of the adverse reaction reports that Health Canada has received with respect to the use of *Salvia divinorum*?**

A6 – Health Canada has received four domestic adverse reaction reports related to the use of *Salvia divinorum* as a hallucinogen through the Canada Vigilance database. The number of reports and the nature of reactions reported are not adequate to characterize the risk to the general population. These data cannot be used to determine incidence of use in the general population, as Health Canada does not have any information about the number of individuals using or who have used *Salvia divinorum*.

**Background**

*Salvia divinorum* is a species of sage belonging to the mint family that is chewed or smoked in order to induce its psychotropic effects. These effects are short-acting in nature and include hallucinations, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are often described as unpleasant.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. While no validated data exist regarding usage in Canada, data from a 2006 National Survey on Drug Use and Health Report, published by the U.S. Substance Abuse and Mental Health Services Administration has estimated that:

- 1.8 million persons aged 12 or older used *Salvia divinorum* at least once in their lifetime, and approximately 750,000 did so in the past year.
- Use was more common among young adults (18 to 25 years old) as opposed to older adults (>26 years of age).
- Young adults were three times more likely than youths aged 12 to 17 to have used *Salvia divinorum* in the past year.
- Use was more common in males than females.

*Salvia divinorum* is widely advertised and promoted on the Internet as a "legal" alternative to street drugs.

While some users have reported that the psychotropic effects of *Salvia divinorum* resemble those induced by other hallucinogens, such as LSD and phencyclidine, the overall experience appears to be quite unique. *Salvia divinorum* does not appear to cause the euphoria often associated with other psychoactive drugs, so many people who try it do not repeat the experience.

**Prepared by:** Cheryl Tremblay, Policy and Regulatory Affairs Division, DSCSD  
Stephanie Mitchell, Communications Advisor (HECSB)  
Darrin Denne, Communications Officer (HPFB)

**Reviewed by:** Mano Murty (MHPD – March 11, 2009)

**Approved by :**

Approved

Andrew Adams, Director, OCS, DSCSD (March 1<sup>st</sup>, 2009)  
Nancy Richards, Director, Bureau of Policy and Regulatory Affairs, NHPD (January 23, 2009)  
Duc Vu, Director, Marketed Biologics, Biotechnology and Natural Health Products Bureau, MHPD (February 3, 2009)

Approved

Cathy Sabiston, DG, TDD, HECS (April 7, 2009)

Approved

Chris Turner, DG, MHPD (March 13, 2009)

Approved

Michelle Boudreau, DG, NHPD (March 19, 2009)

Approved

Sharon Mullins, A/DG, HPFBI (April 3, 2009)

Approved

Ken Polk, Communications Executive, HPFB (April 3, 2009)

Approved

Kathleen Malone, Senior Media Relations, PACCB (April 7, 2009)

Pending

Warren Braun, Director, Strategic Communications, PACCB

Pending

Peter Yendall, Director, Public Affairs, PACCB

Pending

Paul Glover, ADM, HECSB

Pending

Meena Ballantyne, ADM, HPFB

Pending

Anne Lamar, ADM, PACCB

Pending

DMO

Pending

MO

Pending

PCO

DRAFT  
April 7, 2009

### Media Lines Regulatory Control of *Salvia Divinorum*

#### Issue

Since 2006, Health Canada has noted ongoing media interest regarding the availability of *Salvia divinorum* on the Canadian market. Health Canada has also received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum*, particularly given reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties.

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#### Key Messages:

- Health Canada continues to collect and consider information about *Salvia divinorum* and its active ingredient, salvinorin A, from both national and international sources in order to determine what, if any, regulatory controls are needed.
- While the media have reported that use of *Salvia divinorum* is on the rise in certain parts of the country, Health Canada does not currently have statistics on its use across the Canadian population.
- Health Canada is taking steps to address this lack of data. Questions regarding the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey. A general open-ended question about the use of other substances was also included in the 2008 Canadian Alcohol and Drug Use Monitoring Survey.

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Deleted: Ontario Student

Deleted: and Health

#### Supplementary Messages:

##### *On the classification of *Salvia divinorum*:*

- In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA).
- *Salvia divinorum* is not listed under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these conventions.
- Several countries (Australia, Belgium, Denmark, Sweden, Italy, Spain, Finland and South Korea) have placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Although some individual U.S. states have implemented laws

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restricting its use, sale and/or distribution, *Salvia divinorum* and salvinorin A are not federally regulated under the *Controlled Substances Act* in the United States.

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- *Salvia divinorum* meets the definition of a natural health product under the *Natural Health Product Regulations* (NHPR). This means that *Salvia* products that are not in compliance with the NHPR may be subject to compliance and enforcement actions.
- As of January 2009, Health Canada had not issued any Natural Product Numbers (NPN) or Drug Identification Numbers – Homeopathic Medicine (DIN-HM) for *Salvia divinorum* products.

Deleted: , when associated with health claims, could

*If asked for specifics on when the survey data will be available:*

- Data from the Canadian Alcohol and Drug Use Monitoring Survey will be available in summer 2009, while the results of the Youth Smoking Survey and the Canadian Alcohol and Drug Use Monitoring Survey likely will not be available until 2010.

Deleted: Ontario Student

Deleted: and Health

## Questions and Answers

**Q1 – If Health Canada is aware of *Salvia divinorum*'s ill-effects, why isn't it illegal?**

A1 – Very few controlled scientific studies of the physical and psychotropic effects of *Salvia divinorum* on humans have been carried out, and using these studies to predict the potential for addiction and abuse associated with *Salvia divinorum* is difficult. More controlled systematic research in this area is needed.

Health Canada has only received a limited number of communications regarding *Salvia divinorum* from law enforcement agencies, and none of these has advised that the use of *Salvia divinorum* poses any particular threat to public safety.

**Q2 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?**

A2 – The *Natural Health Product Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *Salvia divinorum*.

**Q3 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A3 – *Salvia divinorum* products that are not in compliance with the *Natural Health Product Regulations* and/or are found to pose a risk to the health of Canadians may be subject to compliance and enforcement action by Health Canada. An import target for products containing *Salvia divinorum* has already been placed with Canada Border Services Agency.

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**Q4 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum*. What does that involve and what stage is it at?**

A4 - Health Canada considers several factors in determining whether scheduling a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in regulatory status;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Deleted: control  
Deleted: and scheduling  
Deleted: scheduled  
Deleted: A  
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Deleted: potential of  
Deleted: and misuse

Health Canada has only anecdotal information about the last three of the above-mentioned factors, and thus is not yet convinced that the controls imposed by the CDSA are an appropriate strategy for managing the risks associated with the use of *Salvia divinorum*. The survey results from the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey will help fill some of the information gaps. The data, however, will not likely be available until 2010. In the interim, Health Canada will continue to collect and consider information regarding *Salvia divinorum* as it becomes available.

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**Q5 – Didn't an internal report from Health Canada's Marketed Health Products Directorate recommend that *Salvia divinorum* be scheduled under the CDSA? Why has that recommendation not been acted upon?**

A5 – See A4

**Q6 – What is the significance of the adverse reaction reports that Health Canada has received with respect to the use of *Salvia divinorum*?**

A6 – Health Canada has received four domestic adverse reaction reports related to the use of *Salvia divinorum* as a hallucinogen through the Canada Vigilance database. The number of reports and the nature of reactions reported are not adequate to characterize the risk to the general population. These data cannot be used to determine incidence of use in the general population, as Health Canada does not have any information about the number of individuals using or who have used *Salvia divinorum*.

**Background**

*Salvia divinorum* is a species of sage belonging to the mint family that is chewed or smoked in order to induce its psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are often described as unpleasant.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. While no validated data exist regarding usage in Canada, data from a 2006 National Survey on Drug Use and Health Report, published by the U.S. Substance Abuse and Mental Health Services Administration has estimated that:

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- Use was more common among young adults (18 to 25 years old) as opposed to older adults (>26 years of age).
- Young adults were three times more likely than youths aged 12 to 17 to have used *Salvia divinorum* in the past year.
- Use was more common in males than females.

*Salvia divinorum* is widely advertised and promoted on the Internet and sold in various "head shops" and natural food stores as a "legal" alternative to street drugs.

While some users have reported that the psychotropic effects of *Salvia divinorum* resemble those induced by other hallucinogens, such as LSD and phencyclidine, the overall experience appears to be quite unique.

**Deleted:** *Salvia divinorum* does not appear to cause the euphoria often associated with other psychoactive drugs, so many people who try it do not repeat the experience.

**Prepared by:** Cheryl Tremblay, Policy and Regulatory Affairs Division, DSCSD  
Stephanie Mitchell, Communications Advisor (HECSB)  
Darrin Denne, Communications Officer (HPFB)

**Reviewed by:** Mano Murty (MHPD – March 11, 2009)

**Approved by :**

Approved

Andrew Adams, Director, OCS, DSCSD (March 1<sup>st</sup>, 2009)  
Nancy Richards, Director, Bureau of Policy and Regulatory Affairs, NHPD (January 23, 2009)  
Duc Vu, Director, Marketed Biologics, Biotechnology and Natural Health Products Bureau, MHPD (February 3, 2009)

Approved

Cathy Sabiston, DG, TDD, HECS (April 7, 2009)

Approved

Chris Turner, DG, MHPD (March 13, 2009)

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Michelle Boudreau, DG, NHPD (March 19, 2009)

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Sharon Mullins, A/DG, HPFBI (April 3, 2009)

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Ken Polk, Communications Executive, HPFB (April 3, 2009)

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Paul Glover, ADM, HECSB

Pending

Meena Ballantyne, ADM, HPFB

Pending

Anne Lamar, ADM, PACCB

Pending

DMO

Pending

MO

Pending

PCO



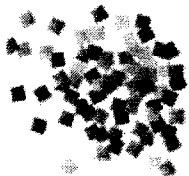


Responses to ADM Comments on Salvia IYH June 23 2009.doc

Let me know if you need anything else.

Thanks,  
Cheryl

Policy and Regulatory Affairs Division / Division des politiques et affaires réglementaires  
Office of Controlled Substances / Bureau des substances contrôlées  
Controlled Substances and Tobacco Directorate / Direction des substances contrôlées et de la lutte au  
tabagisme  
Healthy Environments and Consumer Safety Branch / Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada / Santé Canada  
Tel: (613) 954-6527 Fax: (613) 946-4224  
--- Forwarded by Lisa MacKay/HC-SC/GC/CA on 2009-11-30 11:15 AM ---



Lisa Holmes/HC-SC/GC/CA

2008-10-16 05:07 PM

To Lisa MacKay/HC-SC/GC/CA@HWC

cc Darrin Denne/HC-SC/GC/CA@HWC

Subject It's Your Health re: Salvia

Hi Lisa,

The drug group here at HECS would like to have an It's Your Health article written on Salvia. How do we proceed with scheduling a meeting with one of the writers?

Darrin, I'm copying you as well since HPFB will have to take part in this meeting too.

Thanks!  
Lisa

---

Lisa Holmes  
Senior Communications Advisor | Conseillère principale en communications  
PACRB | DGAPCR  
Strategic Communications Directorate | Direction des communications stratégiques  
Health Canada | Santé Canada  
T: (613) 957-3431  
F: (613) 948-8085  
C: (613) 601-0215  
Suzanne Desjardins/HC-SC/GC/CA

Diane Allan/HC-SC/GC/CA

Diane Allan/HC-SC/GC/CA

2009-11-27 02:41 PM

To Cheryl.Tremblay@hc-sc.gc.ca, "Suzanne Desjardins"  
<Suzanne.Desjardins@hc-sc.gc.ca>

cc "Jocelyn Kula" <jocelyn.kula@hc-sc.gc.ca>, "Denis  
Arsenault" <denis.arsenault@hc-sc.gc.ca>, "Mrs. Patricia  
Rapold" <Patricia.Rapold@hc-sc.gc.ca>, "Stephanie Szick"

<stephanie.szick@hc-sc.gc.ca>  
Subject Fw: Salvia D - IYH

Please help.  
Stephanie Szick

----- Original Message -----

**From:** Stephanie Szick  
**Sent:** 2009-11-27 02:29 PM EST  
**To:** Diane Allan; Patricia Rapold  
**Cc:** Jodi Brown; Kimberly Sorfleet; Arafo Talane; Carmen Berube  
**Subject:** Salvia D - IYH

Hi Diane and Patricia,

Long trail below on this. In short, the Salvia D article is with Paul for his sign-off....he would like clarity on the following:

- **Why would we do an it's your health if we say we have insufficient evidence to regulate it? i.e Why do we have enough about the health impacts yet aren't acting to regulate?**

I've attempted to reply to some of this in my email below to Cathy....

Per my email below, can your shop touch base with comms on this, as these articles are pretty much comms-led and implemented, and let us know by next week.

Clarification in an email is fine, please attach/include from comms the final rationale/proposal (with confirmation of who signed off), and the last version of the article, as well as any formal/approved media lines on the issue.

**Deadline to DGO** - next Wednesday, December 2, noon

Kim - please note for BF.

Thanks very much,

Stephanie

----- Forwarded by Stephanie Szick/HC-SC/GC/CA on 2009-11-27 02:21 PM -----



Stephanie  
Szick/HC-SC/GC/CA  
2009-11-27 02:21 PM

To Cathy A Sabiston/HC-SC/GC/CA  
cc Jodi Brown/HC-SC/GC/CA@HWC, Kimberly  
Sorfleet/HC-SC/GC/CA@HWC  
Subject Re: Salvia D

Hi Cathy,

Pasted here is what was originally provided as rationale in the proposal for the Salvia D article.....keeping in mind IYH articles are comms products. I will ask Diane's shop to touch base also with comms to confirm what final approved rationale was -- the key was the both HECSB and HPFB were both onside with this idea - consensus. I think Paul actually approved the proposal and rationale. Comms should be able to provide more clarity.

The purpose of the article is information, including around current HC role....the dept. receives the same media Qs over and over on this issue and an IYH would be something to point reporters to, rather than the scramble to gather replies and get approvals across HECSB and HPFB. The article is just more efficient - it's approved across the two branches good to go.

**THE ISSUE** - **Salvia Divinorum is a species of sage which belongs to the mint family. It is found in the form of dried leaves, extract and plant cuttings. Salvia Divinorum, also known as "diviner's sage" and/or "magic mint", is chewed or smoked and can induce illusions and hallucinations.**

**Salvia Divinorum continues to attract moderate media attention. It will be beneficial to have an It's Your Health article available on the internet so that the general public can be better informed about the issue, and so that reporters can refer to this article, should they have questions about the issue.**

**HEALTH CANADA'S ROLE** - **There are no regulations or laws prohibiting the possession, use or sale of Salvia divinorum in Canada. While many countries across the globe have prohibited Salvia, it remains legal in Canada. Health Canada is currently exploring our options for prohibiting Salvia in Canada.**

**WHY IS THIS ARTICLE NEEDED AND WHY IT'S YOUR HEALTH?**- **The target audience is the general public. It's Your Health is a good vehicle to use to inform individuals about Salvia because the articles are written in plain language and are easily understood by the vast majority of Canadians.**

Cathy A Sabiston/HC-SC/GC/CA



Cathy A  
Sabiston/HC-SC/GC/CA  
2009-11-27 01:43 PM

To Stephanie Szick/HC-SC/GC/CA@HWC, Jodi  
Brown/HC-SC/GC/CA@HWC  
cc Kimberly Sorfleet/HC-SC/GC/CA@HWC

Subject Salvia D

Paul's question is why wld we do an it's your health if we say we have insufficient evidence to regulate it?  
le why do we have enuff about the health impacts yet aren't acting to regulate

Can you please ask diane to look into this - or whomever!

Cas

s.19(1)



Suzanne Desjardins/HC-SC/GC/CA  
2009-12-08 04:27 PM

To Cheryl Tremblay/HC-SC/GC/CA@HWC  
cc Carmen Berube/HC-SC/GC/CA@HWC, Diane Allan/HC-SC/GC/CA@HWC, Isabel Shanahan/HC-SC/GC/CA@HWC, Jocelyn  
bcc

Subject Re: Fw: 09-135999-128 - Action Request - REDIRECTED TO HECSB - request re: Status of Salvia (Divinorum) in Canada

Thanks Cheryl,

I only have a few comments;

~~- 2nd para: Is it really "head shops"?~~

*alternative lifestyle stores*

~~- Talking points: Health Canada is aware of some of the effects associated with the use of Salvia divinorum including hallucinations, out-of-body experiences, unconsciousness and short-term memory loss~~

~~"... were included in the 2008-2009 Youth Smoking Survey": I would remove reference to the YSS, since data are not yet available~~

*Remark*  
~~Also, the last part refers to HC recommending that use of Salvia be avoided. Was there an advisory on it issued by HHP, or am I confusing it with BZP? In any event, where can we find that HC is recommending that use be avoided? perhaps we should refer to it more formally.~~

Suzanne  
Cheryl Tremblay/HC-SC/GC/CA



Cheryl Tremblay/HC-SC/GC/CA  
2009-12-08 04:06 PM

To Suzanne Desjardins/HC-SC/GC/CA@HWC  
cc Carmen Berube/HC-SC/GC/CA@HWC, Diane Allan/HC-SC/GC/CA@HWC, Isabel Shanahan/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC

Subject Re: Fw: 09-135999-128 - Action Request - REDIRECTED TO HECSB - request re: Status of Salvia (Divinorum) in Canada

Hi Suzanne,

Here are the speaking points on Salvia for [redacted] for your review and approval. Please note that these are due in DGO tomorrow by 10:00am.

JK - These are saved under PRAD/Briefing Notes and Memos/2009

[attachment "09-135999-128-TALKING POINTS\_MP Gord Brown\_Salvia Divinorum\_Dec 8 2009.wpd" deleted by Suzanne Desjardins/HC-SC/GC/CA]

Thank you,

Cheryl Tremblay  
Policy and Regulatory Affairs Division / Division des politiques et affaires réglementaires  
Office of Controlled Substances / Bureau des substances contrôlées  
Controlled Substances and Tobacco Directorate / Direction des substances contrôlées et de la lutte au tabagisme  
Healthy Environments and Consumer Safety Branch / Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada / Santé Canada  
Tel: (613) 954-6527 Fax: (613) 946-4224  
Jocelyn Kula/HC-SC/GC/CA

s.19(1)



Jocelyn Kula/HC-SC/GC/CA

2009-12-08 12:52 PM

To: Suzanne Desjardins/HC-SC/GC/CA@HWC

cc Cheryl Tremblay/HC-SC/GC/CA@HWC, Diane Allan, Isabel Shanahan, Carmen Berube

Subject Re: Fw: 09-135999-128 - Action Request - REDIRECTED TO HECSB - [REDACTED] request re: Status of Salvia (Divinorum) in Canada [REDACTED]

Thanks Suzanne,

Cheryl is working on the speaking points for [REDACTED] right now, and we will send you a draft later today.

Isabel- pls bring docket for 09-076902 to me when it comes in from DO

JK

Jocelyn Kula  
Manager/ Gestionnaire  
Policy and Regulatory Affairs Division/ Division des politiques et affaires réglementaires  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0125 Fax: (613) 946-4224  
Suzanne Desjardins/HC-SC/GC/CA



Suzanne Desjardins/HC-SC/GC/CA

2009-12-08 11:10 AM

To: Jocelyn Kula/HC-SC/GC/CA@HWC, Diane Allan/HC-SC/GC/CA@HWC

cc Annie Berube/HC-SC/GC/CA@HWC

Subject Fw: 09-135999-128 - Action Request - REDIRECTED TO HECSB - [REDACTED] request re: Status of Salvia (Divinorum) in Canada

s.19(1)

I just received another docket on Salvia (number 09-076902-986), which I am re-directing to you. The response you are preparing for the below request will likely only need to be changed a bit to reply to it; again we will be pleased to provide input (HPFB input may also be needed?).

Thanks

s.19(1)



Suzanne

----- Forwarded by Suzanne Desjardins/HC-SC/GC/CA on 2009-12-08 11:08 AM -----



Kimberly  
Sorfleet/HC-SC/GC/CA  
2009-12-08 10:31 AM

To Jocelyn Kula/HC-SC/GC/CA@HWC  
cc Suzanne Desjardins/HC-SC/GC/CA@HWC, Carmen Berube/HC-SC/GC/CA@HWC  
Subject Fw: 09-135999-128 - Action Request - REDIRECTED TO HECSB [REDACTED] request re: Status of Salvia (Divinorum) in Canada

FYI

Kimberly Sorfleet  
Executive Assistant to the Director General / Adjointe Exécutive a la Directrice générale  
Controlled Substances & Tobacco Directorate (CSTD)  
Direction des substances contrôlées et de la lutte au tabagisme (DSCLT)  
Health Canada / Santé Canada  
E-Mail: kimberly.sorfleet@hc-sc.gc.ca  
Tel: (613) 946-9316 Fax: (613) 946-6460

----- Forwarded by Kimberly Sorfleet/HC-SC/GC/CA on 2009-12-08 10:30 AM -----



Suzanne  
Desjardins/HC-SC/GC/CA  
2009-12-08 10:29 AM

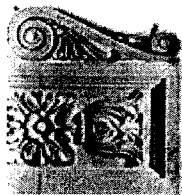
To Carmen Berube/HC-SC/GC/CA@HWC  
cc Diane Allan/HC-SC/GC/CA@HWC, Jodi Brown/HC-SC/GC/CA@HWC, Kimberly Sorfleet/HC-SC/GC/CA@HWC, Manjula Biradar/HC-SC/GC/CA@HWC  
Subject Re: 09-135999-128 - Action Request - REDIRECTED TO HECSB [REDACTED] request re: Status of Salvia (Divinorum) in Canada [REDACTED]

Please let Jocelyn know that we will provide input as requested.

Thanks

Suzanne

Carmen Berube/HC-SC/GC/CA



Carmen  
Berube/HC-SC/GC/CA  
2009-12-08 10:22 AM

To Kimberly Sorfleet/HC-SC/GC/CA@HWC  
cc Diane Allan/HC-SC/GC/CA@HWC, Jodi Brown/HC-SC/GC/CA@HWC, Manjula Biradar/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC  
Subject Re: 09-135999-128 - Action Request - REDIRECTED TO HECSB [REDACTED] request re: Status of Salvia (Divinorum) in Canada [REDACTED]

Kimberly,

I am preparing a docket and will send it over to Jocelyn Kula, Manager of OCS PRAD to proceed with this request.

Carmen

Kimberly Sorfleet/HC-SC/GC/CA



Kimberly  
Sorfleet/HC-SC/GC/CA  
2009-12-08 10:15 AM

To Diane Allan/HC-SC/GC/CA@HWC, Suzanne  
Desjardins/HC-SC/GC/CA@HWC  
cc Jodi Brown/HC-SC/GC/CA@HWC, Carmen  
Berube/HC-SC/GC/CA@HWC, Manjula  
Biradar/HC-SC/GC/CA@HWC

Subject 09-135999-128 - Action Request - REDIRECTED TO  
HECSB - [REDACTED] request re: Status of Salvia  
(Divinorum) in Canada

Hi there,

Further to my email from this morning, we have now been given the full lead on this request. Please work together and provide DGO with a draft version of talking points for Cathy's review and approval by 10:00 a.m. tomorrow, December 9th.

Please do not hesitate to let me know if you have any questions.

Thank you!

Kimberly Sorfleet  
Executive Assistant to the Director General / Adjointe Exécutive a la Directrice générale  
Controlled Substances & Tobacco Directorate (CSTD)  
Direction des substances contrôlées et de la lutte au tabagisme (DSCLT)  
Health Canada / Santé Canada  
E-Mail: kimberly.sorfleet@hc-sc.gc.ca  
Tel: (613) 946-9316 Fax: (613) 946-6460

----- Forwarded by Kimberly Sorfleet/HC-SC/GC/CA on 2009-12-08 10:13 AM -----

Michel  
Prud'Homme/HC-SC/GC/CA  
2009-12-08 10:12 AM

To Kimberly Sorfleet/HC-SC/GC/CA@HWC  
cc Jodi Brown/HC-SC/GC/CA@HWC, Stephanie  
Szick/HC-SC/GC/CA@HWC, Lyne Tassé, Natalie  
Racine/HC-SC/GC/CA@HWC, Jonathan  
Loan/HC-SC/GC/CA@HWC

Subject 09-135999-128 - Action Request - REDIRECTED TO  
HECSB - [REDACTED] request re: Status of Salvia  
(Divinorum) in Canada

Please see the action request below which has been re-directed from HPFB to HECSB and provide your input by noon, tomorrow, Wednesday, December 9, 2009.

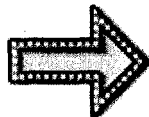
Thanks,



Michel

s.19(1)

----- Forwarded by Michel Prud'Homme/HC-SC/GC/CA on 2009-12-08 10:06 AM -----



Frederick Coyle/HC-SC/GC/CA  
2009-12-08 09:53 AM

To HECSB\_Action Request\_48h, Natalie Racine/HC-SC/GC/CA@HWC, Joan Kennedy/HC-SC/GC/CA@HWC, Jonathan Loan/HC-SC/GC/CA@HWC  
cc sarah-emily\_carle@poc.hc-sc.gc.ca@Exchange, caroline\_pitfield@poc.hc-sc.gc.ca@exchange, Bryan Takeda/HC-SC/GC/CA@HWC, Robert Simms/HC-SC/GC/CA@HWC

Subject REDIRECTED TO HECSB - [redacted] request re: Status of Salvia (Divinorum) in Canada

HECSB:

Please note that HPFB has redirected this request to HECSB. Rationale is below.

"This should be a HECS lead. There are no health products with this ingredient. The questions surround the scheduling status (controlled or not). "

Thank you.  
Fred Coyle  
Ministerial Briefing Unit / Unité d'information ministérielle

----- Forwarded by Frederick Coyle/HC-SC/GC/CA on 2009-12-08 09:50 AM -----

Status: Open/Ouvert  
Close Request

Docket No.: 09-135999 - 128

Branch: HECSB-ADM

cc : HPFB

**ACTION REQUEST - DEMANDE D'ACTION**

REQUESTOR'S NAME - NOM DU DEMANDEUR Frederick Coyle	DATE 2009-12-07	NUMBER - NUMÉRO MECS#09-135999-128
--	--------------------	---------------------------------------

REQUEST ORIGIN - ORIGINE DE LA DEMANDE

- DEC/CHG
- Associate Deputy Minister's Office/ Bureau du Sous-Ministre délégué
- Deputy Minister's Office/Cabinet du Sous-Ministre
- Minister's Office/Cabinet du Ministre
- Ministerial Meeting/Réunion Ministérielle

SUBJECT - OBJET



request re: Status of Salvia (Divinorum) in Canada

s.19(1)

REQUEST - DEMANDE (YYYY-MM-DD)

(1)Date: 2009-12-07

HECSB (Lead) with input from HPFB, if applicable:

The Minister's office has received a request from the office of [REDACTED] who is looking for a short summary and talking points on a substance called Salvia and it's status in Canada. There are active media lines (not yet approved) on this issue in MECS under 09-101970-456, perhaps some of this information can serve to respond to this request.

A constituent for [REDACTED] has some specific questions which are included below (a specific answer to each of these questions is not required, but the background and talking points should provide an overview of these concerns):

1. Do you agree with the fact that it is legal, and marijuana is not, when salvia is much worse than marijuana?
2. Do you believe the government sees this drug as an issue and will take action, or wait till something more devastating than the 17 year old boy who killed himself and wrote a note about the drug just before?
3. I read that the government will not make it illegal until health Canada takes the step to say "it's bad" ... do you think maybe there using this as an excuse?
4. Is there anything you know about Salvia that I might not know?
5. Would you bring this into a meeting, and make awareness?
6. Do you see the problem that many people see, that this drug is legal and being used to the extent that lives are being taken and it is only going to get worse?

Please provide background information and talking points on this issue, which can be shared with the MP's office, to MBU by 12:00PM on Thursday, December 10, 2009.

PLEASE ADVISE MBU IMMEDIATELY IF THIS REQUEST NEEDS TO BE REDIRECTED TO A DIFFERENT BRANCH OR IF OTHER BRANCHES NEED TO BE INVOLVED, OR IF FURTHER CLARIFICATION IS REQUIRED.

(2)Date:

(3)Date:

- Bilingual/Bilingue  
 French/Français  
 English/Anglais

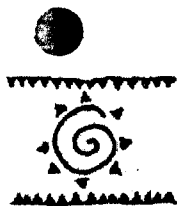
REQUIRED ON - REQUIS LE  
Date: 2009-12-10

AT - À  
Time: 12:00 PM

DEPARTMENTAL CONTACT - AGENT DE LIAISON DU  
MINISTÈRE  
Frederick Coyle

TELEPHONE NUMBER - NUMÉRO DE TÉLÉPHONE  
941-6093

s.19(1)



Cheryl  
Tremblay/HC-SC/GC/CA  
2009-12-08 04:06 PM

To Suzanne Desjardins/HC-SC/GC/CA@HWC  
cc Carmen Berube/HC-SC/GC/CA@HWC, Diane Allan/HC-SC/GC/CA@HWC, Isabel Shanahan/HC-SC/GC/CA@HWC, Jocelyn  
bcc Cheryl Tremblay/HC-SC/GC/CA

Subject Re: Fw: 09-135999-128 - Action Request - REDIRECTED TO HECSB - [redacted] request re: Status of Salvia (Divinorum) in Canada [redacted]

Hi Suzanne,

Here are the speaking points on Salvia for [redacted] for your review and approval. Please note that these are due in DGO tomorrow by 10:00am.

JK - These are saved under PRAD/Briefing Notes and Memos/2009



09-135999-128-TALKING POINTS\_ [redacted] Salvia Divinorum\_Dec 8 2009.wpd

Thank you,

Cheryl Tremblay  
Policy and Regulatory Affairs Division / Division des politiques et affaires réglementaires  
Office of Controlled Substances / Bureau des substances contrôlées  
Controlled Substances and Tobacco Directorate / Direction des substances contrôlées et de la lutte au tabagisme  
Healthy Environments and Consumer Safety Branch / Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada / Santé Canada  
Tel: (613) 954-6527 Fax: (613) 946-4224  
Jocelyn Kula/HC-SC/GC/CA



Jocelyn Kula/HC-SC/GC/CA  
2009-12-08 12:52 PM

To Suzanne Desjardins/HC-SC/GC/CA@HWC  
cc Cheryl Tremblay/HC-SC/GC/CA@HWC, Diane Allan, Isabel Shanahan, Carmen Berube  
Subject Re: Fw: 09-135999-128 - Action Request - REDIRECTED TO HECSB [redacted] request re: Status of Salvia (Divinorum) in Canada [redacted]

Thanks Suzanne,

Cheryl is working on the speaking points for [redacted] right now, and we will send you a draft later today.

Isabel- pls bring docket for 09-076902 to me when it comes in from DO

JK

Jocelyn Kula  
Manager/ Gestionnaire

s.19(1)

Policy and Regulatory Affairs Division/ Division des politiques et affaires réglementaires  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0125 Fax: (613) 946-4224  
Suzanne Desjardins/HC-SC/GC/CA



Suzanne  
Desjardins/HC-SC/GC/CA  
2009-12-08 11:10 AM

To Jocelyn Kula/HC-SC/GC/CA@HWC, Diane  
Allan/HC-SC/GC/CA@HWC  
cc Annie Berube/HC-SC/GC/CA@HWC

Subject Fw: 09-135999-128 - Action Request - REDIRECTED TO  
HECSB - [REDACTED] request re: Status of Salvia  
(Divinorum) in Canada

I just received another docket on Salvia (number 09-076902-986), which I am re-directing to you. The response you are preparing for the below request will likely only need to be changed a bit to reply to it; again we will be pleased to provide input (HPFB input may also be needed?).

Thanks  
Suzanne

----- Forwarded by Suzanne Desjardins/HC-SC/GC/CA on 2009-12-08 11:08 AM -----



Kimberly  
Sorfleet/HC-SC/GC/CA  
2009-12-08 10:31 AM

To Jocelyn Kula/HC-SC/GC/CA@HWC  
cc Suzanne Desjardins/HC-SC/GC/CA@HWC, Carmen  
Berube/HC-SC/GC/CA@HWC

Subject Fw: 09-135999-128 - Action Request - REDIRECTED TO  
HECSB - [REDACTED] request re: Status of Salvia  
(Divinorum) in Canada

FYI

Kimberly Sorfleet  
Executive Assistant to the Director General / Adjointe Exécutive a la Directrice générale  
Controlled Substances & Tobacco Directorate (CSTD)  
Direction des substances contrôlées et de la lutte au tabagisme (DSCLT)  
Health Canada / Santé Canada  
E-Mail: kimberly.sorfleet@hc-sc.gc.ca  
Tel: (613) 946-9316 Fax: (613) 946-6460

----- Forwarded by Kimberly Sorfleet/HC-SC/GC/CA on 2009-12-08 10:30 AM -----



Suzanne  
Desjardins/HC-SC/GC/CA  
2009-12-08 10:29 AM

To Carmen Berube/HC-SC/GC/CA@HWC  
cc Diane Allan/HC-SC/GC/CA@HWC, Jodi  
Brown/HC-SC/GC/CA@HWC, Kimberly  
Sorfleet/HC-SC/GC/CA@HWC, Manjula  
Biradar/HC-SC/GC/CA@HWC

Subject Re: 09-135999-128 - Action Request - REDIRECTED TO  
HECSB - [REDACTED] request re: Status of Salvia

000481

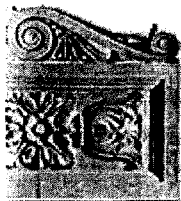


(Divinorum) in Canada

**s.19(1)**

Please let Jocelyn know that we will provide input as requested.

Thanks  
Suzanne  
Carmen Berube/HC-SC/GC/CA



Carmen  
Berube/HC-SC/GC/CA  
2009-12-08 10:22 AM

To Kimberly Sorfleet/HC-SC/GC/CA@HWC

cc Diane Allan/HC-SC/GC/CA@HWC, Jodi Brown/HC-SC/GC/CA@HWC, Manjula Biradar/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC

Subject Re: 09-135999-128 - Action Request - REDIRECTED TO HECSB - request re: Status of Salvia (Divinorum) in Canada

Kimberly,

I am preparing a docket and will send it over to Jocelyn Kula, Manager of OCS PRAD to proceed with this request.

Carmen

Kimberly Sorfleet/HC-SC/GC/CA



Kimberly  
Sorfleet/HC-SC/GC/CA  
2009-12-08 10:15 AM

To Diane Allan/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC

cc Jodi Brown/HC-SC/GC/CA@HWC, Carmen Berube/HC-SC/GC/CA@HWC, Manjula Biradar/HC-SC/GC/CA@HWC

Subject 09-135999-128 - Action Request - REDIRECTED TO HECSB request re: Status of Salvia (Divinorum) in Canada

Hi there,

Further to my email from this morning, we have now been given the full lead on this request. Please work together and provide DGO with a draft version of talking points for Cathy's review and approval by 10:00 a.m. tomorrow, December 9th.

Please do not hesitate to let me know if you have any questions.

Thank you!

Kimberly Sorfleet  
Executive Assistant to the Director General / Adjointe Exécutive a la Directrice générale

Controlled Substances & Tobacco Directorate (CSTD)  
Direction des substances contrôlées et de la lutte au tabagisme (DSCLT)  
Health Canada / Santé Canada  
E-Mail: kimberly.sorfleet@hc-sc.gc.ca  
Tel: (613) 946-9316 Fax: (613) 946-6460

----- Forwarded by Kimberly Sorfleet/HC-SC/GC/CA on 2009-12-08 10:13 AM -----

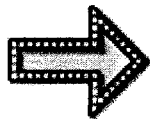
Michel  
Prud'Homme/HC-SC/GC/CA  
2009-12-08 10:12 AM

To Kimberly Sorfleet/HC-SC/GC/CA@HWC  
cc Jodi Brown/HC-SC/GC/CA@HWC, Stephanie  
Szick/HC-SC/GC/CA@HWC, Lyne Tassé, Natalie  
Racine/HC-SC/GC/CA@HWC, Jonathan  
Loan/HC-SC/GC/CA@HWC  
Subject 09-135999-128 - Action Request - REDIRECTED TO  
HECSB - [REDACTED] request re: Status of Salvia  
(Divinorum) in Canada

Please see the action request below which has been re-directed from HPFB to HECSB and provide your input by noon, tomorrow, Wednesday, December 9, 2009.

Thanks,  
Michel

----- Forwarded by Michel Prud'Homme/HC-SC/GC/CA on 2009-12-08 10:06 AM -----



Frederick  
Coyle/HC-SC/GC/CA  
2009-12-08 09:53 AM

To HECSB\_Action Request\_48h, Natalie  
Racine/HC-SC/GC/CA@HWC, Joan  
Kennedy/HC-SC/GC/CA@HWC, Jonathan  
Loan/HC-SC/GC/CA@HWC  
cc sarah-emily\_carle@poc.hc-sc.gc.ca@Exchange,  
caroline\_pitfield@poc.hc-sc.gc.ca@exchange, Bryan  
Takeda/HC-SC/GC/CA@HWC, Robert  
Simms/HC-SC/GC/CA@HWC  
Subject REDIRECTED TO HECSB - [REDACTED] request re:  
Status of Salvia (Divinorum) in Canada

HECSB:

Please note that HPFB has redirected this request to HECSB. Rationale is below.

"This should be a HECS lead. There are no health products with this ingredient. The questions surround the scheduling status (controlled or not). "

Thank you.  
Fred Coyle  
Ministerial Briefing Unit / Unité d'information ministérielle

----- Forwarded by Frederick Coyle/HC-SC/GC/CA on 2009-12-08 09:50 AM -----

Status: Open/Ouvert  
[Close Request](#)

Docket No.: 09-135999 - 128

000483

Healthy Environments and Consumer Safety

MECS# 09-135999-128

s.19(1)

## MINISTER'S OFFICE REQUEST

**ISSUE:** [REDACTED] Office request a brief summary and talking points on *Salvia divinorum* and its status in Canada.

### BACKGROUND:

*Salvia divinorum* is a species of sage which belongs to the mint family. It is found in the form of dried leaves, extract and plant cuttings and is usually chewed or smoked in order to induce its psychotropic effects.

The leaves of this plant have been used traditionally by the Mazatec Indians in Mexico for many years. Traditional use involves chewing the leaves or using them to make a tea for medicinal purposes (e.g., to treat such conditions as headache or stomach upset), or to induce a “mystical” or hallucinogenic experience for spiritual purposes.

Products that claim to contain *S. divinorum* – or its main active ingredient, salvinorin A – are widely available on the Internet and are sold in various “head shops” and natural food stores. The products are sold in a number of formats, including seeds and plant cuttings for growing purposes. Fresh or dried leaves are intended to be chewed, swallowed or smoked. Liquid preparations are also available.

In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA). *Salvia divinorum* is not listed under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these conventions.

Several countries (Australia, Belgium, Denmark, Sweden, Italy, Spain, Finland and South Korea) have however placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Although some individual U.S. states have implemented laws restricting its use, sale and/or distribution, *Salvia divinorum* and salvinorin A are not regulated under the federal *Controlled Substances Act*.

### TALKING POINTS:

- Health Canada is aware of some of the effects associated with the use of *Salvia divinorum* including hallucinations, out-of-body experiences, unconsciousness and short-term memory loss.

- Health Canada considers several factors in determining whether scheduling a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:
  - International requirements and trends in regulatory status;
  - Chemical and pharmacological similarity to other substances already regulated under the CDSA;
  - Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
  - Potential for abuse and risk of addiction associated with the substance;
  - Extent of actual abuse of the substance in Canada and internationally; and
  - Overall risk to public health and safety posed by the substance.

---

- In the case of *Salvia divinorum*, information about these factors is either missing or anecdotal in nature. For example, very few scientific studies looking into the physical and psychotropic effects of *Salvia divinorum* on humans have been carried out. More systematic research in this area is needed.
- In addition, the Department has only received a limited number of communications indicating concern with respect to *Salvia divinorum* from law enforcement agencies, and none of these has advised that the use of *Salvia divinorum* poses any threat to public safety.
- Questions regarding the use of *Salvia divinorum* were included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey (OSDUHS). The results from the 2009 OSDUHS were published on November 18, 2009:
  - Among all students in 2009, 4.4% report using *Salvia divinorum* at least once in the past year;
  - Males (6.2%) are significantly more likely than females (2.3%) to use *Salvia divinorum*;
  - There is significant grade variation, with *Salvia divinorum* use most likely among 11<sup>th</sup> graders (8.6%) and 12<sup>th</sup> graders (8.4%); and
  - There are significant regional variations, with students in the North (9.2%) most likely to use *Salvia divinorum*.
- Health Canada recommends that the use of *Salvia divinorum* be avoided because very little is known about the effects it may have on the body, including the brain. There is also no way to predict how it will affect different individuals and the effects may differ from one use to the next, depending on the potency of the product; how much is used; the purity of the product (it may be mixed with other substances); how it is taken (e.g., chewed, swallowed or smoked); and the user's mood and expectations.

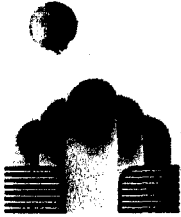
Prepared by: Cheryl Tremblay  
Telephone: 613-954-6527

Approved by: *ADM sign-off is required.*



Telephone:





Jocelyn Kula/HC-SC/GC/CA  
2009-12-09 09:04 AM

To Suzanne Desjardins/HC-SC/GC/CA@HWC, Cheryl Tremblay/HC-SC/GC/CA@HWC  
cc Carmen Berube/HC-SC/GC/CA@HWC, Diane Allan/HC-SC/GC/CA@HWC, Isabel Shanahan/HC-SC/GC/CA@HWC

bcc

Subject Re: Fw: 09-135999-128 - Action Request - REDIRECTED TO HECSB - request re: Status of Salvia (Divinorum) in Canada

History: This message has been replied to.

Yes although I am sad that we can't say more about the IYH and its content- perhaps it is better to remove. Only other option would be to get into all the stuff about salvia being an unapproved NHP but I really think it is too technical for this purpose.

JK

Sent by blackberry

Jocelyn Kula  
Manager/ Gestionnaire  
Policy and Regulatory Affairs Division/ Division des politiques et affaires réglementaires  
Suzanne Desjardins

----- Original Message -----

From: Suzanne Desjardins  
Sent: 2009-12-09 08:55 AM EST  
To: Cheryl Tremblay  
Cc: Carmen Berube; Diane Allan; Isabel Shanahan; Jocelyn Kula  
Subject: Re: Fw: 09-135999-128 - Action Request - REDIRECTED TO HECSB request re: Status of Salvia (Divinorum) in Canada

that would be my suggestion. Diane/Jocelyn : what do you think?

Suzanne

Cheryl Tremblay/HC-SC/GC/CA



Cheryl Tremblay/HC-SC/GC/CA  
2009-12-09 08:49 AM

To Suzanne Desjardins/HC-SC/GC/CA@HWC  
cc Carmen Berube/HC-SC/GC/CA@HWC, Diane Allan/HC-SC/GC/CA@HWC, Isabel Shanahan/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC

Subject Re: Fw: 09-135999-128 - Action Request - REDIRECTED TO HECSB - request re: Status of Salvia (Divinorum) in Canada

Good morning Suzanne,

Thank you for your comments. As for the last point on where HC formally recommends that the use of Salvia be avoided, nothing has been published as of yet. That point stemmed from the IYH which we don't definitively know the status of at this point in time so perhaps we should remove all together?

Thanks,

Cheryl Tremblay  
Policy and Regulatory Affairs Division / Division des politiques et affaires réglementaires

Office of Controlled Substances / Bureau des substances contrôlées  
Controlled Substances and Tobacco Directorate / Direction des substances contrôlées et de la lutte au  
tabagisme  
Healthy Environments and Consumer Safety Branch / Direction générale de la santé environnementale et  
de la sécurité consommateurs  
Health Canada / Santé Canada  
Tel: (613) 954-6527 Fax: (613) 946-4224  
Suzanne Desjardins/HC-SC/GC/CA



Suzanne  
Desjardins/HC-SC/GC/CA

2009-12-08 04:27 PM

To Cheryl Tremblay/HC-SC/GC/CA@HWC

cc Carmen Berube/HC-SC/GC/CA@HWC, Diane  
Allan/HC-SC/GC/CA@HWC, Isabel  
Shanahan/HC-SC/GC/CA@HWC, Jocelyn  
Kula/HC-SC/GC/CA@HWC

Subject Re: Fw: 09-135999-128 - Action Request - REDIRECTED  
TO HECSB [REDACTED] request re: Status of Salvia  
(Divinorum) in Canada

Thanks Cheryl,

I only have a few comments;

- 2nd para : is it really "head shops" ?

- Talking points: Health Canada is aware of ~~some~~ of the effects associated with the use of *Salvia  
divinorum* including hallucinations, out-of-body experiences, unconsciousness and short-term  
memory loss

- "...were included in the 2008-2009 Youth Smoking Survey ": I would remove reference to the  
YSS, since data are not yet available

Also, the last part refers to HC recommending that sue of Salvia be avoided. Was there an  
advisory on it issued by HHP, or am I confusing it with BZP? In any event, where can we find  
that HC is recommending that use be avoided? perhaps we should refer to it more formally.

Suzanne

Cheryl Tremblay/HC-SC/GC/CA



Cheryl  
Tremblay/HC-SC/GC/CA

2009-12-08 04:06 PM

To Suzanne Desjardins/HC-SC/GC/CA@HWC

cc Carmen Berube/HC-SC/GC/CA@HWC, Diane  
Allan/HC-SC/GC/CA@HWC, Isabel  
Shanahan/HC-SC/GC/CA@HWC, Jocelyn  
Kula/HC-SC/GC/CA@HWC

Subject Re: Fw: 09-135999-128 - Action Request - REDIRECTED  
TO HECSB [REDACTED] request re: Status of Salvia  
(Divinorum) in Canada



*"Clients come first"*

**Branch Correspondence**  
 Protected - HC only

Document Profile			
Document Number: ?	09-136999 - 128	File Number: ?	
Branch: ?	DMO	Directorate: ?	MBU-FC
*Last Name: ?	Coyle	First Name: ?	Fred
Province: ?	Ontario	Organization: ?	
*Document Type: ?	Action Request - Minister's Office / Demande d'action - Cabinet du ministre	Cross Reference #: ?	
*Correspond. Date: ?	2009-12-07	*Date Received: ?	2009-12-07
Due Date: ?	2009-12-21	*Status: ?	Closed/Fermé
Category: ?		*Incoming Type: ?	Departmental/Direction générale
Language: ?	English/Anglais	Priority: ?	
Security Designation: ?			
Special Instructions: ?			
Outgoing Type: ?		B.F. Date: ?	
*Subject / Title: ?	request re: Status of Salvia (Divinorum) in Canada		
Document Remarks: ?			
Signed By: ?	Closed	Signature Date: ?	2009-12-14

In-Depth Subject: ?

Audit Trail

Comments

Records Office

MECS# 09-135999-128

## MINISTER'S OFFICE REQUEST

s.19(1)

**ISSUE:** [REDACTED] Office requested information on *Salvia divinorum* and its status in Canada.

### BACKGROUND:

*Salvia divinorum* is a species of sage which belongs to the mint family. It is found in a number of formats, including seeds, extract and plant cuttings for growing purposes. Fresh or dried leaves can be chewed, swallowed or smoked to induce psychotropic effects. Liquid preparations are also available. Products that claim to contain *S. divinorum* – or its main active ingredient, salvinorin A – are widely available on the Internet and sold in alternative lifestyle stores.

The leaves of this plant have been used traditionally by the Mazatec Indians in Mexico for many years. Traditional use involves chewing the leaves or using them to make a tea for medicinal purposes (e.g. to treat such conditions as headache or stomach upset), or to induce a “mystical” or hallucinogenic experience for spiritual purposes.

In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act*. *Salvia divinorum* is not listed under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these conventions.

Several countries (Australia, Belgium, Denmark, Sweden, Italy, Spain, Finland and South Korea) have however placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Although some individual states in the U.S. have implemented laws restricting its use, sale and/or distribution, *Salvia divinorum* and salvinorin A are not regulated under the federal *Controlled Substances Act*.

Questions regarding the use of *Salvia divinorum* were included in the 2009 Ontario Student Drug Use and Health Survey. The results from this survey were published on November 18, 2009:

1. Among all students in 2009, 4.4 per cent report using *Salvia divinorum* at least once in the past year;
2. Males (6.2 per cent) are significantly more likely than females (2.3 per cent) to use *Salvia divinorum*;
3. There is significant grade variation, with *Salvia divinorum* use most likely among 11<sup>th</sup> graders (8.6 per cent) and 12<sup>th</sup> graders (8.4 per cent); and
4. There are significant regional variations, with students in the North (9.2 per cent) most likely to use *Salvia divinorum*.

Health Canada will consider this data in its ongoing examination of 000490  
salvinorin A.

**TALKING POINTS:**

- Health Canada considers several factors in determining whether scheduling a substance under the *Controlled Drugs and Substances Act* is warranted. These include:
  - International requirements and trends in regulatory status;
  - Chemical and pharmacological similarity to other substances already regulated under the *Controlled Drugs and Substances Act*;
  - Legitimate uses of the substance (i.e. therapeutic, industrial or commercial);
  - Potential for abuse and risk of addiction associated with the substance;
  - Extent of actual abuse of the substance in Canada and internationally; and,
  - Overall risk to public health and safety posed by the substance.
  
- In the case of *Salvia divinorum*, information about these factors is either missing or anecdotal in nature. For example, very few scientific studies looking into the physical and psychotropic effects of *Salvia divinorum* on humans have been carried out. More systematic research in this area is needed.
  
- In addition, the Department has only received a limited number of communications indicating concern with respect to *Salvia divinorum* from law enforcement agencies, and none of these have advised that the use of *Salvia divinorum* poses any threat to public safety.
  
- Questions regarding the use of *Salvia divinorum* were included in the 2009 Ontario Student Drug Use and Health Survey, the results of which were published very recently.
  
- Health Canada will consider this data in its ongoing examination of *Salvia divinorum* and salvinorin A.

Branch Head: Paul Glover, ADM, HECSB  
Telephone: 613-946-6701



*"Clients come first"*

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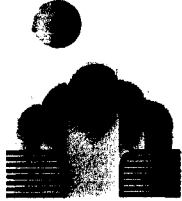
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Jocelyn Kula/HC-SC/GC/CA  
2009-12-10 08:58 PM

To Jodi Brown/HC-SC/GC/CA@HWC  
cc "Cheryl Tremblay" <Cheryl.Tremblay@hc-sc.gc.ca>, "Diane  
Allan" <diane.allan@hc-sc.gc.ca>, "Denis Arsenault"  
<denis.arsenault@hc-sc.gc.ca>

bcc

Subject Re: CMAJ: Banning 'magic mint' could slow research

Yes saw this but that said it is validation of some of the great work that comes out of OCS and CSTD-  
there are several sections of the piece that are direct quotes from our media lines....  
Of note is that it would be hard to get for reasearch if banned in the US, but of course the system here is  
different in that we can issue an exemption- that is if the political will allows of course!!

JK  
Sent by blackberry

Jocelyn Kula  
Manager/ Gestionnaire  
Policy and Regulatory Affairs Division/ Division des politiques et affaires reglementaires  
Jodi Brown

----- Original Message -----

**From:** Jodi Brown  
**Sent:** 2009-12-10 03:28 PM EST  
**To:** Jocelyn Kula; Diane Allan; Suzanne Desjardins  
**Subject:** Fw: CMAJ: Banning 'magic mint' could slow research  
cleaning email....can't remember if you received this....another issue to keep in mind once we have to  
address this one again....re: research angle

----- Forwarded by Jodi Brown/HC-SC/GC/CA on 2009-12-10 03:26 PM -----

HC\_Media\_SC/HC-SC/GC/C

A

Sent by: Nicolas Frate

To

cc

2009-11-30 01:24 PM

Subject CMAJ: Banning 'magic mint' could slow research

November 23 2009  
**Banning 'magic mint' could slow research**  
Source: CMAJ, by Roger Collier

Salvia divinorum can beam you to Mars. It can eradicate gravity. It can show you things that will make you  
howl with laughter and things that will make you scream in fear. But it only does these things in your head  
—and only for about 15 minutes.

Millions of people have embarked on short-haul head trips after smoking Salvia divinorum, a plant from  
the mint family. Thousands have posted their hallucinogenic journeys on YouTube. In one video, viewed  
some two million times, a young woman says her mouth is falling off.

Some lawmakers believe Salvia divinorum, a.k.a. 'magic mint' or 'diviner's sage,' is dangerous. About a  
dozen countries have banned it, including Australia and Belgium. Selling it in parts of the United States will  
also earn you a fine and jail time. But it's legal in Canada. In some Canadian cities, a shop selling bongis is  
likely to have a cardboard sign in the window that says "Salvia sold here."

Though many politicians have the plant on their not-in-my-jurisdiction lists, there is no scientific data to

suggest the plant's active ingredient, Salvinorin A, has any long-term effects. Some researchers studying the plant—which may prove useful in treating mental illness—are worried that bans may make their work more difficult. They say the herb doesn't appear to be addictive or toxic. Hospital emergency rooms aren't reporting major problems with patients suffering "bad trips" from *Salvia divinorum*. Nor have police made much noise about the herb.

"Health Canada has only received a limited number of communications regarding *Salvia divinorum* from law enforcement agencies, and none of these has advised that the use of *Salvia divinorum* poses any threat to public safety," Health Canada spokesman Gary Holub writes in an email.

Holub notes, however, that Health Canada is attempting to learn how many Canadians are using *Salvia divinorum*. It included questions about the plant in the 2008–2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. Health Canada is also collecting data about the herb, from national and international sources, to determine if it should be regulated.

"Very few controlled scientific studies of the physical and psychotropic effects of *Salvia divinorum* on humans have been carried out, and using these studies to predict the potential for addiction and abuse associated with *Salvia divinorum* is difficult," writes Holub. "Health Canada recommends that the use of this substance be avoided because very little is known about the damage it may cause to the body, including the brain. There is also no way to predict how it will affect an individual with each use."

*Salvia divinorum* has been used by the Mazatecs in Oaxaca, Mexico, for centuries. Folk healers chew the leaves to produce mild hallucinations they believe provide spiritual guidance. In the early 1960s, Gordon Wasson, an American anthropologist, became the first person from a Western nation to take and write about the herb. In the early 1980s, a Mexican researcher isolated its active ingredient. But it wasn't until the 1990s that people began extracting that ingredient and adding it to fresh *Salvia divinorum* leaves.

These fortified leaves are what people buy, often over the Internet, and smoke in a bong or pipe. In the US, about 1.8 million people have tried *Salvia divinorum*, according to the 2008 National Survey on Drug Use and Health. As with crack cocaine, the effects upon inhalation are almost instantaneous and though short-lived, anything but mild.

"It is the most potent naturally occurring hallucinogen," says Dr. Bryan Roth, project director of the National Institute of Mental Health Psychoactive Drugs Screening Program. "It rivals LSD [lysergic acid diethylamide] in potency."

In 2002, Roth discovered that Salvinorin A had a different chemical structure than any other hallucinogen, natural or synthetic (PNAS 2002;99: 11934–9). He also found that it didn't activate the serotonin receptor responsible for the mind-bending effects of other hallucinogens. Because of its unique properties, Salvinorin A might be a novel compound for use in therapies for diseases that distort perception, such as schizophrenia and bipolar disorder.

"What we are hoping, when we find drugs that affect human consciousness, is to use them to make better treatments for mental illness," says Roth, a professor at the University of North Carolina in Chapel Hill.

That research might prove challenging, however, if the US Food and Drug Administration outlaws *Salvia divinorum*, which Roth says is likely. Though supportive of regulating distribution, he isn't looking forward to widespread legal barriers to accessing Salvinorin A. Such laws would not only keep the herb out of the hands of teenagers hoping to visit Jupiter on purple unicorns, but also out of the labs of scientists.

"It will make subsequent studies very difficult," says Roth. "It won't make them impossible but will make it difficult to obtain for therapeutic research."





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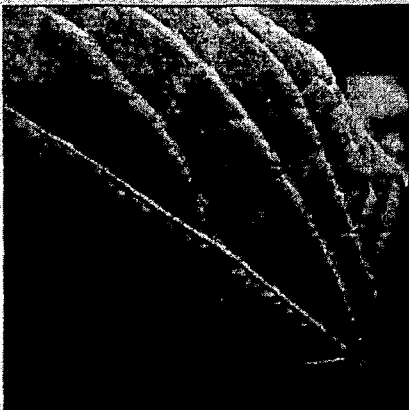
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home &gt; health &gt; Salvia divinorum

## Salvia divinorum - Health Issues

### Diviners' Sage, Ska Pastora



Salvia divinorum is a perennial herb from Mexico, related to Common Sage. It is native to an area known as Sierra Mazatec. It has been used by the native Mazatec for an unknown amount of time. Its use was first recorded by western science in 1938 when a young anthropologist, Jean B. Johnson wrote:

Shamans, as well as other persons, use certain narcotic plants in order to find lost objects. In some cases teonanacatl is used, while in others a seed called 'semilla de la Virgen' is used. 'Hierba María' is similarly used. The Zapotecs use a plant called 'bador', the little children, and the Aztecs used narcotic plants in a similar manner.

It has also been suggested that Salvia divinorum is the *Pipiltzintzintli* of the Aztecs, although there is scant evidence for this.

The leaves of Salvia divinorum contain Salvinorin, a novel psychoactive and the most potent naturally occurring psychoactive compound yet found. It is active in doses as low as 200 mcg (micrograms).

The traditional methods of consuming Salvia divinorum (by the Mazatec) are chewing fresh leaves and imbibing an infusion/suspension of shredded or crushed leaves in cold water. Its use as a recreational drug in the United States and Europe usually involves the smoking of dried leaves or extracts of the leaves, although the practice of chewing fresh or re-hydrated leaves is also present.

### On to the Health Issues

Unfortunately, almost nothing is known about either the long-term or short-term health issues relating to Salvia divinorum. This vacuum of information can lead to some *potentially* dangerous assumptions being

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made.

You may have heard an argument along these lines:

*The Mazatec have been using Salvia divinorum for ages, and it doesn't seem to harm them, so it must be safe.*

There are a few ways to answer this:

- Firstly, yes, the Mazatec have been using Salvia divinorum for a long time, but, no studies have ever been conducted on the Mazatec to discover what effects Salvia divinorum has on them. We know nothing of the long or short-term health risks relating to Mazatec Salvia divinorum use.
- Secondly, there is quite a disparity between Mazatec usage practices and Western usage practices. The effects of Salvia divinorum when chewed or imbibed rise gradually to a peak and last several hours. They have been described as 'more subtle'. Conversely, the effects of smoked Salvia divinorum (or an extract of it) begin suddenly, rise swiftly to a peak and subside again quite quickly, with lingering after-effects lasting 15-60 minutes. The rapid onset can be quite unexpected and provokes fear in some users. It should be noted that the Mazatec *never* smoke Salvia divinorum, considering it basically a sacrilege. This difference invalidates Mazatec usage patterns as a useful comparison for expected effects when Salvia leaves or extract are smoked.
- Thirdly, the significance of set and setting must be considered. The set (thoughts, mood, expectations) and setting (physical and social location) of a Mazatec user and a Western user are not comparable. The influence these elements can have on an experience are highly significant. Again, the set and setting of a Mazatec user are an invalid comparison to use when discussing effects expected from a non-Mazatec user.

You may also have heard an argument along these lines:

*There are no recorded cases of Salvia divinorum causing physical or psychological harm. So it must be safe.*

This statement is partially true. There are no cases in the scientific literature of individuals being harmed from using Salvia divinorum. However, this statement is only *provisionally* true; as nobody has yet looked into whether Salvia divinorum causes harm. In the future, we may find that Salvia divinorum can cause psychosis or cancer; at present, nobody knows.

### **So what can be said about the dangers of Salvia divinorum?**

There are a couple points about the physical effects of Salvia divinorum which can be stated with reasonable confidence.

- Salvia divinorum can sometimes affect motor co-ordination and balance. This can make it difficult to walk and perform simple tasks.



The risk posed to the user can be quite significant. Even simple tasks such as walking down stairs could be dangerous if this effect is pronounced. It goes without saying that more demanding tasks, such as driving or operating machinery really should not be performed under the influence of Salvia divinorum, as the risk posed to the user in these circumstances is great. This effect can continue well after the subjective effects have subsided (perhaps up to an hour when smoked).

- It is widely known that natural products other than tobacco can also be quite injurious to health when smoked. For example, there is much debate over whether Cannabis is itself carcinogenic when smoked. The one thing that is quite clear is that inhaling smoke of any kind is not good for your physical health. Although the effects of smoke from Salvia divinorum leaves and extracts have not been studied, it can be said with a fair amount of confidence that smoking Salvia divinorum is unlikely to be good for your lungs or general health.

What about psychological effects?

Before discussing the psychological effects Salvia divinorum may have, there is one consideration rarely touched upon when Salvia divinorum is discussed:

Many users of Salvia divinorum can act quite erratically and out of character while under the influence. It is entirely possible for a user to act in a way at odds with their usual behaviour. Although unlikely, it is possible for a user to become violent, or to perform actions which may potentially harm themselves. For this reason, the **Salvia Divinorum Research and Information Center** (the website of Daniel Siebert) recommends that dangerous objects, such as knives and guns are removed from the area before usage commences. It is also common to recommend a sitter (a sober person to watch over the user/users). Although this advice is basically sound, there is also the possibility that a user could become violent towards their sitter. Until research is conducted into the effects of Salvia divinorum, the likelihood of violent behaviour is an unknown quantity.

OK. So what about the other potential psychological effects of Salvia divinorum?

- For want of a better word, Salvia divinorum is described as an hallucinogenic or visionary plant. It provokes sometimes powerful experiences broadly comparable to other substances such as LSD, Psilocybin and DMT (although the visually 'hallucinogenic' effects of Salvia are a lot less pronounced than these substances). Any experience with a profound effect on the psyche (whether caused by psychoactive drugs or otherwise) can have a permanent effect on an individual. Strongly negative experiences can cause psychological damage. Again, the long-term effects of Salvia divinorum on the psyche have not been studied, but it can be said with a fair amount of confidence (by comparing with similar substances), that in rare cases Salvia divinorum *may* cause psychosis in some users. These may be users with pre-existing mental illness, users with no history of mental illness but a latent predisposition to psychosis, or just ordinary users who go too far one day.

It is impossible to say with confidence who may be susceptible to drug induced psychosis as the causes of this effect are not yet



clearly understood even among more well known and well used drugs such as LSD and Cannabis

Also, it is fairly well understood that the dangers posed by drugs are magnified when drugs are taken in combination. This may also be true with Salvia divinorum. Little is known about the effects of Salvia divinorum in combination with other drugs (other than anecdotal reports or first-hand experience reports available via websites such as Erowid.org). This means that any user trying out Salvia divinorum in combination with other drugs is experimenting with their own body and mind, and the potential outcomes (both physical and psychological) are far from clear.

### **In Conclusion**

Although, as has been said, little is known about the short- or long-term effects of Salvia divinorum on the body and psyche, it is important to remember that a lack of data about the dangers of Salvia do not prove it is safe. Too many websites espouse the idea that Salvia divinorum is safe when at present, so little is known about its effects, it is impossible to say either way. There is no scientific data on Western use patterns to base judgements on, and the practice has not been widely used in the West for long enough to form judgements based on large arrays of anecdotal data either.

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This the author of this website supports [Salvia divinorum](#)

## LETTERS TO THE EDITOR

rated, subjects who smoked persistently (those who smoked at both baseline and follow-up) had significantly higher HPA activity than subjects who did not smoke (2). In addition, adolescents who did not smoke at baseline but initiated smoking during follow-up and continued to smoke regularly had higher HPA activity (measured at baseline) compared with non-smokers. These data suggest that elevated HPA activity might serve as a vulnerability marker for both nicotine-related as well as non-nicotine-related substance use disorders.

It was not possible to examine cigarette smoking as a potential mediator/moderator of the relationship between HPA activity and the development of substance use disorder because the onset of smoking did not always precede the initiation of alcohol or drug use. Again, there was a high co-occurrence of smoking and non-nicotine substance use at both baseline and follow-up. In our article, the effect of prior substance use on the development of substance use disorder was examined. Although prior substance use had a significant influence on the development of substance use disorder, the effects of HPA activity and stressful life experiences persisted after accounting for the effect of prior substance use. We agree with Drs. Schütz and Sepehry that future investigations should include more careful assessments of nicotine use. Such studies also should examine the complex relationships among nicotine use, neurobiological markers, psychosocial factors, and clinical outcomes.

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*The author's disclosures accompany the original article.*

*This letter (doi: 10.1176/appi.ajp.2009.09030349r) was accepted for publication in March 2009.*

### Persistent Psychosis Associated With *Salvia Divinorum* Use

TO THE EDITOR: *Salvia divinorum* (salvia) is a sage plant that is easily obtained in the United States. Its active ingredient, Salvinorin A, is a novel and highly selective pure kappa opiate receptor agonist with rapid onset and powerful hallucinogenic properties (1). *Salvia* has become increasingly popular as a drug of abuse when smoked. No long-term negative outcomes have been reported from the use of salvia. We present a case in which salvia precipitated persistent psychosis.

"Mr. J" was a 21-year-old man with no family or personal psychiatric history or laboratory abnormalities. He was reported to have normal social interactions, behavior, and cognitive skills. He was transferred to our psychiatric

unit for acute psychosis and paranoia, which occurred shortly after smoking salvia. In transport, the patient became suspicious and attempted to jump from the vehicle. Upon presentation, he demonstrated echolalia, paranoia, flight of ideas, and psychomotor agitation. The patient remained agitated for the first 2 days of hospitalization. He attempted to barricade himself in his room. Risperidone (3 mg by mouth/three times per day) was administered, and the patient was eventually stabilized. The dosage, however, resulted in the parkinsonian features of rigidity, bradykinesia, and masked facies.

Mr. J was transferred to the chemical dependency unit for further treatment. He was stabilized, and treatment with risperidone was slowly tapered. During the taper from risperidone, the patient continued to improve and manifested better insight and logical thought processes. He participated in group therapy and interacted with peers, and the parkinsonian features subsided. One day after risperidone was withdrawn, the patient's symptoms abruptly returned. He became agitated, paranoid, and aggressive and believed he was able to project and receive thoughts. He returned to the inpatient psychiatry unit where risperidone (3 mg by mouth/twice daily) was reinstated. He was once again stabilized and transferred to the referring psychiatric facility for further treatment. At the 4-month follow-up, the patient exhibited no perceptible improvement.

To the best of our knowledge, this is the first reported case of a persistent negative outcome from the use of salvia. We suspect that our patient was genetically predisposed to schizophrenia, and salvia precipitated the clinical manifestations. This may relate to the drug's ability to influence dopamine levels in the brain and potentiate plastic changes in frontal lobe networks (3).

Previous studies have cited salvia as a potential treatment option for CNS illnesses (2). This is surprising, considering the paucity of research regarding its efficacy. Salvia's ability to increase dopamine levels in the nucleus accumbens increases its potential for dependence. Consistently, patients at our clinic who have used the drug report that its psychological effects are abrupt and frightening. Clinicians should be aware that salvia use can be associated with psychiatric illness.

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*The authors report no competing interests.*

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Reprints are not available; however, Letters to the Editor can be downloaded at <http://ajp.psychiatryonline.org>.



## Light drugs available in free sale in Russia

14.04.2009    **Source:** [Pravda.Ru](http://pravda.ru)    **URL:** [http://english.pravda.ru/hotspots/crimes/107400-Light\\_drugs-0](http://english.pravda.ru/hotspots/crimes/107400-Light_drugs-0)

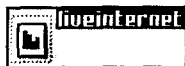
Light drugs are still available in free sale in Russia despite the official decree issued by Surgeon General Gennady Onischenko. One can purchase a blend of dry herbs in specialized shops. Dope sellers assure their customers that their products are absolutely harmless.

"The narcotic herbs were originally used in spa parlors as fragrance, but it later occurred to someone to smoke grass, and that's how it all started. One gram of weed costs 900 rubles (\$27), and this dose is enough for five adults. We have been receiving many calls lately from people who suffered from smoking these herbs. It is possible to develop an addiction to this kind of smoking. Others say that a person may start acting inadequately as a result of smoking," a specialist with the Drug Control Service of Samara, Ekaterina Kondareva said.

Russia's Surgeon General Gennady Onischenko issued a special decree to ban the sales of herbal smoke blends in the Russian Federation. The decree particularly banned the sales of blends containing such herbs as *Salvia Divinorum* and/or *Argyreia Nervosa* (Hawaiian rose) and/or *Nymphaea caerulea* (blue lotus). The blends containing the herbs are available under such names as AM-HI-CO, Dream, Spice (Gold, Diamond), Zoom, Ex-ses, Pep Spice, Yucatan Fire and some others.

The official decree has not stopped the sales of herbal smoke blends. "We have heard of the decree, but we are not going to scrap our sales, we have not received any instructions from our manager," sellers say.

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# THE LEGAL STATUS OF *SALVIA DIVINORUM*

(This page was last updated on September 5, 2009)

The *Salvia divinorum* Research and Information Center  
is created and maintained by  
Daniel Siebert

## Legal Status

*Salvia divinorum* is a valuable medicinal herb. Because it produces profoundly introspective states intrinsically unsuitable for recreational use (i.e., it is not a "party drug"). It is not habit-forming, does not present a significant risk to public health or safety. Because it is a powerful consciousness-altering agent, its sale is sensible and appropriate. It is reasonable to require that vendors provide detailed safety information for responsible use. It also makes sense to limit the salvinorin A content of extracts sold in bulk. Bulk extracts should only be sold in pre-measured individual doses. It is appropriate to prohibit delivery of extracts in a manner appropriate to prohibit reckless use, such as driving a vehicle while inebriated. There are many other specific laws that can be enforced against reckless *salvia* users (e.g., laws that prohibit public intoxication, reckless driving, etc.). Legislation should only penalize irresponsible use, not all use. Punishment for possession of *Salvia divinorum* is neither useful nor humane. The idea of making *salvia* a controlled substance is absurd — after all, every species is a precious and irreplaceable part of our natural heritage. A sensible way to regulate *Salvia divinorum* in a similar manner as alcohol and tobacco. Another sensible option would be to require prescription medication, as some US states have done with cannabis. Certainly, physicians and pharmacists should be able to prescribe *salvia* to patients who might benefit from it. It should also remain available for use in research.

Decisions regarding the regulation of *Salvia divinorum* (or any substance) should always be based on scientific evidence. The evidence shows that this herb is relatively safe and non-addictive. The pharmacology of its primary active constituent, salvinorin A, is unique and shows great promise as a lead compound for the development of useful medications. Restrictive regulation would seriously impede further scientific research. For a well-reasoned, scientific perspective on the relative safety of *Salvia divinorum* and its importance in medical research, I encourage you to read the documents by Dr. Roland Griffiths and Dr. Matthew Johnson of Johns Hopkins University School of Medicine, presented as testimony opposing efforts to make *salvia* a Schedule I controlled substance in the US. I encourage you to read my open letter to lawmakers, which I have sent to legislators in several states.

Unfortunately, several countries have enacted laws that prohibit possession and/or sale of *Salvia divinorum*. In some cases, the penalties for violating these laws are quite severe. There are some countries that do not prohibit possession but do prohibit importation. The following listing describes all of the laws, regulations, and proposals regarding *Salvia divinorum* that I am currently aware of. Because of the controversial nature of vision-altering substances in general, it is probable that the legal status of *Salvia divinorum* will continue to change in the future. As changes in the legal status of *Salvia divinorum*, I encourage you to subscribe to my free email newsletter.



*divinorum* Observer. If you are aware of any attempts to prohibit *Salvia divinorum* in countries or territories, please click here to send me an email.

US States with Laws Prohibiting <i>Salvia</i>	Other Countries with Laws
<p><b>Illegal (Schedule I)</b>                      Delaware                      Florida                      Illinois                      Kansas                      Mississippi                      Missouri                      Nebraska                      North Dakota                      Ohio                      Oklahoma                      South Dakota                      Virginia</p> <p><b>Only Legal When Not Intended for Human Consumption</b>                      Louisiana                      North Carolina (beginning December 1, 2009)                      Tennessee</p> <p><b>Legal for Adults, but Illegal To Sell to Minors</b>                      California                      Maine (possession by minors also illegal)</p>	<p><b>Illegal to Possess or Sell</b>                      Australia                      Belgium                      Croatia                      Denmark                      Germany                      Italy                      Japan                      Latvia                      Lithuania                      Poland                      South Korea                      Sweden</p> <p><b>Illegal to Sell, but Legal to Possess</b>                      Spain                      Russia</p> <p><b>Treated as a Medicinal Herb that Requires Prescription</b>                      Estonia                      Finland                      Iceland                      Norway</p>

**Australia**

Australia was the first country to prohibit *Salvia divinorum* and salvinorin A. The committee responsible admitted that there is "no evidence of a major public health hazard." The ban went into effect July 2006. Australia or its territories who is considering being involved with this plant is urged to first obtain a license. Readers are urged *not* to ship *Salvia divinorum*, or products made from it, to Australia or its territories who receives the shipment could face severe criminal penalties. Please go here for more details on Australia's government and to learn what you can do to fight it.



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Drugs and Chemicals of Concern > Salvia Divinorum

## Drugs and Chemicals of Concern

### SALVIA DIVINORUM AND SALVINORIN A

(Street Names: Maria Pastora, Sage of the Seers, Diviner's Sage, Salvia, Sally-D, Magic Mint)

October 2009 DE

#### Introduction:

Salvia divinorum is a perennial herb in the mint family native to certain areas of the Sierr Mazateca region of Oaxaca, Mexico. The plant, which can grow to over three feet in height has large green leaves, hollow square stems and white flowers with purple calyces, can be grown successfully outside of this region. Salvia divinorum has been used by the Mazatec Indians for its ritual divination and healing. The active constituent of Salvia divinorum has been identified as salvinorin A. Currently, neither Salvia divinorum nor any of its constituents including salvinorin A, are controlled under the federal Controlled Substances Act (CSA).

#### Licit Uses:

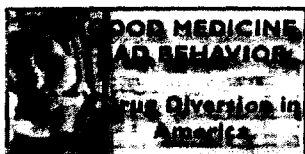
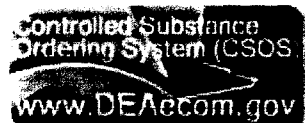
Neither Salvia divinorum nor its active constituent salvinorin A has an approved medicinal use in the U.S.

#### Chemistry and Pharmacology:

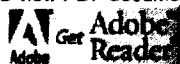
Salvinorin A, also called Divinorin A, is believed to be the ingredient responsible for the hallucinogenic effects of Salvia divinorum. Chemically, it is a neoclerodane diterpene found primarily in the leaves, and to a lesser extent in the stems. Although several other substances have been isolated from the plant, none have been shown to be psychoactive.

In the U.S., plant material is typically either chewed or smoked. When chewed, the leaves and juice are maintained within the cheek area with absorption occurring across the lining of the oral mucosa (buccal). Effects first appear within 5 to 10 minutes. Dried leaves, as well as extract enhanced leaves purported to be enriched with salvinorin A, are also smoked. Pure salvinorin A, at a dose of 200-500 micrograms, results in effects within 30 seconds that last about 30 minutes.

A limited number of studies have reported the effects of using either plant material or salvinorin A. Psychic effects include perceptions of bright light, vivid colors and changes in sound, as well as... 000504



To view PDF documents



External links included in this website should not be construed as an official endorsement of the views contained therein.

movements and body or object distortions. Other effects include dysphoria, uncontrolled laughter, a sense of loss of body, overlapping realities, and hallucinations (seeing objects not present). Adverse physical effects may include incoordination, dizziness, and slurred speech.

Scientific studies show that salvinorin A is a potent and selective kappa opioid receptor agonist. Other drugs that act at the kappa opioid receptor also produce hallucinogenic and dysphoria similar to that produced by salvinorin A. Salvinorin A does not activate the serotonin 2A receptor, which mediates the effects of other schedule I hallucinogens.

**Illicit Uses:**

Salvinorin A and Salvia divinorum products are abused for their ability to evoke hallucinogenic effects, which, in general, are similar to those of other scheduled hallucinogenic substances.

**User Population:**

According to the National Survey on Drug Use and Health Report (NSDUH), Use of Synthetic Hallucinogens: 2006, published by SAMHSA in February 2008, it is estimated that 1.8 million persons aged 12 or older used Salvia divinorum in their lifetime, and approximately 750,000 did so in the past year. Use was more common among young adults (18 to 25 years of age) than among older adults (>26 years of age). Young adults were 3 times more likely than older adults to have used Salvia divinorum in the past year. Use is more common among males than females according to NSDUH.

Seizures of Salvia divinorum and salvinorin A by federal, state and local law enforcement officials have increased from 1 in 2004 to 70 in 2008, according to the National Forensic Laboratory Information System (NFLIS). In the first half of 2009, 34 seizures have already been reported to forensic laboratories.

**Illicit Distribution:**

Salvia divinorum is grown domestically and imported from Mexico and Central and South America. The Internet is used for the promotion and distribution of Salvia divinorum. It is available as seeds, plant cuttings, whole plants, fresh and dried leaves, extract-enhanced leaves, and various strengths (e.g., 5x, 10x, 20x, 30x), and liquid extracts purported to contain salvinorin. These products are also sold at local shops (e.g., head shops and tobacco shops).

**Control Status:**


Salvia divinorum and salvinorin A are not currently controlled under the CSA. As of October 2009, fourteen states have enacted legislation placing regulatory controls on Salvia divinorum and/or salvinorin A. Delaware, Florida, Illinois, Kansas, North Dakota, Oklahoma, Virginia, Ohio, and Nebraska have placed Salvia divinorum and/or salvinorin A into schedule I controlled substance law. California, Louisiana, Maine, North Carolina, and Tennessee enacted legislation restricting the distribution of the plant. Legislative bills proposing regulatory controls died in Alaska, Indiana, South Carolina, Maryland, Texas, West Virginia and Georgia.

Salvinorin A and/or Salvia divinorum have been placed under regulatory controls in Australia, Belgium, Denmark, Estonia, Finland, Italy, Japan, Spain, and Sweden.

Comments and additional information are welcomed by the Drug and Chemical Evaluation Section; Fax 202-353-1263, telephone 202-307-7183 or Email ODE@usdoj.gov.



Lisa MacKay/HC-SC/GC/CA  
2009-12-18 03:04 PM

To Cheryl Tremblay/HC-SC/GC/CA@HWC  
cc Denis Arsenault/HC-SC/GC/CA@HWC, Jocelyn  
Kula/HC-SC/GC/CA@HWC  
bcc  
Subject Re: IYH Salvia Divinorum 

Hi Cheryl,


NHPD is ok with the proposed modifications to the IYH on Salvia

Have a good weekend!

Lisa  
Cheryl Tremblay/HC-SC/GC/CA



Cheryl  
Tremblay/HC-SC/GC/CA  
2009-12-17 02:45 PM

To Lisa MacKay/HC-SC/GC/CA@HWC  
cc Denis Arsenault/HC-SC/GC/CA@HWC, Jocelyn  
Kula/HC-SC/GC/CA@HWC  
Subject Re: IYH Salvia Divinorum 

Hi again Lisa,

Do you anticipate that we would have to get HPFB to sign off if we were to include the following additional revision to the background section of the IYH on Salvia?

### **Background**

*S. divinorum* is a species of sage that belongs to the mint family. It is known to have psychotropic effects, which means it affects the mind and mental processes.

The leaves of this plant have been used traditionally for spiritual and medicinal purposes by the Mazatec Indians in Mexico for many years. ~~Traditional use involves chewing the leaves or using them to make a tea for medicinal purposes (e.g., to treat such conditions as headache or stomach upset), or to induce a "mystical" or hallucinogenic experience for spiritual purposes.~~


Thanks,  
Cheryl Tremblay  
Policy and Regulatory Affairs Division / Division des politiques et affaires réglementaires  
Office of Controlled Substances / Bureau des substances contrôlées  
Controlled Substances and Tobacco Directorate / Direction des substances contrôlées et de la lutte au tabagisme  
Healthy Environments and Consumer Safety Branch / Direction générale de la santé environnementale et de la sécurité consommateurs  
Health Canada / Santé Canada  
Tel: (613) 954-6527 Fax: (613) 946-4224  
Lisa MacKay/HC-SC/GC/CA

Lisa MacKay /HC-SC/GC/CA

2009-12-16 10:15 AM

To Cheryl Tremblay/HC-SC/GC/CA@HWC

cc Denis Arsenault/HC-SC/GC/CA@HWC, Jocelyn  
Kula/HC-SC/GC/CA@HWC

Subject Re: IYH Salvia Divinorum 

Hi Cheryl,

No I think it should be fine as you are only adding the information on the Survey.

Thank you

Lisa Mackay

It's Your Health Project Manager/Gestionnaire du projet Votre santé et vous

Public Affairs Division | Division des affaires publiques

Public Affairs, Consultation and Communications Branch/ Direction générale des affaires publiques, de la  
consultation et des communications

Health Canada | Santé Canada

Tel 613.954.0105

Fax 613.952.8644

Lisa\_Mackay@hc-sc.gc.ca

Cheryl Tremblay/HC-SC/GC/CA



Cheryl

Tremblay/HC-SC/GC/CA

2009-12-16 10:12 AM

To Lisa MacKay/HC-SC/GC/CA@HWC

cc Jocelyn Kula/HC-SC/GC/CA@HWC, Denis  
Arsenault/HC-SC/GC/CA@HWC

Subject IYH Salvia Divinorum

Hi Lisa,

Given the amount of time that has passed since the IYH on *Salvia Divinorum* has been in the formal approvals process we have been asked to review the content to ensure that it is as current as possible before it is approved by our ADM. I have attached the revisions that we would like to propose below. Do you anticipate that these changes would require HPFB sign off again?



IYH - Salvia divinorum - June 8 2009\_HECSB Proposed Revisions\_Dec 16 2009.wpd

Thank you,

Cheryl Tremblay

Policy and Regulatory Affairs Division / Division des politiques et affaires réglementaires

Office of Controlled Substances / Bureau des substances contrôlées

Controlled Substances and Tobacco Directorate / Direction des substances contrôlées et de la lutte au  
tabagisme

Healthy Environments and Consumer Safety Branch / Direction générale de la santé environnementale et

de la sécurité consommateurs  
Health Canada / Santé Canada  
Tel: (613) 954-6527 Fax: (613) 946-4224



Cheryl  
Tremblay/HC-SC/GC/CA  
2009-12-21 09:41 AM

To Diane Allan/HC-SC/GC/CA@HWC  
cc Jocelyn Kula/HC-SC/GC/CA@HWC, Denis  
Arsenault/HC-SC/GC/CA@HWC, Isabel  
Shanahan/HC-SC/GC/CA@HWC, Carmen  
bcc Cheryl Tremblay/HC-SC/GC/CA  
Subject Re: Fw: Fw: Salvia D - IYH

Hi Diane,

The revisions to the IYH on Salvia have been reviewed/approved by NHPD.

Here they are in redline and clean version.



IYH - Salvia Divinorum - June 8 2009 - HECSB Proposed Revisions - Dec 16 2009\_Redline.doc



IYH - Salvia Divinorum - June 8 2009 - HECSB Proposed Revisions - Dec 16 2009\_Clean.doc

Do we need any kind of routing slip or MECS to get it back through DGO?

Thanks,  
Cheryl  
Diane Allan/HC-SC/GC/CA

Diane Allan/HC-SC/GC/CA  
2009-12-19 07:15 PM

To Cheryl Tremblay/HC-SC/GC/CA@HWC  
cc  
Subject Re: Fw: Fw: Salvia D - IYH

Cheryl, I provide you with minimal corrections last week. Curious when I can get these back? Are they back with Jocelyn?

Diane Allan

Director / Directrice  
Office of Controlled Substances / Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch / Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada / Santé Canada  
Tel: 613-952-2177  
Fax: 613-946-4224

\*effective immediately, my new email address is [diane.allan@hc-sc.gc.ca](mailto:diane.allan@hc-sc.gc.ca)  
Cheryl Tremblay/HC-SC/GC/CA



Cheryl  
Tremblay/HC-SC/GC/CA  
2009-12-16 11:12 AM

To Diane Allan/HC-SC/GC/CA@HWC  
cc "Carmen Berube" <carmen.berube@hc-sc.gc.ca>, "Cheryl



Tremblay" <Cheryl.Tremblay@hc-sc.gc.ca>, "Jocelyn Kula" <jocelyn.kula@hc-sc.gc.ca>, "Mrs. Patricia Rapold" <Patricia.Rapold@hc-sc.gc.ca>, Suzanne Desjardins/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC

Subject Re: Fw: Fw: Salvia D - IYH

Good morning Diane,

Here are the proposed revisions to the IYH on *Salvia divinorum* for your review and approval. We have added the information with respect to the OSDUHS and have included Germany (March 1, 2008) and Japan (November 9, 2008) in the list of countries that have placed restrictions on Salvia. These are not new developments, the list simply gave some examples and was not intended to be exhaustive.

FYI - Suzanne has approved the following. We also spoke with Lisa Mackay (IYH coordinator) and she advised that these changes would not require HPFB sign off again.



IYH - Salvia Divinorum - June 8 2009 - HECSB Proposed Revisions - Dec 16 2009\_Clean.doc



IYH - Salvia Divinorum - June 8 2009 - HECSB Proposed Revisions - Dec 16 2009\_Redline.doc

Thanks,  
Cheryl  
Diane Allan/HC-SC/GC/CA

Diane Allan/HC-SC/GC/CA  
2009-12-07 03:24 PM

To Suzanne.Desjardins@hc-sc.gc.ca, "Cheryl Tremblay" <Cheryl.Tremblay@hc-sc.gc.ca>, "Jocelyn Kula" <jocelyn.kula@hc-sc.gc.ca>  
cc "Mrs. Patricia Rapold" <Patricia.Rapold@hc-sc.gc.ca>, "Carmen Berube" <carmen.berube@hc-sc.gc.ca>  
Subject Fw: Fw: Salvia D - IYH

Not urgent but could we see if any further international updates since time has passed.

Perhaps next week?

Jodi Brown

----- Original Message -----

**From:** Jodi Brown  
**Sent:** 2009-12-07 03:11 PM EST  
**To:** Diane Allan  
**Subject:** Re: Fw: Salvia D - IYH

I've forwarded to ADMO and have asked them how they wish to proceed. In the meantime, however, given how long we've held this up, is there content that needs to be updated, particularly with respect to the status of Salvia D in other countries that is included in the IYH????



will let you know once I hear from ADMO whether they are okay with this going forward...thanks, JB

Diane Allan/HC-SC/GC/CA

Diane Allan/HC-SC/GC/CA  
2009-12-01 03:23 PM

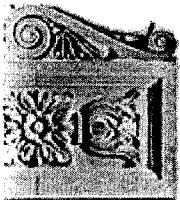
To Jodi Brown/HC-SC/GC/CA@HWC  
cc Cathy A Sabiston/HC-SC/GC/CA@HWC, CSTD-DGO  
Subject Fw: Salvia D - IYH

Hi Jodi - for your review.....

Diane Allan

Director / Directrice  
Office of Controlled Substances / Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch / Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada / Santé Canada  
Tel: 613-952-2177  
Fax: 613-946-4224

\*effective immediately, my new email address is [diane.allan@hc-sc.gc.ca](mailto:diane.allan@hc-sc.gc.ca)  
----- Forwarded by Diane Allan/HC-SC/GC/CA on 2009-12-01 03:22 PM -----



Cheryl  
Tremblay/HC-SC/GC/CA  
2009-12-01 03:16 PM

To Diane Allan/HC-SC/GC/CA@HWC, Patricia  
Rapold/HC-SC/GC/CA@HWC  
cc Jocelyn Kula/HC-SC/GC/CA@HWC, Suzanne  
Desjardins/HC-SC/GC/CA@HWC, Denis  
Arsenault/HC-SC/GC/CA@HWC  
Subject Re: Fw: Salvia D - IYH

Hi Diane/Patricia,

Here are the documents pertaining to the IYH on Salvia. The development of this article was initiated following a series of HPFB and HECSB DG-level discussions in 2007-2008 about the lack of data regarding Salvia and the department's obligation to address ongoing media interest and public/law enforcement enquiries. Both branches agreed that an IYH article was an option because it aims to provide the general public with information about an issue and/or influence behaviour, which in this case, would be the reduced use of *Salvia divinorum* for its hallucinogenic properties.

I spoke with Lisa Mackay (IYH Project Manager) regarding who signed off on the proposal and while we did have an opportunity to provide input on the proposal itself, she mentioned that proposals for IYH articles rarely seek formal approvals. I have attached the email from Lisa Holmes (Senior Communications Advisor, PACRB) requesting the article below. I have also attached the Approval Slips for the article itself from both HECSB and HPFB. FYI the article has been approved up to ADM level at HPFB.

Response to ADM's Questions



Response to ADM Comments on Salvia IYH Dec 1 2009.doc

**Final Rationale/Proposal**



Proposed Article IYH Salvia-D.wpd

**Approval Slips for Article Itself** (i.e. not proposal)



Apps Slip DG&ADM HECS Salvia May2009.wpd Apps Slip DG&ADM HPFB Salvia May2009.wpd

**Media Lines**

These are the most recent media lines on Salvia provided by comms. They have not been formally approved. We provided additional comments after the discussions that came out of the drafting of the IYH but comms was holding off on imputing our comments until they knew what needed to be changed in the IYH article, so they could update the media lines as necessary and send the IYH and media lines back to ADMO as a package. I have attached our comments on the lines below as well.



Salvia ML v.7 April 2009.doc Salvia ML v.7 April 2009\_CSTD Comments re IYH.doc

**Previous Response to Paul's Comments on the IYH**



Responses to ADM Comments on Salvia IYH June 23 2009.doc

Let me know if you need anything else.

Thanks,  
Cheryl

Policy and Regulatory Affairs Division / Division des politiques et affaires réglementaires  
Office of Controlled Substances / Bureau des substances contrôlées  
Controlled Substances and Tobacco Directorate / Direction des substances contrôlées et de la lutte au  
tabagisme  
Healthy Environments and Consumer Safety Branch / Direction générale de la santé environnementale et  
de la sécurité consommateurs  
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Tel: (613) 954-6527 Fax: (613) 946-4224

----- Forwarded by Lisa MacKay/HC-SC/GC/CA on 2009-11-30 11:15 AM -----

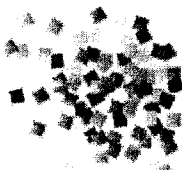
Lisa Holmes/HC-SC/GC/CA

2008-10-16 05:07 PM

To Lisa MacKay/HC-SC/GC/CA@HWC

cc Darrin Denne/HC-SC/GC/CA@HWC

Subject It's Your Health re: Salvia



Hi Lisa,

The drug group here at HECS would like to have an It's Your Health article written on Salvia. How do we proceed with scheduling a meeting with one of the writers?

Darrin, I'm copying you as well since HPFB will have to take part in this meeting too.

Thanks!  
Lisa

---

Lisa Holmes  
Senior Communications Advisor | Conseillère principale en communications  
PACRB | DGAPCR  
Strategic Communications Directorate | Direction des communications stratégiques  
Health Canada | Santé Canada  
T: (613) 957-3431  
F: (613) 948-8085  
C: (613) 601-0215  
Suzanne Desjardins/HC-SC/GC/CA

Diane Allan/HC-SC/GC/CA

Diane Allan/HC-SC/GC/CA  
2009-11-27 02:41 PM

To Cheryl.Tremblay@hc-sc.gc.ca, "Suzanne Desjardins"  
<Suzanne.Desjardins@hc-sc.gc.ca>  
cc "Jocelyn Kula" <jocelyn.kula@hc-sc.gc.ca>, "Denis  
Arsenault" <denis.arsenault@hc-sc.gc.ca>, "Mrs. Patricia  
Rapold" <Patricia.Rapold@hc-sc.gc.ca>, "Stephanie Szick"  
<stephanie.szick@hc-sc.gc.ca>  
Subject Fw: Salvia D - IYH

Please help.  
Stephanie Szick

----- Original Message -----

**From:** Stephanie Szick  
**Sent:** 2009-11-27 02:29 PM EST  
**To:** Diane Allan; Patricia Rapold  
**Cc:** Jodi Brown; Kimberly Sorfleet; Arafo Talane; Carmen Berube  
**Subject:** Salvia D - IYH

Hi Diane and Patricia,

Long trail below on this. In short, the Salvia D article is with Paul for his sign-off....he would like clarity on the following:

- **Why would we do an it's your health if we say we have insufficient evidence to regulate? i.e Why do we have enough about the health impacts yet aren't acting to regulate?**

I've attempted to reply to some of this in my email below to Cathy....

Per my email below, can your shop touch base with comms on this, as these articles are pretty much comms-led and implemented, and let us know by next week.

Clarification in an email is fine, please attach/include from comms the final rationale/proposal (with confirmation of who signed off), and the last version of the article, as well as any formal/approved media lines on the issue.

Deadline to DGO - next Wednesday, December 2, noon

Kim - please note for BF.


Thanks very much,

Stephanie

----- Forwarded by Stephanie Szick/HC-SC/GC/CA on 2009-11-27 02:21 PM -----



Stephanie  
Szick/HC-SC/GC/CA  
2009-11-27 02:21 PM

To Cathy A Sabiston/HC-SC/GC/CA  
cc Jodi Brown/HC-SC/GC/CA@HWC, Kimberly  
Sorfleet/HC-SC/GC/CA@HWC  
Subject Re: Salvia D 

Hi Cathy,

Pasted here is what was originally provided as rationale in the proposal for the Salvia D article.....keeping in mind IYH articles are comms products. I will ask Diane's shop to touch base also with comms to confirm what final approved rationale was -- the key was the both HECSB and HPFB were both onside with this idea - consensus. I think Paul actually approved the proposal and rationale. Comms should be able to provide more clarity.

The purpose of the article is information, including around current HC role....the dept. receives the same media Qs over and over on this issue and an IYH would be something to point reporters to, rather than the scramble to gather replies and get approvals across HECSB and HPFB. The article is just more efficient - it's approved across the two branches good to go.

**THE ISSUE - Salvia Divinorum is a species of sage which belongs to the mint family. It is found in the form of dried leaves, extract and plant cuttings. Salvia Divinorum, also known as "diviner's sage" and/or "magic mint", is chewed or smoked and can induce illusions and hallucinations.**

**Salvia Divinorum continues to attract moderate media attention. It will be beneficial to have an It's Your Health article available on the internet so that the general public can be better informed about the issue, and so that reporters can refer to this article, should they have questions about the issue.**

**HEALTH CANADA'S ROLE - There are no regulations or laws prohibiting the possession, use or sale of Salvia divinorum in Canada. While many countries across the globe have prohibited Salvia, it remains legal in Canada. Health Canada is currently exploring our options for prohibiting Salvia in Canada.**

**WHY IS THIS ARTICLE NEEDED AND WHY IT'S YOUR HEALTH?- The target audience is the general public. It's Your Health is a good vehicle to use to inform individuals about Salvia because the articles are written in plain language and are**

**easily understood by the vast majority of Canadians.**

Cathy A Sabiston/HC-SC/GC/CA



Cathy A  
Sabiston/HC-SC/GC/CA  
2009-11-27 01:43 PM

To Stephanie Szick/HC-SC/GC/CA@HWC, Jodi  
Brown/HC-SC/GC/CA@HWC  
cc Kimberly Sorfleet/HC-SC/GC/CA@HWC

Subject Salvia D

Paul's question is why wld we do an it's your health if we say we have insufficient evidence to regulate it?  
le why do we have enuff about the heallth impacts yet aren't acting to regulate

Can you please ask diane to look into this - or whomever!

Cas

## ***Salvia divinorum***

### **The Issue**

Recently there have been reports suggesting that Canadian teens and young adults are using a substance called *Salvia divinorum* (*S. divinorum*) for its ability to produce hallucinations. Certain Web sites are also promoting the use of *S. divinorum* as a “legal” alternative to street drugs.

Street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastra, ska Maria pastora, ska pastora, diviner’s sage, magic mint, puff encens special, and salvia.

Health Canada recommends that you avoid using this substance because very little is known about the damage it may cause to the body, including the brain. There is also no way to predict how it will affect you with each use.

### **Background**

*S. divinorum* is a species of sage that belongs to the mint family. It is known to have psychotropic effects, which means it affects the mind and mental processes.

The leaves of this plant have been used traditionally for spiritual and medicinal purposes by the Mazatec Indians in Mexico for many years.

Products that claim to contain *S. divinorum* – or its main active ingredient, salvinorin A – are widely available on the Internet and are sold in various “head shops” and natural food stores. The products are sold in a number of formats, including seeds and plant cuttings for growing purposes. Fresh or dried leaves are intended to be chewed, swallowed or smoked. Liquid preparations are also available.

### **Risks of Using *Salvia divinorum***

*S. divinorum*’s effects, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations;
- dysphoria (feeling unwell, uneasy or unhappy);
- out-of-body experiences;
- uncontrollable laughter;
- loss of consciousness;
- short-term memory loss;
- lack of physical coordination;
- slurred speech and awkward sentence patterns.

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product;
- how much is used;

- the extent of actual abuse of the substance in Canada and elsewhere;
- overall risk to public health and safety posed by the substance.

In the case of *S. divinorum*, there is simply not enough information available to determine whether regulation under the CDSA is the best option to manage the potential risks. Questions about the use of *S. divinorum* have been included in the 2008-2009 Youth Smoking Survey, the 2009 Canadian Alcohol and Drug Use Monitoring Survey and the 2009 Ontario Student Drug Use and Health Survey (OSDUHS). The results from the 2009 OSDUHS were published on November 18, 2009 and indicate that among responding students in Ontario in 2009, 4.4% reported using *Salvia divinorum* at least once in the past year. Data like this, and that from the two national surveys which will be available in 2010, will help fill some of these information gaps and contribute to future decisions that Health Canada may make about this plant and its active ingredient. See the Need More Info? section below for more information on the surveys that are collecting information about *Salvia divinorum* use in Canada and for more detailed findings from the 2009 OSDUHS.

#### In Other Countries

Several countries (e.g., Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) have placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on their sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution (e.g., no sales to anyone under the age of 18).

#### **Health Canada's Role**

Health Canada continues to collect and consider information regarding *S. divinorum* and continues to consult with key stakeholders, including health officials in other countries, and law enforcement officials here at home. This will assist in determining the most appropriate strategy to manage the risks associated with the use of *S. divinorum*.

#### **Reporting Adverse Reactions**

You can report any adverse reactions to the Canada Vigilance Program by one of the following three ways:

- Report online at the MedEffect™ Canada Web site
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and either:
- Fax toll-free to 1-866-678-6789
- Mail to:  
Canada Vigilance Program  
Health Canada  
AL 0701C  
Ottawa, ON K1A 0K9

**s.19(1)**

Writer: Sue Lumsden [REDACTED]

Version/date: Draft Seven. May 27, 2009. Removes highlighter marking changes in Draft Six, which have been agreed to by the Program Contacts. Replaces reference (and link) to the Ontario Student Drug Use and Health Survey with a reference (and link) to the (national) Canadian Alcohol and Drug Use Monitoring Survey.

Contacts: HECSB: Jocelyn Kula, Cheryl Tremblay, Brittany Sauvé  
HPFB-NHPD: Valerie Hurry, Robin Marles  
HPFB-MHPD: Scott Jordan (Draft Two only), Robert Leitch, Mano Murty



## ***Salvia divinorum* (Redline)**

### **The Issue**

Recently there have been reports suggesting that Canadian teens and young adults are using a substance called *Salvia divinorum* (*S. divinorum*) for its ability to produce hallucinations. Certain Web sites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs.

Street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastra, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff encens special, and salvia.

Health Canada recommends that you avoid using this substance because very little is known about the damage it may cause to the body, including the brain. There is also no way to predict how it will affect you with each use.

### **Background**

*S. divinorum* is a species of sage that belongs to the mint family. It is known to have psychotropic effects, which means it affects the mind and mental processes.

The leaves of this plant have been used traditionally for spiritual and medicinal purposes by the Mazatec Indians in Mexico for many years.

Products that claim to contain *S. divinorum* – or its main active ingredient, salvinorin A – are widely available on the Internet and are sold in various “head shops” and natural food stores. The products are sold in a number of formats, including seeds and plant cuttings for growing purposes. Fresh or dried leaves are intended to be chewed, swallowed or smoked. Liquid preparations are also available.

**Deleted:** Traditional use involves chewing the leaves or using them to make a tea for medicinal purposes (e.g., to treat such conditions as headache or stomach upset), or to induce a “mystical” or hallucinogenic experience for spiritual purposes.¶

### Risks of Using *Salvia divinorum*

*S. divinorum*'s effects, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations;
- dysphoria (feeling unwell, uneasy or unhappy);
- out-of-body experiences;
- uncontrollable laughter;
- loss of consciousness;
- short-term memory loss;
- lack of physical coordination;
- slurred speech and awkward sentence patterns.

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product;
- how much is used;
- the purity of the product (it may be mixed with other substances);
- how it is taken (e.g., chewed, swallowed or smoked);
- the user's mood and expectations.

A major concern about *S. divinorum* is that there have only been a few scientific studies about the way it affects the body and the brain. Scientists know which brain receptors are targeted by the active ingredient, salvinorin A, but very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or permanent damage;
- how it interacts with other substances, including other drugs, natural health products and alcohol.

**Deleted:** the fact

The information regarding physical dependence or addiction to *S. divinorum* is unclear, although it appears the potential for either is low.

### Minimizing Your Risk

Health Canada recommends that you avoid using *S. divinorum*. Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs and other substances that distort

reality. (See the "Need More Info?" section below for links to resources that can help you with this.)

Also, remember that just because a drug is plant-based or "natural," it does not mean it is safe. Under certain conditions of use, *S. divinorum* meets the definition of a "natural health product" (NHP) under Health Canada's *Natural Health Products Regulations*. However, no NHPs containing this substance have been approved for sale in Canada. This means that products claiming to contain *S. divinorum* have not been reviewed by Health Canada for safety, efficacy or quality. As such, they may be counterfeit or contain other ingredients that pose risks to health, and consumers should apply the "buyer beware" principle.

Deleted: heed

Natural health products that have been reviewed and approved by Health Canada are labelled with one of the following:

- a Natural Product Number (NPN); or
- a Drug Identification Number - Homeopathic Medicine (DIN-HM).

### The Legal Status of *Salvia divinorum*

#### In Canada

Neither *S. divinorum* nor salvininorin A is currently regulated under the *Controlled Drugs and Substances Act* (CDSA). When assessing whether to add a substance to one of the Schedules to the CDSA, Health Canada considers the following factors:

- international requirements and trends in controlling the substance;
- similarity to other substances already regulated under the CDSA;
- whether there may be legitimate uses of the substance (e.g., potential health benefits, use in manufacturing, etc.);
- the potential for abuse and the risk of addiction associated with the substance;
- the extent of actual abuse of the substance in Canada and elsewhere;
- overall risk to public health and safety posed by the substance.

In the case of *S. divinorum*, there is simply not enough information available to determine whether regulation under the CDSA is the best option to manage the potential risks. Questions about the use of *S. divinorum* have been included in the 2008-2009 Youth Smoking Survey, the 2009 Canadian Alcohol and Drug Use Monitoring Survey, and the 2009 Ontario Student Drug Use and Health Survey (OSDUHS). The results from the 2009 OSDUHS were published on November 18, 2009 and indicate that among responding students in Ontario in 2009, 4.4% reported using *Salvia divinorum* at least once in the past year. Data like this, and that from the two national surveys which will be available in 2010, will help fill some of these information gaps and contribute to future decisions that Health Canada may make about this plant and its active ingredient. See the Need More Info? section below for more information on the surveys that are collecting information about *Salvia divinorum* use in Canada and for more detailed findings from the 2009 OSDUHS.

Deleted: and

Deleted: ,

Deleted: these survey results

Deleted: The data, however, will not likely be available until 2010.

#### In Other Countries

Several countries (e.g., Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) have placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on their sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution (e.g., no sales to anyone under the age of 18).

Deleted: Sweden

Deleted: Spain,

Deleted: Finland and

Comment [C1]: Alphabetize?

### Health Canada's Role

Health Canada continues to collect and consider information regarding *S. divinorum* and continues to consult with key stakeholders, including health officials in other countries, and law enforcement officials here at home. This will assist in determining the most appropriate strategy to manage the risks associated with the use of *S. divinorum*.

### Reporting Adverse Reactions

You can report any adverse reactions to the Canada Vigilance Program by one of the following three ways:

- Report online at the MedEffect™ Canada Web site

- Call toll-free at 1-866-234-2345

- Complete a Canada Vigilance Reporting Form and either:

- Fax toll-free to 1-866-678-6789

- Mail to: Canada Vigilance Program  
Health Canada  
AL 0701C

Ottawa, ON K1A 0K9

To have postage pre-paid, download the postage paid label from the MedEffect™ Canada Web site. The Canada Vigilance Reporting Form and the adverse reaction reporting guidelines may also be obtained via this Web site.

### Need More Info?

For information about the Government of Canada's Anti-Drug Strategy, go to: <http://www.nationalantidrugstrategy.gc.ca/>. The Prevention section on this site has a number of helpful resources for parents, including "Tips on Talking to Your Teenager" and "What to Do if Your Teen is Using Drugs."

Information on natural health products and the *Natural Health Products Regulations* can be found at: <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php>

For more on the surveys that are collecting information about *Salvia divinorum* use in Canada, see:

The 2008-2009 Youth Smoking Survey, at:  
[http://www.yss.uwaterloo.ca/ysss/site\\_app/controller/index.cfm](http://www.yss.uwaterloo.ca/ysss/site_app/controller/index.cfm) and

The 2009 Canadian Alcohol and Drug Use Monitoring Survey, at: <http://www.hc-sc.gc.ca/hl-vs/drug-drogues/cadums-escad-eng.php>

The 2009 Ontario Student Drug Use and Health Survey, at:  
<http://www.camh.net/Research/osdus.html>

**Additional Resources:**

U.S. Drug Enforcement Administration: Drugs and Chemicals of Concern: *Salvia divinorum* and Salvinorin A at: [http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)

U.S. Department of Health & Human Services, National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006 at:  
<http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf>

For additional articles on health and safety issues go to the *It's Your Health* Web section at:

<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/index-eng.php>

<http://www.hc-sc.gc.ca/english/iyh/index.html>

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

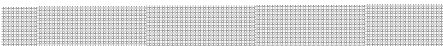
Original:

©Her Majesty the Queen in Right of Canada, represented by the Minister of Health, 2009

Catalogue#  
ISBN#

----- 0 -----

**s.19(1)**

Writer: Sue Lumsden 

Version/date: Draft Seven. May 27, 2009. Removes highlighter marking changes in Draft Six, which have been agreed to by the Program Contacts. Replaces reference (and link) to the Ontario Student Drug Use and Health Survey with a reference (and link) to the (national) Canadian Alcohol and Drug Use Monitoring Survey.

Contacts: HECSB: Jocelyn Kula, Cheryl Tremblay, Brittany Sauvé  
HPFB-NHPD: Valerie Hurry, Robin Marles  
HPFB-MHPD: Scott Jordan (Draft Two only), Robert Leitch, Mano Murty



Jocelyn Kula/HC-SC/GC/CA

2009-12-22 01:49 PM

To Diane Allan/HC-SC/GC/CA@HWC, Jodi  
Brown/HC-SC/GC/CA@HWC  
cc Kimberly Sorfleet/HC-SC/GC/CA@HWC, Cheryl  
Tremblay/HC-SC/GC/CA@HWC  
Subject Re: salvia D docket

Only to say that we only got a verbal approval from HPFB so if a routing slip is required, we would have to get one.

JK

Sent by blackberry

Jocelyn Kula

Manager/ Gestionnaire

Policy and Regulatory Affairs Division/ Division des politiques et affaires réglementaires

Diane Allan

----- Original Message -----

**From:** Diane Allan

**Sent:** 2009-12-22 01:40 PM EST

**To:** Jodi Brown; Jocelyn Kula

**Cc:** Kimberly Sorfleet; Cheryl Tremblay; Jocelyn Kula

**Subject:** Re: salvia D docket

Yes and yes for approvals.

Can email approval be provided or would DGO prefer a signed routing slip?

Jodi Brown

----- Original Message -----

**From:** Jodi Brown

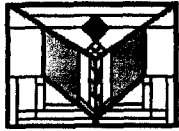
**Sent:** 2009-12-22 01:37 PM EST

**To:** Diane Allan; Jocelyn Kula

**Cc:** Kimberly Sorfleet

**Subject:** salvia D docket

I see this docket has risen (!). Can you please let me know of status and process at this stage (e.g. are we re-issuing this in a formal docket form to try and get ADM sign off due to delay on original process? has HPFB approved this version? to what level? ...) thanks.....JB



Jodi Brown/HC-SC/GC/CA  
2009-12-22 04:00 PM

To Diane Allan/HC-SC/GC/CA@HWC  
cc Cheryl Tremblay/HC-SC/GC/CA@HWC, Jocelyn  
Kula/HC-SC/GC/CA@HWC, Kimberly  
Sorfleet/HC-SC/GC/CA@HWC

bcc

Subject Re: salvia D docket

hey, there's no one here pushing for this as far as I know (unless you tell me otherwise!) - that was why I was asking all of the questions about rationale for moving it forward now as I was surprised to see it come back up given all of the workload pressures on your gang!

Diane Allan/HC-SC/GC/CA

Diane Allan/HC-SC/GC/CA  
2009-12-22 03:54 PM

To Jodi Brown/HC-SC/GC/CA@HWC  
cc Cheryl Tremblay/HC-SC/GC/CA@HWC, Jocelyn  
Kula/HC-SC/GC/CA@HWC, Kimberly  
Sorfleet/HC-SC/GC/CA@HWC

Subject Re: salvia D docket

well is all of this needs to be done to get approvals, then it will have to wait to the New year. Would this be OK?

Diane Allan

Director / Directrice  
Office of Controlled Substances / Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch / Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada / Santé Canada  
Tel: 613-952-2177  
Fax: 613-946-4224

\*effective immediately, my new email address is [diane.allan@hc-sc.gc.ca](mailto:diane.allan@hc-sc.gc.ca)  
Jodi Brown/HC-SC/GC/CA



Jodi Brown/HC-SC/GC/CA  
2009-12-22 03:25 PM

To Jocelyn Kula/HC-SC/GC/CA@HWC  
cc Cheryl Tremblay/HC-SC/GC/CA@HWC, Diane  
Allan/HC-SC/GC/CA@HWC, Kimberly  
Sorfleet/HC-SC/GC/CA@HWC

Subject Re: salvia D docket

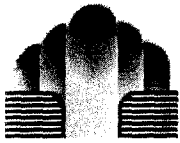
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I would suggest one minor change to page 3, where there's a couple lines re: the survey/latest data that are a bit clunky. Change to "...4.4% reported using....in the past year. FURTHER DATA FROM THE TWO NATIONAL SURVEYS WILL BE AVAILABLE IN 2010. IT IS ANTICIPATED THAT SUCH DATA WILL HELP ADDRESS SOME OF THE INFORMATION GAPS ABOUT THIS SUBSTANCE and contribute to ...."


.....thanks, JB

Jocelyn Kula/HC-SC/GC/CA



Jocelyn Kula/HC-SC/GC/CA

2009-12-22 01:49 PM

To: Diane Allan/HC-SC/GC/CA@HWC, Jodi Brown/HC-SC/GC/CA@HWC  
cc: Kimberly Sorfleet/HC-SC/GC/CA@HWC, Cheryl Tremblay/HC-SC/GC/CA@HWC  
Subject: Re: salvia D docket 

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JK

Sent by blackberry

Jocelyn Kula  
Manager/ Gestionnaire  
Policy and Regulatory Affairs Division/ Division des politiques et affaires réglementaires  
Diane Allan

----- Original Message -----

**From:** Diane Allan  
**Sent:** 2009-12-22 01:40 PM EST  
**To:** Jodi Brown; Jocelyn Kula  
**Cc:** Kimberly Sorfleet; Cheryl Tremblay; Jocelyn Kula  
**Subject:** Re: salvia D docket

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----- Original Message -----

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**Sent:** 2009-12-22 01:37 PM EST  
**To:** Diane Allan; Jocelyn Kula  
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**Subject:** salvia D docket

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Health  
Canada

Healthy Environments  
and Consumer Safety  
Branch

Santé  
Canada

Direction générale,  
Santé environnementale et  
sécurité des consommateurs

Your file / Votre référence

Our file / Notre référence  
09-076902-986

23 DEC. 2009

Dr. Ian MacDonald Gemmill  
Kingston, Frontenac and Lennox & Addington Public Health  
221 Portsmouth Avenue  
Kingston, Ontario  
K7M 1V5

Dear Dr. MacDonald Gemmill:

Thank you for your correspondence of November 26, 2009, addressed to Deputy Minister Morris Rosenberg, regarding Health Canada's position on *Salvia divinorum*. In your letter you also request information with respect to the health risks associated with this plant and its active ingredient, salvinorin A. The Deputy Minister has forwarded your letter to my office for a response.

Health Canada is aware of some of the experiences that are being reported by individuals that have experimented with the use of *Salvia divinorum*, including hallucinations, out-of-body experiences, unconsciousness and short-term memory loss.

As for Health Canada's position, the Department has not yet decided whether *Salvia divinorum* or salvinorin A warrant regulation as controlled substances. This is because information about the factors considered in contemplating whether to add a substance to one of the schedules to the *Controlled Drugs and Substances Act*, including the potential for abuse and risk of addiction associated with the substance, the extent of actual abuse of the substance in Canada and internationally, the overall risk to public health and safety posed by the substance, etc., is either missing or anecdotal in nature. For example, very few scientific studies looking into the physical and psychotropic effects of *Salvia divinorum* on humans have been carried out, and using these studies to predict the potential for addiction and abuse associated with *Salvia divinorum* is difficult.

..2

- 2 -

In addition, the Department has only received a limited number of communications indicating concern with respect to *Salvia divinorum* from law enforcement agencies, and none of these have advised that the use of *Salvia divinorum* poses any threat to public safety.

Health Canada is taking steps to address the lack of data regarding the use and the extent of abuse involving *Salvia divinorum*. Questions regarding its use were included in the 2008-2009 Youth Smoking Survey, the 2009 Canadian Alcohol and Drug Use Monitoring Survey, and the 2009 Ontario Student Drug Use and Health Survey (OSDUHS). The results from the 2009 OSDUHS were published on November 18, 2009 and indicate that among responding students in Ontario in 2009, 4.4% reported using *Salvia divinorum* at least once in the past year. Data like this, and that from the two national surveys which will be available in 2010, will help fill some of these information gaps and contribute to future decisions that Health Canada may make about this plant and its active ingredient. Please visit <http://www.camh.net/Research/osdus.html> for more detailed findings from the 2009 OSDUHS.

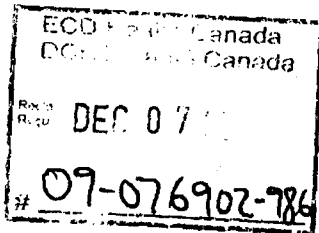
Health Canada will continue to collect and consider information regarding *Salvia divinorum* and to consult with key stakeholders, including health officials in other countries, and law enforcement officials here at home to determine the most appropriate strategy to manage the risks associated with the use of *Salvia divinorum*.

Thank you for writing.

Sincerely,



Diane Allan  
Director  
Office of Controlled Substances  
Controlled Substances and Tobacco Directorate  
Healthy Environments and Consumer Branch



# Public Health

An accredited local public health agency affiliated with Queen's University  
I.M. Gemmill MD, CCFP, FRCPC Medical Officer of Health

Telephone: 613.549.1232 Ext. 1234

Email: MOH@kflapublichealth.ca

26 November 2009

Deputy Minister Morris Rosenberg  
Health Canada  
Brooke Claxton Building, Tunney's Pasture  
Postal Locator: 0906C  
Ottawa, Ontario K1A 0K9

Dear Deputy Minister:

**RE: *Salvia divinorum***

I am writing to enquire about the Health Canada position on *Salvia divinorum*, and herb common in parts of the Western hemisphere and containing a psychoactive chemical called *salvinorin A*. We have had reports of its sale in shops in this area and are aware that it has psychotropic effects.

I am writing to enquire from you about your opinion of the health risks of this plant and the chemical involved. In addition, I am writing to enquire about Health Canada's position and what action, if any, your department intends to take on this plant and chemical. Your response will assist us in deciding what action we might take locally to restrict or prevent its sale to youth in this area.

Thank you in advance for your assistance and look forward to an informative response.

Yours truly,

Ian MacDonald Gemmill, MD, CCFP, FCFP, FRCPC(C)  
Medical Officer of Health

IMG:cbk

Copy to: Board of Health members  
E. Gardner, Manager, Environmental Health  
P. Lavalley, Director, Infectious Disease Prevention and Environmental Health

## KINGSTON, FRONTENAC AND LENNOX & ADDINGTON PUBLIC HEALTH

Main Office  
221 Portsmouth Avenue, Kingston, Ontario K7M 1V5  
Tel: 613-549-1232 1-800-267-7875  
Fax: 613-549-7896 www.kflapublichealth.ca



Branch Offices  
Cloyne Tel: 613-336-8989 Fax: 613-336-0529  
Sharbot Lake Tel: 613-000529  
Napanee Tel: 613-



Cheryl  
Tremblay/HC-SC/GC/CA  
2009-12-23 11:02 AM

To Lisa MacKay/HC-SC/GC/CA@HWC  
cc Jocelyn Kula/HC-SC/GC/CA@HWC, Diane  
Allan/HC-SC/GC/CA@HWC, Kimberly  
Sorfleet/HC-SC/GC/CA@HWC, Jodi  
bcc Cheryl Tremblay/HC-SC/GC/CA

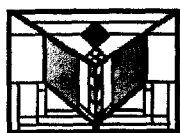
Subject Fw: salvia D docket

Good morning Lisa,

Please see string of emails re: IYH on Salvia below. Should we work through your office for the approval from HPFB?

Thanks,

Cheryl Tremblay  
Policy and Regulatory Affairs Division / Division des politiques et affaires réglementaires  
Office of Controlled Substances / Bureau des substances contrôlées  
Controlled Substances and Tobacco Directorate / Direction des substances contrôlées et de la lutte au tabagisme  
Healthy Environments and Consumer Safety Branch / Direction générale de la santé environnementale et de la sécurité consommateurs  
Health Canada / Santé Canada  
Tel: (613) 954-6527 Fax: (613) 946-4224  
— Forwarded by Cheryl Tremblay/HC-SC/GC/CA on 2009-12-23 10:59 AM —



Jodi Brown/HC-SC/GC/CA  
2009-12-23 10:32 AM

To Jocelyn Kula/HC-SC/GC/CA@HWC  
cc Cheryl Tremblay/HC-SC/GC/CA@HWC, Diane  
Allan/HC-SC/GC/CA@HWC, Kimberly  
Sorfleet/HC-SC/GC/CA@HWC  
Subject Re: salvia D docket

Spoke with ADMO and we will move the docket forward. So if you have the updated media lines from Comms, pls advise, and yes, if you can get HPFB to send approval (even if it is an email for now), pls forward ASAP.

Thanks...JB

Jocelyn Kula/HC-SC/GC/CA



Jocelyn Kula/HC-SC/GC/CA  
2009-12-22 03:59 PM

To Jodi Brown/HC-SC/GC/CA@HWC  
cc Cheryl Tremblay/HC-SC/GC/CA@HWC, Diane  
Allan/HC-SC/GC/CA@HWC, Kimberly  
Sorfleet/HC-SC/GC/CA@HWC  
Subject Re: salvia D docket

Yes there are pressures to move this through ADMO as Paul's approval has been pending since the Spring and HPFB signed off months ago, it would be nice to get this one up on the website and then start

using it in standard responses etc.

Re. media lines, I am copying Bronwyn so she can confirm, but last I remember, we had suggested some changes to the approved lines in order to align the text with the proposed IYH article but nothing ever got approved because ADMO wanted them to go forward for approval at the same time as the IYH and Paul had questions about the IYH over the summer. I am attaching the latest version that Comms had prepared and that we edited. I would suggest that we flag both docs to ADMO so that they get approved at the same time.



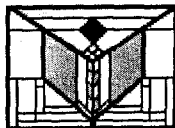
Salvia ML v.7 April 2009\_CSTD Comments re IYH.doc

Re. your proposed change, while I see what you are saying, I have to be honest and say that as we have worked with Suzanne D on the current text and HPFB has now approved it, making any more changes will now only further delay things. Your call I suppose but if the change is really a nice to have rather than a must have, I say we leave it for now.

Jocelyn


---

Jocelyn Kula  
Manager/ Gestionnaire  
Policy and Regulatory Affairs Division/ Division des politiques et affaires réglementaires  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0125 Fax: (613) 946-4224  
Jodi Brown/HC-SC/GC/CA



Jodi Brown/HC-SC/GC/CA  
2009-12-22 03:25 PM

To Jocelyn Kula/HC-SC/GC/CA@HWC  
cc Cheryl Tremblay/HC-SC/GC/CA@HWC, Diane Allan/HC-SC/GC/CA@HWC, Kimberly Sorfleet/HC-SC/GC/CA@HWC

Subject Re: salvia D docket 

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..... thanks, JB

Jocelyn Kula/HC-SC/GC/CA

DRAFT  
April 7, 2009

### Media Lines Regulatory Control of *Salvia Divinorum*

#### Issue

Since 2006, Health Canada has noted ongoing media interest regarding the availability of *Salvia divinorum* on the Canadian market. Health Canada has also received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum*, particularly given reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties.

Deleted: observed a steady increase in the amount of

#### Key Messages:

- Health Canada continues to collect and consider information about *Salvia divinorum* and its active ingredient, salvinorin A, from both national and international sources in order to determine what, if any, regulatory controls are needed.
- While the media have reported that use of *Salvia divinorum* is on the rise in certain parts of the country, Health Canada does not currently have statistics on its use across the Canadian population.
- Health Canada is taking steps to address this lack of data. Questions regarding the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey. A general open-ended question about the use of other substances was also included in the 2008 Canadian Alcohol and Drug Use Monitoring Survey.

Deleted: relevant

Deleted: S

Deleted: Ontario Student

Deleted: and Health

#### Supplementary Messages:

##### *On the classification of *Salvia divinorum*:*

- In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA).
- *Salvia divinorum* is not listed under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these conventions.
- Several countries (Australia, Belgium, Denmark, Sweden, Italy, Spain, Finland and South Korea) have placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Although some individual U.S. states have implemented laws

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restricting its use, sale and/or distribution, *Salvia divinorum* and salvinorin A are not federally regulated under the *Controlled Substances Act* in the United States.

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- *Salvia divinorum* meets the definition of a natural health product under the *Natural Health Product Regulations* (NHPR). This means that *Salvia* products that are not in compliance with the NHPR may be subject to compliance and enforcement actions.
- As of January 2009, Health Canada had not issued any Natural Product Numbers (NPN) or Drug Identification Numbers – Homeopathic Medicine (DIN-HM) for *Salvia divinorum* products.

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***If asked for specifics on when the survey data will be available:***

- Data from the Canadian Alcohol and Drug Use Monitoring Survey will be available in summer 2009, while the results of the Youth Smoking Survey and the Canadian Alcohol and Drug Use Monitoring Survey likely will not be available until 2010.

Deleted: Ontario Student

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**Questions and Answers**

**Q1 – If Health Canada is aware of *Salvia divinorum*'s ill-effects, why isn't it illegal?**

A1 – Very few controlled scientific studies of the physical and psychotropic effects of *Salvia divinorum* on humans have been carried out, and using these studies to predict the potential for addiction and abuse associated with *Salvia divinorum* is difficult. More controlled systematic research in this area is needed.

Health Canada has only received a limited number of communications regarding *Salvia divinorum* from law enforcement agencies, and none of these has advised that the use of *Salvia divinorum* poses any particular threat to public safety.

**Q2 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?**

A2 – The *Natural Health Product Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *Salvia divinorum*.

**Q3 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A3 – *Salvia divinorum* products that are not in compliance with the *Natural Health Product Regulations* and/or are found to pose a risk to the health of Canadians may be subject to compliance and enforcement action by Health Canada. An import target for products containing *Salvia divinorum* has already been placed with Canada Border Services Agency.

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**Q4 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum*. What does that involve and what stage is it at?**

A4 - Health Canada considers several factors in determining whether scheduling a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in regulatory status;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

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Health Canada has only anecdotal information about the last three of the above-mentioned factors, and thus is not yet convinced that the controls imposed by the CDSA are an appropriate strategy for managing the risks associated with the use of *Salvia divinorum*. The survey results from the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey will help fill some of the information gaps. The data, however, will not likely be available until 2010. In the interim, Health Canada will continue to collect and consider information regarding *Salvia divinorum* as it becomes available.

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**Q5 – Didn't an internal report from Health Canada's Marketed Health Products Directorate recommend that *Salvia divinorum* be scheduled under the CDSA? Why has that recommendation not been acted upon?**

A5 – See A4

**Q6 – What is the significance of the adverse reaction reports that Health Canada has received with respect to the use of *Salvia divinorum*?**

A6 – Health Canada has received four domestic adverse reaction reports related to the use of *Salvia divinorum* as a hallucinogen through the Canada Vigilance database. The number of reports and the nature of reactions reported are not adequate to characterize the risk to the general population. These data cannot be used to determine incidence of use in the general population, as Health Canada does not have any information about the number of individuals using or who have used *Salvia divinorum*.

**Background**

*Salvia divinorum* is a species of sage belonging to the mint family that is chewed or smoked in order to induce its psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are often described as unpleasant.



The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. While no validated data exist regarding usage in Canada, data from a 2006 National Survey on Drug Use and Health Report, published by the U.S. Substance Abuse and Mental Health Services Administration has estimated that:

- 1.8 million persons aged 12 or older have used *Salvia divinorum* at least once in their lifetime, and approximately 750,000 did so in the past year.
- Use was more common among young adults (18 to 25 years old) as opposed to older adults (>26 years of age).
- Young adults were three times more likely than youths aged 12 to 17 to have used *Salvia divinorum* in the past year.
- Use was more common in males than females.

*Salvia divinorum* is widely advertised and promoted on the Internet and sold in various "head shops" and natural food stores as a "legal" alternative to street drugs.

While some users have reported that the psychotropic effects of *Salvia divinorum* resemble those induced by other hallucinogens, such as LSD and phencyclidine, the overall experience appears to be quite unique.

**Deleted:** *Salvia divinorum* does not appear to cause the euphoria often associated with other psychoactive drugs, so many people who try it do not repeat the experience.

**Prepared by:** Cheryl Tremblay, Policy and Regulatory Affairs Division, DSCSD  
Stephanie Mitchell, Communications Advisor (HECSB)  
Darrin Denne, Communications Officer (HPFB)

**Reviewed by:** Mano Murty (MHPD – March 11, 2009)

**Approved by :**

Approved	Andrew Adams, Director, OCS, DSCSD (March 1 <sup>st</sup> , 2009)
	Nancy Richards, Director, Bureau of Policy and Regulatory Affairs, NHPD (January 23, 2009)
	Duc Vu, Director, Marketed Biologics, Biotechnology and Natural Health Products Bureau, MHPD (February 3, 2009)
Approved	Cathy Sabiston, DG, TDD, HECS (April 7, 2009)
Approved	Chris Turner, DG, MHPD (March 13, 2009)
Approved	Michelle Boudreau, DG, NHPD (March 19, 2009)
Approved	Sharon Mullins, A/DG, HPFBI (April 3, 2009)
Approved	Ken Polk, Communications Executive, HPFB (April 3, 2009)
Approved	Kathleen Malone, Senior Media Relations, PACCB (April 7, 2009)
Pending	Warren Braun, Director, Strategic Communications, PACCB
Pending	Peter Yendall, Director, Public Affairs, PACCB
Pending	Paul Glover, ADM, HECSB
Pending	Meena Ballantyne, ADM, HPFB
Pending	Anne Lamar, ADM, PACCB
Pending	DMO
Pending	MO
Pending	PCO



Cheryl  
Tremblay/HC-SC/GC/CA  
2009-12-23 01:51 PM

To Bronwyn Cline/HC-SC/GC/CA@HWC  
cc Jodi Brown/HC-SC/GC/CA@HWC, Kimberly  
Sorfleet/HC-SC/GC/CA@HWC, Diane  
Allan/HC-SC/GC/CA@HWC, Jocelyn  
bcc Cheryl Tremblay/HC-SC/GC/CA

Subject Fw: salvia D docket

Hi Bronwyn,

Here are the proposed revisions to the IYH and ML on Saliva. They have been approved by Diane Allan (below).

Q - Can we include a line about the IYH in the ML yet or would it be added once published?

Thanks,  
Cheryl

— Forwarded by Cheryl Tremblay/HC-SC/GC/CA on 2009-12-23 01:45 PM —

Diane Allan/HC-SC/GC/CA  
2009-12-23 01:45 PM

To Cheryl Tremblay/HC-SC/GC/CA@HWC  
cc

Subject Re: Fw: Fw: salvia D docket 

Approved.

Diane Allan

Director / Directrice  
Office of Controlled Substances / Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch / Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada / Santé Canada  
Tel: 613-952-2177  
Fax: 613-946-4224

\*effective immediately, my new email address is [diane.allan@hc-sc.gc.ca](mailto:diane.allan@hc-sc.gc.ca)  
Cheryl Tremblay/HC-SC/GC/CA



Cheryl  
Tremblay/HC-SC/GC/CA  
2009-12-23 01:04 PM

To Diane Allan/HC-SC/GC/CA@HWC  
cc

Subject Re: Fw: Fw: salvia D docket 

Hi Diane,

Here are the latest versions of the proposed revisions to the IYH and ML on Saliva for your review/approval.

FYI - Denis has not reviewed and is currently on lunch, would you like me to have him look over them prior to your approval?

IYH



IYH - Salvia Divinorum - June 8 2009 - HECSB Proposed Revisions - Dec 23 2009\_Clean.doc



IYH - Salvia Divinorum - June 8 2009 - HECSB Proposed Revisions - Dec 23 2009\_Redline.doc

Media Lines



Salvia ML v.7\_CSTD Comments re IYH\_Dec 23 2009.doc

Thanks,

Cheryl Tremblay

Policy and Regulatory Affairs Division / Division des politiques et affaires réglementaires

Office of Controlled Substances / Bureau des substances contrôlées

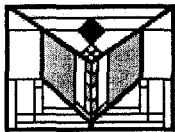
Controlled Substances and Tobacco Directorate / Direction des substances contrôlées et de la lutte au tabagisme

Healthy Environments and Consumer Safety Branch / Direction générale de la santé environnementale et de la sécurité consommateurs

Health Canada / Santé Canada

Tel: (613) 954-6527 Fax: (613) 946-4224

Jodi Brown/HC-SC/GC/CA



Jodi Brown/HC-SC/GC/CA

2009-12-23 11:34 AM

To Diane Allan/HC-SC/GC/CA@HWC

cc Bronwyn Cline/HC-SC/GC/CA@HWC, Cheryl

Tremblay/HC-SC/GC/CA@HWC, Kimberly

Sorfleet/HC-SC/GC/CA@HWC

Subject Re: Fw: Fw: salvia D docket

This is why I didn't understand why a new docket was opened yesterday by OCS on this. Can you pls close the docket/file, and I will pull from CAthy's signature book. Bronwyn said Comms will send an entire package (media lines and IYH) for approvals to our DG and HPFB DG. As such, since its needs to get approved again, can we fix the 'clunky line' as per my original email below and have HPFB and our DG review that once finalised with comms and MLs.

Thanks...JB

Diane Allan/HC-SC/GC/CA

Diane Allan/HC-SC/GC/CA

2009-12-23 11:18 AM

To Cheryl Tremblay/HC-SC/GC/CA@HWC

cc Jodi Brown/HC-SC/GC/CA@HWC, Bronwyn

Cline/HC-SC/GC/CA@HWC  
Subject Re: Fw: Fw: salvia D docket

Well then no further action for us Jodi then.

Thanks Cheryl.  
Cheryl Tremblay

----- Original Message -----

**From:** Cheryl Tremblay  
**Sent:** 2009-12-23 11:17 AM EST  
**To:** Diane Allan  
**Cc:** Jodi Brown; Bronwyn Cline  
**Subject:** Re: Fw: Fw: salvia D docket

Bronwyn said that they would push both the IYH and the media lines through approvals together.

Diane Allan/HC-SC/GC/CA

Diane Allan/HC-SC/GC/CA  
2009-12-23 11:15 AM

To Jodi Brown/HC-SC/GC/CA@HWC  
cc "Cheryl Tremblay" <Cheryl.Tremblay@hc-sc.gc.ca>  
Subject Fw: Fw: salvia D docket

So comms handles comms products we would have to handle the IYH on its own.  
Cheryl Tremblay

----- Original Message -----

**From:** Cheryl Tremblay  
**Sent:** 2009-12-23 11:08 AM EST  
**To:** Diane Allan  
**Subject:** Re: Fw: salvia D docket

Hi Diane,

I just spoke with Bronwyn and she said that the approvals have been handled through comms in the past and to forward the article on to her and let her know who has approved, etc. I am updating the proposed revisions to the media lines now and will forward them on shortly.

Thanks,  
Cheryl  
Diane Allan/HC-SC/GC/CA

Diane Allan/HC-SC/GC/CA  
2009-12-23 11:05 AM

To "Cheryl Tremblay" <Cheryl.Tremblay@hc-sc.gc.ca>  
cc  
Subject Fw: salvia D docket

## ***Salvia divinorum* (Clean) – CSTD Proposed Revisions - December 23, 2009**

### **The Issue**

Recently there have been reports suggesting that Canadian teens and young adults are using a substance called *Salvia divinorum* (*S. divinorum*) for its ability to produce hallucinations. Certain Web sites are also promoting the use of *S. divinorum* as a “legal” alternative to street drugs.

Street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastra, ska Maria pastora, ska pastora, diviner’s sage, magic mint, puff encens special, and salvia.

Health Canada recommends that you avoid using this substance because very little is known about the damage it may cause to the body, including the brain. There is also no way to predict how it will affect you with each use.

### **Background**

*S. divinorum* is a species of sage that belongs to the mint family. It is known to have psychotropic effects, which means it affects the mind and mental processes.

The leaves of this plant have been used traditionally for spiritual and medicinal purposes by the Mazatec Indians in Mexico for many years.

Products that claim to contain *S. divinorum* – or its main active ingredient, salvinorin A – are widely available on the Internet and are sold in various “head shops” and natural food stores. The products are sold in a number of formats, including seeds and plant cuttings for growing purposes. Fresh or dried leaves are intended to be chewed, swallowed or smoked. Liquid preparations are also available.

### **Risks of Using *Salvia divinorum***

*S. divinorum*’s effects, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations;
- dysphoria (feeling unwell, uneasy or unhappy);
- out-of-body experiences;
- uncontrollable laughter;
- loss of consciousness;
- short-term memory loss;
- lack of physical coordination;
- slurred speech and awkward sentence patterns.

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product;
- how much is used;

- the purity of the product (it may be mixed with other substances);
- how it is taken (e.g., chewed, swallowed or smoked);
- the user's mood and expectations.

A major concern about *S. divinorum* is that there have only been a few scientific studies about the way it affects the body and the brain. Scientists know which brain receptors are targeted by the active ingredient, salvinorin A, but very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or permanent damage;
- how it interacts with other substances, including other drugs, natural health products and alcohol.

The information regarding physical dependence or addiction to *S. divinorum* is unclear, although it appears the potential for either is low.

### **Minimizing Your Risk**

Health Canada recommends that you avoid using *S. divinorum*. Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs and other substances that distort reality. (See the "Need More Info?" section below for links to resources that can help you with this.)

Also, remember that just because a drug is plant-based or "natural," it does not mean it is safe. Under certain conditions of use, *S. divinorum* meets the definition of a "natural health product" (NHP) under Health Canada's *Natural Health Products Regulations*. However, no NHPs containing this substance have been approved for sale in Canada. This means that products claiming to contain *S. divinorum* have not been reviewed by Health Canada for safety, efficacy or quality. As such, they may be counterfeit or contain other ingredients that pose risks to health, and consumers should apply the "buyer beware" principle.

Natural health products that have been reviewed and approved by Health Canada are labelled with one of the following:

- a Natural Product Number (NPN); or
- a Drug Identification Number - Homeopathic Medicine (DIN-HM).

### **The Legal Status of *Salvia divinorum***

#### In Canada

Neither *S. divinorum* nor salvinorin A is currently regulated under the *Controlled Drugs and Substances Act* (CDSA). When assessing whether to add a substance to one of the Schedules to the CDSA, Health Canada considers the following factors:

- international requirements and trends in controlling the substance;
- similarity to other substances already regulated under the CDSA;
- whether there may be legitimate uses of the substance (e.g., potential health benefits, use in manufacturing, etc.);
- the potential for abuse and the risk of addiction associated with the substance;

- the extent of actual abuse of the substance in Canada and elsewhere;
- overall risk to public health and safety posed by the substance.

In the case of *S. divinorum*, there is simply not enough information available to determine whether regulation under the CDSA is the best option to manage the potential risks. Questions about the use of *S. divinorum* have been included in the 2008-2009 Youth Smoking Survey, the 2009 Canadian Alcohol and Drug Use Monitoring Survey and the 2009 Ontario Student Drug Use and Health Survey (OSDUHS). The results from the 2009 OSDUHS were published on November 18, 2009 and indicate that among responding students in Ontario, 4.4% reported using *Salvia divinorum* at least once in the past year. Further data from the two national surveys will be available in 2010. It is anticipated that such data will help address some of the information gaps about this substance and contribute to future decisions that Health Canada may make about this plant and its active ingredient. See the Need More Info? section below for more information on the surveys that are collecting information about *Salvia divinorum* use in Canada and for more detailed findings from the 2009 OSDUHS.

#### In Other Countries

Several countries (e.g., Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) have placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on their sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution (e.g., no sales to anyone under the age of 18).

#### **Health Canada's Role**

Health Canada continues to collect and consider information regarding *S. divinorum* and continues to consult with key stakeholders, including health officials in other countries, and law enforcement officials here at home. This will assist in determining the most appropriate strategy to manage the risks associated with the use of *S. divinorum*.

#### **Reporting Adverse Reactions**

You can report any adverse reactions to the Canada Vigilance Program by one of the following three ways:

- Report online at the MedEffect™ Canada Web site
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and either:
- Fax toll-free to 1-866-678-6789
-

Mail to: Canada Vigilance Program  
Health Canada  
AL 0701C

Ottawa, ON K1A 0K9

To have postage pre-paid, download the [postage paid label](#) from the [MedEffect™ Canada Web site](#). The [Canada Vigilance Reporting Form](#) and the adverse reaction reporting guidelines may also be obtained via this Web site.

### **Need More Info?**

For information about the Government of Canada's Anti-Drug Strategy, go to: <http://www.nationalantidrugstrategy.gc.ca/>. The Prevention section on this site has a number of helpful resources for parents, including "Tips on Talking to Your Teenager" and "What to Do if Your Teen is Using Drugs."

Information on natural health products and the *Natural Health Products Regulations* can be found at: <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php>

For more on the surveys that are collecting information about *Salvia divinorum* use in Canada, see:

The 2008-2009 Youth Smoking Survey, at: [http://www.yss.uwaterloo.ca/ysssite\\_app/controller/index.cfm](http://www.yss.uwaterloo.ca/ysssite_app/controller/index.cfm) and

The 2009 Canadian Alcohol and Drug Use Monitoring Survey, at: <http://www.hc-sc.gc.ca/hl-vs/drug-drogues/cadums-esccad-eng.php>

The 2009 Ontario Student Drug Use and Health Survey, at: <http://www.camh.net/Research/osdus.html>

### **Additional Resources:**

U.S. Drug Enforcement Administration: Drugs and Chemicals of Concern: *Salvia divinorum* and Salvinorin A at: [http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)

U.S. Department of Health & Human Services, National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006 at: <http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf>

For additional articles on health and safety issues go to the *It's Your Health* Web section at: <http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/index-eng.php>  
<http://www.hc-sc.gc.ca/english/iyh/index.html>

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

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Catalogue#  
ISBN#

**s.19(1)**

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Writer: Sue Lumsden 

Version/date: Draft Seven. May 27, 2009. Removes highlighter marking changes in Draft Six, which have been agreed to by the Program Contacts. Replaces reference (and link) to the Ontario Student Drug Use and Health Survey with a reference (and link) to the (national) Canadian Alcohol and Drug Use Monitoring Survey.

Contacts: HECSB: Jocelyn Kula, Cheryl Tremblay, Brittany Sauvé  
HPFB-NHPD: Valerie Hurry, Robin Marles  
HPFB-MHPD: Scott Jordan (Draft Two only), Robert Leitch, Mano Murty

**Salvia divinorum (Redline) – CSTD Proposed Revisions - December 23, 2009**

**The Issue**

Recently there have been reports suggesting that Canadian teens and young adults are using a substance called *Salvia divinorum* (*S. divinorum*) for its ability to produce hallucinations. Certain Web sites are also promoting the use of *S. divinorum* as a “legal” alternative to street drugs.

Street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastra, ska Maria pastora, ska pastora, diviner’s sage, magic mint, puff encens special, and salvia.

Health Canada recommends that you avoid using this substance because very little is known about the damage it may cause to the body, including the brain. There is also no way to predict how it will affect you with each use.

**Background**

*S. divinorum* is a species of sage that belongs to the mint family. It is known to have psychotropic effects, which means it affects the mind and mental processes.

The leaves of this plant have been used traditionally for spiritual and medicinal purposes by the Mazatec Indians in Mexico for many years.

Products that claim to contain *S. divinorum* – or its main active ingredient, salvinorin A – are widely available on the Internet and are sold in various “head shops” and natural food stores. The products are sold in a number of formats, including seeds and plant cuttings for growing purposes. Fresh or dried leaves are intended to be chewed, swallowed or smoked. Liquid preparations are also available.

**Deleted:** Traditional use involves chewing the leaves or using them to make a tea for medicinal purposes (e.g., to treat such conditions as headache or stomach upset), or to induce a “mystical” or hallucinogenic experience for spiritual purposes.¶

### Risks of Using *Salvia divinorum*

*S. divinorum*'s effects, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations;
- dysphoria (feeling unwell, uneasy or unhappy);
- out-of-body experiences;
- uncontrollable laughter;
- loss of consciousness;
- short-term memory loss;
- lack of physical coordination;
- slurred speech and awkward sentence patterns.

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product;
- how much is used;
- the purity of the product (it may be mixed with other substances);
- how it is taken (e.g., chewed, swallowed or smoked);
- the user's mood and expectations.

A major concern about *S. divinorum* is that there have only been a few scientific studies about the way it affects the body and the brain. Scientists know which brain receptors are targeted by the active ingredient, salvinorin A, but very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or permanent damage;
- how it interacts with other substances, including other drugs, natural health products and alcohol.

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The information regarding physical dependence or addiction to *S. divinorum* is unclear, although it appears the potential for either is low.

### Minimizing Your Risk

Health Canada recommends that you avoid using *S. divinorum*. Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs and other substances that distort

reality. (See the "Need More Info?" section below for links to resources that can help you with this.)

Also, remember that just because a drug is plant-based or "natural," it does not mean it is safe. Under certain conditions of use, *S. divinorum* meets the definition of a "natural health product" (NHP) under Health Canada's *Natural Health Products Regulations*. However, no NHPs containing this substance have been approved for sale in Canada. This means that products claiming to contain *S. divinorum* have not been reviewed by Health Canada for safety, efficacy or quality. As such, they may be counterfeit or contain other ingredients that pose risks to health, and consumers should apply the "buyer beware" principle.

Deleted: heed

Natural health products that have been reviewed and approved by Health Canada are labelled with one of the following:

- a Natural Product Number (NPN); or
- a Drug Identification Number - Homeopathic Medicine (DIN-HM).

### The Legal Status of *Salvia divinorum*

#### In Canada

Neither *S. divinorum* nor salvinin A is currently regulated under the *Controlled Drugs and Substances Act* (CDSA). When assessing whether to add a substance to one of the Schedules to the CDSA, Health Canada considers the following factors:

- international requirements and trends in controlling the substance;
- similarity to other substances already regulated under the CDSA;
- whether there may be legitimate uses of the substance (e.g., potential health benefits, use in manufacturing, etc.);
- the potential for abuse and the risk of addiction associated with the substance;
- the extent of actual abuse of the substance in Canada and elsewhere;
- overall risk to public health and safety posed by the substance.

In the case of *S. divinorum*, there is simply not enough information available to determine whether regulation under the CDSA is the best option to manage the potential risks. Questions about the use of *S. divinorum* have been included in the 2008-2009 Youth Smoking Survey, the 2009 Canadian Alcohol and Drug Use Monitoring Survey, and the 2009 Ontario Student Drug Use and Health Survey (OSDUHS). The results from the 2009 OSDUHS were published on November 18, 2009 and indicate that among responding students in Ontario, 4.4% reported using *Salvia divinorum* at least once in the past year. Further data from the two national surveys will be available in 2010. It is anticipated that such data will help address some of the information gaps about this substance and contribute to future decisions that Health Canada may make about this plant and its active ingredient. See the Need More Info? section below for more information on the surveys that are collecting information about *Salvia divinorum* use in Canada and for more detailed findings from the 2009 OSDUHS.

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#### In Other Countries

Several countries (e.g., Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) have placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on their sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution (e.g., no sales to anyone under the age of 18).

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Deleted: Finland and

Comment [C1]: Alphabetize?

### Health Canada's Role

Health Canada continues to collect and consider information regarding *S. divinorum* and continues to consult with key stakeholders, including health officials in other countries, and law enforcement officials here at home. This will assist in determining the most appropriate strategy to manage the risks associated with the use of *S. divinorum*.

### Reporting Adverse Reactions

You can report any adverse reactions to the Canada Vigilance Program by one of the following three ways:

- Report online at the MedEffect™ Canada Web site

- Call toll-free at 1-866-234-2345

- Complete a Canada Vigilance Reporting Form and either:

- Fax toll-free to 1-866-678-6789

- Mail to: Canada Vigilance Program  
Health Canada  
AL 0701C

Ottawa, ON K1A 0K9

To have postage pre-paid, download the postage paid label from the MedEffect™ Canada Web site. The Canada Vigilance Reporting Form and the adverse reaction reporting guidelines may also be obtained via this Web site.

### Need More Info?

For information about the Government of Canada's Anti-Drug Strategy, go to: <http://www.nationalantidrugstrategy.gc.ca/>. The Prevention section on this site has a number of helpful resources for parents, including "Tips on Talking to Your Teenager" and "What to Do if Your Teen is Using Drugs."

Information on natural health products and the *Natural Health Products Regulations* can be found at: <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php>

For more on the surveys that are collecting information about *Salvia divinorum* use in Canada,  
see:

The 2008-2009 Youth Smoking Survey, at:  
[http://www.yss.uwaterloo.ca/ysss/site\\_app/controller/index.cfm](http://www.yss.uwaterloo.ca/ysss/site_app/controller/index.cfm) and

The 2009 Canadian Alcohol and Drug Use Monitoring Survey, at: <http://www.hc-sc.gc.ca/hl-vs/drug-drogues/cadums-escad-eng.php>

The 2009 Ontario Student Drug Use and Health Survey, at:  
<http://www.camh.net/Research/osdus.html>

**Additional Resources:**

U.S. Drug Enforcement Administration: Drugs and Chemicals of Concern: *Salvia divinorum* and  
Salvinorin A at: [http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)

U.S. Department of Health & Human Services, National Survey on Drug Use and Health: Use of  
Specific Hallucinogens: 2006 at:  
<http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf>

For additional articles on health and safety issues go to the *It's Your Health* Web section at:  
<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/index-eng.php>  
<http://www.hc-sc.gc.ca/english/iyh/index.html>

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

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**Writer:** Sue Lumsden [lumsden@xplomet.com](mailto:lumsden@xplomet.com) 613-835-2878

**Version/date:** Draft Seven. May 27, 2009. Removes highlighter marking changes in Draft Six,  
which have been agreed to by the Program Contacts. Replaces reference (and link)  
to the Ontario Student Drug Use and Health Survey with a reference (and link) to  
the (national) Canadian Alcohol and Drug Use Monitoring Survey.

**Contacts:** HECSB: Jocelyn Kula, Cheryl Tremblay, Brittany Sauvé  
HPFB-NHPD: Valerie Hurry, Robin Marles  
HPFB-MHPD: Scott Jordan (Draft Two only), Robert Leitch, Mano Murty

DRAFT  
December 23, 2009

Deleted: April 7

### Media Lines Regulatory Control of *Salvia Divinorum*

#### Issue

Since 2006, Health Canada has noted ongoing media interest regarding the availability of *Salvia divinorum* on the Canadian market. Health Canada has also received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum*, particularly given reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties.

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#### Key Messages:

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- Health Canada is taking steps to address this lack of data. Questions about the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey, the 2009 Canadian Alcohol and Drug Use Monitoring Survey and the 2009 Ontario Student Drug Use and Health Survey. It is anticipated that the data from these surveys will help address some of the information gaps about this substance and contribute to future decisions that Health Canada may make about this plant and its active ingredient.
- Health Canada continues to collect and consider information regarding *Salvia divinorum* and to consult with key stakeholders, including health officials in other countries, and law enforcement here at home to determine the most appropriate strategy to manage the risks associated with the use of *Salvia divinorum*.

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- In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA).
- *Salvia divinorum* is not listed under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these conventions.

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- Several countries (Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) have placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Although some individual U.S. states have implemented laws restricting its use, sale and/or distribution, *Salvia divinorum* and salvinorin A are not federally regulated under the *Controlled Substances Act* in the United States.

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**If asked for specifics on the survey data:**

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## Questions and Answers

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Health Canada has only received a limited number of communications indicating concern with respect to *Salvia divinorum* from law enforcement agencies, and none of these has advised that the use of *Salvia divinorum* poses any threat to public safety.

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Q2 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?



A2 – The *Natural Health Product Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *Salvia divinorum*.

**Q3 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A3 – *Salvia divinorum* products that are not in compliance with the *Natural Health Product Regulations* and/or are found to pose a risk to the health of Canadians may be subject to compliance and enforcement action by Health Canada. An import target for products containing *Salvia divinorum* has already been placed with Canada Border Services Agency.

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- International requirements and trends in controlling the substance;
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Health Canada has only anecdotal information about the last three of the above-mentioned factors, and thus is not yet convinced that the controls imposed by the CDSA are an appropriate strategy for managing the risks associated with the use of *Salvia divinorum*. It is anticipated that the data from the 2008-2009 Youth Smoking Survey, the 2009 Canadian Alcohol and Drug Use Monitoring Survey and the 2009 Ontario Student Drug Use and Health Survey will help address some of the information gaps about this substance and contribute to future decisions that Health Canada may make about this plant and its active ingredient. The data from the two national surveys will be available in 2010.

Health Canada will continue to collect and consider information regarding *Salvia divinorum* as it becomes available.

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**Q5 – Didn't an internal report from Health Canada's Marketed Health Products Directorate recommend that *Salvia divinorum* be scheduled under the CDSA? Why has that recommendation not been acted upon?**

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**Q6 – What is the significance of the adverse reaction reports that Health Canada has received with respect to the use of *Salvia divinorum*?**

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### **Background**

*Salvia divinorum* is a species of sage belonging to the mint family that is chewed or smoked in order to induce its psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are often described as unpleasant.

The leaves of this plant have been used traditionally for spiritual and medicinal purposes by the Mazatec Indians in Mexico for many years.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago.

The results from the 2009 Ontario Student Drug Use and Health Survey, which were published on November 18, 2009, indicate that among responding students in Ontario, 4.4% reported using *Salvia divinorum* at least once in the past year. Health Canada will consider this data in its ongoing examination of *Salvia divinorum* and salvinorin A.

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Data from a 2006 National Survey on Drug Use and Health Report, published by the U.S. Substance Abuse and Mental Health Services Administration has estimated that:

- 1.8 million persons aged 12 or older have used *Salvia divinorum* at least once in their lifetime, and approximately 750,000 did so in the past year.
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**Reviewed by:** Mano Murty (MHPD – March 11, 2009)

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DRAFT

December 23, 2009

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Deleted: <#>Data from the Canadian Alcohol and Drug Use Monitoring Survey will be available in summer 2009, while the results of the Youth Smoking Survey and the Ontario Student Drug Use and Health Survey likely will not be available until 2010. ¶

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#### **Questions and Answers**

**Q1 – If Health Canada is aware of *Salvia divinorum*'s ill-effects, why isn't it illegal?**

A1 – Very few controlled scientific studies of the physical and psychotropic effects of *Salvia divinorum* on humans have been carried out, and using these studies to predict the potential for addiction and abuse associated with *Salvia divinorum* is difficult. More controlled systematic research in this area is needed.

Health Canada has only received a limited number of communications indicating concern with respect to *Salvia divinorum* from law enforcement agencies, and none of these has advised that the use of *Salvia divinorum* poses any threat to public safety.

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**Q2 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?**

A2 – The *Natural Health Product Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *Salvia divinorum*.

**Q3 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A3 – *Salvia divinorum* products that are not in compliance with the *Natural Health Product Regulations* and/or are found to pose a risk to the health of Canadians may be subject to compliance and enforcement action by Health Canada. An import target for products containing *Salvia divinorum* has already been placed with Canada Border Services Agency.

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**Q4 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum*. What does that involve and what stage is it at?**

A4 - Health Canada considers several factors in determining whether scheduling a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in controlling the substance;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

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Health Canada has only anecdotal information about the last three of the above-mentioned factors, and thus is not yet convinced that the controls imposed by the CDSA are an appropriate strategy for managing the risks associated with the use of *Salvia divinorum*. It is anticipated that the data from the 2008-2009 Youth Smoking Survey, the 2009 Canadian Alcohol and Drug Use Monitoring Survey and the 2009 Ontario Student Drug Use and Health Survey will help address some of the information gaps about this substance and contribute to future decisions that Health Canada may make about this plant and its active ingredient. The data from the two national surveys will be available in 2010.

Health Canada will continue to collect and consider information regarding *Salvia divinorum* as it becomes available.

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**Q5 – Didn't an internal report from Health Canada's Marketed Health Products Directorate recommend that *Salvia divinorum* be scheduled under the CDSA? Why has that recommendation not been acted upon?**

A5 – See A4

**Q6 – What is the significance of the adverse reaction reports that Health Canada has received with respect to the use of *Salvia divinorum*?**

A6 – Health Canada has received four domestic adverse reaction reports related to the use of *Salvia divinorum* as a hallucinogen through the Canada Vigilance database. The number of reports and the nature of reactions reported are not adequate to characterize the risk to the general population. These data cannot be used to determine incidence of use in the general population, as Health Canada does not have any information about the number of individuals using or who have used *Salvia divinorum*.

### **Background**

*Salvia divinorum* is a species of sage belonging to the mint family that is chewed or smoked in order to induce its psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are often described as unpleasant.

The leaves of this plant have been used traditionally for spiritual and medicinal purposes by the Mazatec Indians in Mexico for many years.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago.

The results from the 2009 Ontario Student Drug Use and Health Survey, which were published on November 18, 2009, indicate that among responding students in Ontario, 4.4% reported using *Salvia divinorum* at least once in the past year. Health Canada will consider this data in its ongoing examination of *Salvia divinorum* and salvinorin A.

It is anticipated that the data from the 2008-2009 Youth Smoking Survey, the 2009 Canadian Alcohol and Drug Use Monitoring Survey and the 2009 Ontario Student Drug Use and Health Survey will help address some of the information gaps about the use of this substance and contribute to future decisions that Health Canada may make about this plant and its active ingredient. The data from the two national surveys will be available in 2010.

Data from a 2006 National Survey on Drug Use and Health Report, published by the U.S. Substance Abuse and Mental Health Services Administration has estimated that:

- 1.8 million persons aged 12 or older have used *Salvia divinorum* at least once in their lifetime, and approximately 750,000 did so in the past year.
- Use was more common among young adults (18 to 25 years old) as opposed to older adults (>26 years of age).
- Young adults were three times more likely than youths aged 12 to 17 to have used *Salvia divinorum* in the past year.
- Use was more common in males than females.

*Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

*★ natural*  
**Deleted:** While no validated data exist regarding usage in Canada, d

**Comment [C2]:** Leave in?

While some users have reported that the psychotropic effects of *Salvia divinorum* resemble those induced by other hallucinogens, such as LSD and phencyclidine, the overall experience appears to be quite unique.

**Deleted:** *Salvia divinorum* does not appear to cause the euphoria often associated with other psychoactive drugs, so many people who try it do not repeat the experience.

**Prepared by:** Cheryl Tremblay, Policy and Regulatory Affairs Division, DSCSD  
Stephanie Mitchell, Communications Advisor (HECSB)  
Darrin Denne, Communications Officer (HPFB)

**Reviewed by:** Mano Murty (MHPD – March 11, 2009)

**Approved by :**

Approved

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Nancy Richards, Director, Bureau of Policy and Regulatory Affairs, NHPD (January 23, 2009)  
Duc Vu, Director, Marketed Biologics, Biotechnology and Natural Health Products Bureau, MHPD (February 3, 2009)

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Approved

Sharon Mullins, A/DG, HPFBI (April 3, 2009)

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Ken Polk, Communications Executive, HPFB (April 3, 2009)

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DMO

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MO

Pending

PCO

→ Salvia

DRAFT  
December 23, 2009

### Media Lines Regulatory Control of Salvia Divinorum

#### Issue

Since 2006, Health Canada has noted ongoing media interest regarding the availability of *Salvia divinorum* on the Canadian market. Health Canada has also received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum*, particularly given reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties.

#### Key Messages:

- When sold for the purpose of modifying organic functions, *Salvia divinorum* meets the definition of a natural health product under the *Natural Health Product Regulations* (NHPR). This means that *Salvia* products that are not in compliance with the NHPR may be subject to compliance and enforcement actions.
- There is currently insufficient information available to determine whether *Salvia divinorum* and its active ingredient salvinorin A should be scheduled under the *Controlled Drugs and Substances Act* to manage the potential risks associated with the use of *Salvia divinorum*.
- Health Canada continues to collect and consider information regarding *Salvia divinorum* and to consult with key stakeholders, including health officials in other countries, and law enforcement here at home to determine the most appropriate strategy to manage the risks associated with the use of *Salvia divinorum*.

#### Supplementary Messages:

##### *On the classification of Salvia divinorum:*

- In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA).
- *Salvia divinorum* is not listed under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these conventions.
- Several countries (Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) have placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Although some individual U.S. states have

**Comment [D1]:** HPFB to provide new bullet to clearly define the term "modifying organic functions". Should this bullet be positioned in the "Key Messages" or "Supplementary Messages" section?

**Deleted:** The Department has not yet decided whether to regulate *Salvia divinorum* or its active ingredient salvinorin A as controlled substances under the *Controlled Drugs and Substances Act* (CDSA).

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implemented laws restricting its use, sale and/or distribution, *Salvia divinorum* and salvinorin A are not federally regulated under the *Controlled Substances Act* in the United States,

- As of January 2009, Health Canada had not issued any Natural Product Numbers (NPN) or Drug Identification Numbers – Homeopathic Medicine (DIN-HM) for *Salvia divinorum* products.

***If pressed on the lack of statistics on Salvia divinorum use in Canada:***

- Health Canada is taking steps to address this lack of data. Questions about the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey, the 2009 Canadian Alcohol and Drug Use Monitoring Survey and the 2009 Ontario Student Drug Use and Health Survey. This data will be available in 2010.
- It is anticipated that the data from these surveys will help address some of the information gaps about this substance and contribute to future decisions that Health Canada may make about this plant and its active ingredient.

***If pressed regarding the results of the 2009 Ontario Student Drug Use and Health Survey:***

- The results from the 2009 Ontario Student Drug Use and Health Survey were published on November 18, 2009 and indicate that among responding students in Ontario, 4.4% reported using *Salvia divinorum* at least once in the past year. Health Canada will consider this data in its ongoing examination of *Salvia divinorum* and salvinorin A.

**Questions and Answers**

**Q1 – What are the risks of using *Salvia divinorum*?**

A1 – Very few controlled scientific studies of the physical and psychotropic effects of *Salvia divinorum* on humans have been carried out, and using these studies to predict the potential for addiction and abuse associated with *Salvia divinorum* is difficult. There is no way to predict what effect this substances may have on an individual as the effect may differ from one use to the next. The effect of using *Salvia divinorum* depends on a number of factors including the potency and purity (it may be mixed with other substances) of the product, how much is used, how it is taken (e.g., chewed, swallowed or smoked) and the user's mood and expectations. More controlled systematic research in this area is needed. Health Canada will continue to collect and consider information regarding *Salvia divinorum* as it becomes available.

**Q2 – If Health Canada is aware of *Salvia divinorum*'s ill-effects, why isn't it illegal?**

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¶  
*Salvia divinorum* meets the definition of a natural health product under the *Natural Health Product Regulations* (NHPR). This means that *Salvia* products that are not in compliance with the NHPR may be subject to compliance and enforcement actions.

**Comment [D2]:** HECSCB Office of Research and Surveillance to clarify when this data should be available.

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A2 – When sold for the purpose of modifying organic functions, *Salvia divinorum* meets the definition of a natural health product under the *Natural Health Product Regulations* (NHPR). This means that *Salvia* products that are not in compliance with the NHPR may be subject to compliance and enforcement actions.

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Q3 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?

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A3 – The *Natural Health Product Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *Salvia divinorum*.

Q4 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?

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A4 – *Salvia divinorum* products that are not in compliance with the *Natural Health Product Regulations* and/or are found to pose a risk to the health of Canadians may be subject to compliance and enforcement action by Health Canada. An import target for products containing *Salvia divinorum* has already been placed with Canada Border Services Agency.

Q5 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum*. What does that involve and what stage is it at?

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A5 –

Comment [D3]: The first part of the response to this questions should focus on the regulation of *Salvia divinorum* under the NHPR. HPFB to provide this material. The corresponding section in the IYH would also need to be changed to this effect.

With regard to the possible scheduling of *Salvia divinorum* under the *Controlled Drugs and Substances Act* (CDSA), Health Canada considers several factors, including;

- International requirements and trends in controlling the substance;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

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There is currently insufficient information available to determine whether *Salvia divinorum* and its active ingredient salvinorin A should be regulated under the CDSA ~~to~~ manage the potential risks associated with *Salvia divinorum*. It is anticipated that the data from the 2008-2009 Youth Smoking Survey, the 2009 Canadian Alcohol and Drug Use Monitoring Survey and the 2009 Ontario Student Drug Use and Health Survey will help address some of the information gaps about this substance and contribute to future decisions that Health Canada may make about this plant and its active ingredient. ~~The~~ Data from the two national surveys will be available in 2010.

Deleted: Health Canada has only anecdotal information about the last three of the above-mentioned factors, and thus is not yet convinced that the controls imposed by the CDSA are an appropriate strategy for managing the risks associated with the use of *Salvia divinorum*.

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Health Canada will continue to collect and consider information regarding *Salvia divinorum* as it becomes available.

**Q6 – Didn't an internal report from Health Canada's Marketed Health Products Directorate recommend that *Salvia divinorum* be scheduled under the CDSA? Why has that recommendation not been acted upon?**

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A6 – See A5.

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**Q7 – What is the significance of the adverse reaction reports that Health Canada has received with respect to the use of *Salvia divinorum*?**

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A7 – Health Canada has received four domestic adverse reaction reports related to the use of *Salvia divinorum* as a hallucinogen through the Canada Vigilance database. The number of reports and the nature of reactions reported are not adequate to characterize the risk to the general population. These data cannot be used to determine incidence of use in the general population, as Health Canada does not have any information about the number of individuals using or who have used *Salvia divinorum*.

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**If pressed: Q. Has Health Canada issued any kind of warning to Canadians about the use of *Salvia divinorum*?**

A. Health Canada is developing an It's Your Health (IYH) article on *Salvia divinorum* to help inform the general public about the risks associated with the use of this substance.

### **Background**

*Salvia divinorum* is a species of sage belonging to the mint family that is chewed or smoked in order to induce its psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are often described as unpleasant.

The leaves of this plant have been used traditionally for spiritual and medicinal purposes by the Mazatec Indians in Mexico for many years,

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago.

Data from a 2006 National Survey on Drug Use and Health Report, published by the U.S. Substance Abuse and Mental Health Services Administration has estimated that:

- 1.8 million persons aged 12 or older have used *Salvia divinorum* at least once in their lifetime, and approximately 750,000 did so in the past year.
- Use was more common among young adults (18 to 25 years old) as opposed to older adults (>26 years of age).
- Young adults were three times more likely than youths aged 12 to 17 to have used *Salvia divinorum* in the past year.

- Use was more common in males than females.

*Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a “legal” alternative to street drugs.

While some users have reported that the psychotropic effects of *Salvia divinorum* resemble those induced by other hallucinogens, such as LSD and phencyclidine, the overall experience appears to be quite unique.

**Prepared by:** Cheryl Tremblay, OCS, CSTD

**Approved by:**

[NAME] Director, Bureau of Policy and Regulatory Affairs, NHPD (pending)  
[NAME] Director, Marketed Biologics, Biotechnology and Natural Health Products Bureau,  
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DMO (pending)  
MO (pending)  
PCO (pending)

## ***Salvia divinorum***

### **The Issue**

Recently there have been reports suggesting that Canadian teens and young adults are using a substance called *Salvia divinorum* (*S. divinorum*) for its ability to produce hallucinations. Certain Web sites are also promoting the use of *S. divinorum* as a “legal” alternative to street drugs.

Street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastra, ska Maria pastora, ska pastora, diviner’s sage, magic mint, puff encens special, and salvia.

Health Canada recommends that you avoid using this substance because very little is known about the damage it may cause to the body, including the brain. There is also no way to predict how it will affect you with each use.

### **Background**

*S. divinorum* is a species of sage that belongs to the mint family. It is known to have psychotropic effects, which means it affects the mind and mental processes.

The leaves of this plant have been used traditionally for spiritual and medicinal purposes by the Mazatec Indians in Mexico for many years. Traditional use involves chewing the leaves or using them to make a tea for medicinal purposes (e.g., to treat such conditions as headache or stomach upset), or to induce a “mystical” or hallucinogenic experience for spiritual purposes.

**Comment [D1]:** This section re-inserted.

Products that claim to contain *S. divinorum* – or its main active ingredient, salvinorin A – are widely available on the Internet and are sold in various “head shops” and natural food stores. The products are sold in a number of formats, including seeds and plant cuttings for growing purposes. Fresh or dried leaves are intended to be chewed, swallowed or smoked. Liquid preparations are also available.

### **Risks of Using *Salvia divinorum***

*S. divinorum*'s effects, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations;
- dysphoria (feeling unwell, uneasy or unhappy);
- out-of-body experiences;
- uncontrollable laughter;
- loss of consciousness;
- short-term memory loss;
- lack of physical coordination;
- slurred speech and awkward sentence patterns.

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product;
- how much is used;
- the purity of the product (it may be mixed with other substances);
- how it is taken (e.g., chewed, swallowed or smoked);
- the user's mood and expectations.

A major concern about *S. divinorum* is that there have only been a few scientific studies about the way it affects the body and the brain. Scientists know which brain receptors are targeted by the active ingredient, salvinorin A, but very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or permanent damage;
- how it interacts with other substances, including other drugs, natural health products and alcohol.

The information regarding physical dependence or addiction to *S. divinorum* is unclear.

### **Minimizing Your Risk**

Health Canada recommends that you avoid using *S. divinorum*. Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs and other substances that distort

reality. (See the "Need More Info?" section below for links to resources that can help you with this.)

Also, remember that just because a drug is plant-based or "natural," it does not mean it is safe. Under certain conditions of use, *S. divinorum* meets the definition of a "natural health product" (NHP) under Health Canada's *Natural Health Products Regulations*. However, no NHPs containing this substance have been approved for sale in Canada. This means that products claiming to contain *S. divinorum* have not been reviewed by Health Canada for safety, efficacy or quality. As such, they may be counterfeit or contain other ingredients that pose risks to health, and consumers should apply the "buyer beware" principle.

Natural health products that have been reviewed and approved by Health Canada are labelled with one of the following:

- a Natural Product Number (NPN); or
- a Drug Identification Number - Homeopathic Medicine (DIN-HM).

### **The Legal Status of *Salvia divinorum***

**Comment [D2]:** Revise to be in line with response to question #5 in the media lines.

#### In Canada

Neither *S. divinorum* nor salvinorin A is currently regulated under the *Controlled Drugs and Substances Act* (CDSA). When assessing whether to add a substance to one of the Schedules to the CDSA, Health Canada considers the following factors:

- international requirements and trends in controlling the substance;
- similarity to other substances already regulated under the CDSA;
- whether there may be legitimate uses of the substance (e.g., potential health benefits, use in manufacturing, etc.);
- the potential for abuse and the risk of addiction associated with the substance;
- the extent of actual abuse of the substance in Canada and elsewhere;
- overall risk to public health and safety posed by the substance.

In the case of *S. divinorum*, there is simply not enough information available to determine whether regulation under the CDSA is the best option to manage the potential risks. Questions about the use of *S. divinorum* have been included in the 2008-2009 Youth Smoking Survey, the 2009 Canadian Alcohol and Drug Use Monitoring Survey and the 2009 Ontario Student Drug Use and Health Survey (OSDUHS). The results from the 2009 OSDUHS were published on November 18, 2009 and indicate that among responding students in Ontario, 4.4% reported using *Salvia divinorum* at least once in the past year. Further data from the two national surveys will be available in 2010. It is anticipated that such data will help address some of the information gaps about this substance and contribute to future decisions that Health Canada may make about this plant and its active ingredient. See the Need More Info? section below for more information on the surveys that are collecting information about *Salvia divinorum* use in Canada and for more detailed findings from the 2009 OSDUHS.

#### In Other Countries

Several countries (e.g., Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) have placed controls on the import and/or sale of *S. divinorum* and/or

salvinorin A. In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on their sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution (e.g., no sales to anyone under the age of 18).

### Health Canada's Role

Health Canada continues to collect and consider information regarding *S. divinorum* and continues to consult with key stakeholders, including health officials in other countries, and law enforcement officials here at home. This will assist in determining the most appropriate strategy to manage the risks associated with the use of *S. divinorum*, ~~including its possible~~ regulation under the *Controlled Drugs and Substances Act*.

*which may include*

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### ~~Reporting Adverse Reactions~~

**Comment [D3]:** This section deleted. As agreed during the meeting, this section should focus instead on reporting a complaint from a retail perspective. HPFB to provide this material.

### Need More Info?

For information about the Government of Canada's Anti-Drug Strategy, go to: <http://www.nationalantidrugstrategy.gc.ca/>. The Prevention section on this site has a number of helpful resources for parents, including "Tips on Talking to Your Teenager" and "What to Do if Your Teen is Using Drugs."

Information on natural health products and the *Natural Health Products Regulations* can be found at: <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php>

For more on the surveys that are collecting information about *Salvia divinorum* use in Canada, see:

The 2008-2009 Youth Smoking Survey, at: [http://www.yss.uwaterloo.ca/ysss\\_site\\_app/controller/index.cfm](http://www.yss.uwaterloo.ca/ysss_site_app/controller/index.cfm) and

The 2009 Canadian Alcohol and Drug Use Monitoring Survey, at: <http://www.hc-sc.gc.ca/hl-vs/drug-drogués/cadums-escad-eng.php>

The 2009 Ontario Student Drug Use and Health Survey, at: <http://www.camh.net/Research/osdus.html>

### Additional Resources:

U.S. Drug Enforcement Administration: Drugs and Chemicals of Concern: *Salvia divinorum* and Salvinorin A at: [http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)

U.S. Department of Health & Human Services, National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006 at:

<http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf>

For additional articles on health and safety issues go to the *It's Your Health* Web section at:

[www.healthcanada.gc.ca/iyh](http://www.healthcanada.gc.ca/iyh)

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

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Bronwyn Cline/HC-SC/GC/CA  
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To Cheryl Tremblay/HC-SC/GC/CA@HWC  
cc Diane Allan/HC-SC/GC/CA@HWC, Jocelyn  
Kula/HC-SC/GC/CA@HWC, Jodi  
Brown/HC-SC/GC/CA@HWC, Kimberly  
bcc

Subject Re: Fw: IYH Salvia Divinorum 

I'll talk to Lisa about updating the approval form once I have the media lines back from you, so that I can see what more is required.

Thanks,

Bronwyn Cline  
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To Bronwyn Cline/HC-SC/GC/CA@HWC  
cc Diane Allan/HC-SC/GC/CA@HWC, Jodi  
Brown/HC-SC/GC/CA@HWC, Kimberly  
Sorfleet/HC-SC/GC/CA@HWC, Jocelyn  
Kula/HC-SC/GC/CA@HWC  
Subject Fw: IYH Salvia Divinorum

FYI - We had received approval from NHPD through Lisa Mackay. Not sure if that is sufficient for the time being?

Cheryl

— Forwarded by Cheryl Tremblay/HC-SC/GC/CA on 2009-12-23 11:23 AM —

Lisa MacKay/HC-SC/GC/CA  
2009-12-18 03:04 PM

To Cheryl Tremblay/HC-SC/GC/CA@HWC  
cc Denis Arsenault/HC-SC/GC/CA@HWC, Jocelyn  
Kula/HC-SC/GC/CA@HWC  
Subject Re: IYH Salvia Divinorum 

Hi Cheryl,

NHPD is ok with the proposed modifications to the IYH on Salvia

Have a good weekend!

Lisa



Cheryl Tremblay/HC-SC/GC/CA



Cheryl  
Tremblay/HC-SC/GC/CA  
2009-12-17 02:45 PM

To Lisa MacKay/HC-SC/GC/CA@HWC  
cc Denis Arsenault/HC-SC/GC/CA@HWC, Jocelyn  
Kula/HC-SC/GC/CA@HWC  
Subject Re: IYH Salvia Divinorum

Hi again Lisa,

Do you anticipate that we would have to get HPFB to sign off if we were to include the following additional revision to the background section of the IYH on Salvia?

### Background

*S. divinorum* is a species of sage that belongs to the mint family. It is known to have psychotropic effects, which means it affects the mind and mental processes.

The leaves of this plant have been used traditionally for spiritual and medicinal purposes by the Mazatec Indians in Mexico for many years. ~~Traditional use involves chewing the leaves or using them to make a tea for medicinal purposes (e.g., to treat such conditions as headache or stomach-upset), or to induce a "mystical" or hallucinogenic experience for spiritual purposes.~~

Thanks,  
Cheryl Tremblay  
Policy and Regulatory Affairs Division / Division des politiques et affaires réglementaires  
Office of Controlled Substances / Bureau des substances contrôlées  
Controlled Substances and Tobacco Directorate / Direction des substances contrôlées et de la lutte au tabagisme  
Healthy Environments and Consumer Safety Branch / Direction générale de la santé environnementale et de la sécurité consommateurs  
Health Canada / Santé Canada  
Tel: (613) 954-6527 Fax: (613) 946-4224  
Lisa MacKay/HC-SC/GC/CA

Lisa MacKay/HC-SC/GC/CA  
2009-12-16 10:15 AM

To Cheryl Tremblay/HC-SC/GC/CA@HWC  
cc Denis Arsenault/HC-SC/GC/CA@HWC, Jocelyn  
Kula/HC-SC/GC/CA@HWC  
Subject Re: IYH Salvia Divinorum

Hi Cheryl,

No I think it should be fine as you are only adding the information on the Survey.

Thank you

Lisa Mackay  
It's Your Health Project Manager/Gestionnaire du projet Votre santé et vous  
Public Affairs Division | Division des affaires publiques  
Public Affairs, Consultation and Communications Branch/ Direction générale des affaires publiques, de la  
consultation et des communications  
Health Canada | Santé Canada  
Tel 613.954.0105  
Fax 613.952.8644  
Lisa\_Mackay@hc-sc.gc.ca

Cheryl Tremblay/HC-SC/GC/CA



Cheryl  
Tremblay/HC-SC/GC/CA  
2009-12-16 10:12 AM

To Lisa MacKay/HC-SC/GC/CA@HWC  
cc Jocelyn Kula/HC-SC/GC/CA@HWC, Denis  
Arsenault/HC-SC/GC/CA@HWC  
Subject IYH Salvia Divinorum

Hi Lisa,

Given the amount of time that has passed since the IYH on *Salvia Divinorum* has been in the formal approvals process we have been asked to review the content to ensure that it is as current as possible before it is approved by our ADM. I have attached the revisions that we would like to propose below. Do you anticipate that these changes would require HPFB sign off again?



IYH - Salvia divinorum - June 8 2009\_HECSB Proposed Revisions\_Dec 16 2009.wpd

Thank you,  
Cheryl Tremblay  
Policy and Regulatory Affairs Division / Division des politiques et affaires réglementaires  
Office of Controlled Substances / Bureau des substances contrôlées  
Controlled Substances and Tobacco Directorate / Direction des substances contrôlées et de la lutte au  
tabagisme  
Healthy Environments and Consumer Safety Branch / Direction générale de la santé environnementale et  
de la sécurité consommateurs  
Health Canada / Santé Canada  
Tel: (613) 954-6527 Fax: (613) 946-4224

## ***Salvia divinorum***

### **The Issue**

Recently there have been reports suggesting that Canadian teens and young adults are using a substance called *Salvia divinorum* (*S. divinorum*) for its ability to produce hallucinations. Certain Web sites are also promoting the use of *S. divinorum* as a “legal” alternative to street drugs.

Street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastra, ska Maria pastora, ska pastora, diviner’s sage, magic mint, puff encens special, and salvia.

Health Canada recommends that you avoid using this substance because very little is known about the damage it may cause to the body, including the brain. There is also no way to predict how it will affect you with each use.

### **Background**

*S. divinorum* is a species of sage that belongs to the mint family. It is known to have psychotropic effects, which means it affects the mind and mental processes.

The leaves of this plant have been used traditionally by the Mazatec Indians in Mexico for many years. Traditional use involves chewing the leaves or using them to make a tea for medicinal purposes (e.g., to treat such conditions as headache or stomach upset), or to induce a “mystical” or hallucinogenic experience for spiritual purposes.

Products that claim to contain *S. divinorum* – or its main active ingredient, salvinorin A – are widely available on the Internet and are sold in various “head shops” and natural food stores. The products are sold in a number of formats, including seeds and plant cuttings for growing purposes. Fresh or dried leaves are intended to be chewed, swallowed or smoked. Liquid preparations are also available.

### **Risks of Using *Salvia divinorum***

*S. divinorum*’s effects, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations;
- dysphoria (feeling unwell, uneasy or unhappy);
- out-of-body experiences;
- uncontrollable laughter;
- loss of consciousness;
- short-term memory loss;
- lack of physical coordination;
- slurred speech and awkward sentence patterns.

There is no way to predict what effect this substance may have on you. In addition, the effects

may differ from one use to the next, depending on factors such as:

- the potency of the product;
- how much is used;
- the purity of the product (it may be mixed with other substances);
- how it is taken (e.g., chewed, swallowed or smoked);
- the user's mood and expectations.

A major concern about *S. divinorum* is the fact that there have only been a few scientific studies about the way it affects the body and the brain. Scientists know which brain receptors are targeted by the active ingredient, salvinorin A, but very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or permanent damage;
- how it interacts with other substances, including other drugs, natural health products and alcohol.

The information regarding physical dependence or addiction to *S. divinorum* is unclear, although it appears the potential for either is low.

### **Minimizing Your Risk**

Health Canada recommends that you avoid using *S. divinorum*. Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs and other substances that distort reality. (See the "Need More Info?" section below for links to resources that can help you with this.)

Also, remember that just because a drug is plant-based or "natural," it does not mean it is safe. Under certain conditions of use, *S. divinorum* meets the definition of a "natural health product" (NHP) under Health Canada's *Natural Health Products Regulations*. However, no NHPs containing this substance have been approved for sale in Canada. This means that products claiming to contain *S. divinorum* have not been reviewed by Health Canada for safety, efficacy or quality. As such, they may be counterfeit or contain other ingredients that pose risks to health, and consumers should heed the "buyer beware" principle.

Natural health products that have been reviewed and approved by Health Canada are labelled with one of the following:

- a Natural Product Number (NPN); or
- a Drug Identification Number - Homeopathic Medicine (DIN-HM).

### **The Legal Status of *Salvia divinorum***

#### In Canada

Neither *S. divinorum* nor salvinorin A is currently regulated under the *Controlled Drugs and Substances Act* (CDSA). When assessing whether to add a substance to one of the Schedules to the CDSA, Health Canada considers the following factors:

- international requirements and trends in controlling the substance;

- similarity to other substances already regulated under the CDSA;
- whether there may be legitimate uses of the substance (e.g., potential health benefits, use in manufacturing, etc.);
- the potential for abuse and the risk of addiction associated with the substance;
- the extent of actual abuse of the substance in Canada and elsewhere;
- overall risk to public health and safety posed by the substance.

In the case of *S. divinorum*, there is simply not enough information available to determine whether regulation under the CDSA is the best option to manage the potential risks. Questions about the use of *S. divinorum* have been included in the 2008-2009 Youth Smoking Survey, and the 2009 Canadian Alcohol and Drug Use Monitoring Survey; and the 2009 Ontario Student Drug Use and Health Survey (OSDUHS). The results from the 2009 OSDUHS were published on November 18, 2009 and indicate that among responding students in Ontario in 2009, 4.4% reported using *Salvia divinorum* at least once in the past year. Data like this, and that from the two national surveys which will be available in 2010, ~~these survey results will help fill some of these information gaps~~ and contribute to future decisions that Health Canada may make about this plant and its active ingredient. ~~The data, however, will not likely be available until 2010.~~ See the Need More Info? section below for more information on the surveys that are collecting information about *Salvia divinorum* use in Canada and for more detailed findings from the 2009 OSDUHS.

#### In Other Countries

Several countries (e.g., Australia, Belgium, Denmark, Germany, Japan, Sweden, Italy, Spain, Finland and South Korea) have placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on their sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution (e.g., no sales to anyone under the age of 18).

#### **Health Canada's Role**

Health Canada continues to collect and consider information regarding *S. divinorum* and continues to consult with key stakeholders, including health officials in other countries, and law enforcement officials here at home. This will assist in determining the most appropriate strategy to manage the risks associated with the use of *S. divinorum*.

#### **Reporting Adverse Reactions**

You can report any adverse reactions to the Canada Vigilance Program by one of the following three ways:

- Report online at the MedEffect™ Canada Web site
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and either:
- Fax toll-free to 1-866-678-6789

- Mail to: Canada Vigilance Program  
Health Canada  
AL 0701C  
Ottawa, ON K1A 0K9

To have postage pre-paid, download the postage paid label from the MedEffect™ Canada Web site. The Canada Vigilance Reporting Form and the adverse reaction reporting guidelines may also be obtained via this Web site.

### **Need More Info?**

For information about the Government of Canada's Anti-Drug Strategy, go to: <http://www.nationalantidrugstrategy.gc.ca/>. The Prevention section on this site has a number of helpful resources for parents, including "Tips on Talking to Your Teenager" and "What to Do if Your Teen is Using Drugs."

Information on natural health products and the *Natural Health Products Regulations* can be found at: <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php>

For more on the surveys that are collecting information about *Salvia divinorum* use in Canada, see:

The 2008-2009 Youth Smoking Survey, at: [http://www.yss.uwaterloo.ca/ysss/site\\_app/controller/index.cfm](http://www.yss.uwaterloo.ca/ysss/site_app/controller/index.cfm) and

The 2009 Canadian Alcohol and Drug Use Monitoring Survey, at: <http://www.hc-sc.gc.ca/hl-vs/drug-drogues/cadums-escad-eng.php>

The 2009 Ontario Student Drug Use and Health Survey, at: <http://www.camh.net/Research/osdus.html>

### **Additional Resources:**

U.S. Drug Enforcement Administration: Drugs and Chemicals of Concern: *Salvia divinorum* and Salvinorin A at: [http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)

U.S. Department of Health & Human Services, National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006 at: <http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf>

For additional articles on health and safety issues go to the *It's Your Health* Web section at: <http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/index-eng.php>

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

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ISBN#

s.19(1)

----- 0 -----

Writer: Sue Lumsden [REDACTED]

Version/date: Draft Seven. May 27, 2009. Removes highlighter marking changes in Draft Six, which have been agreed to by the Program Contacts. Replaces reference (and link) to the Ontario Student Drug Use and Health Survey with a reference (and link) to the (national) Canadian Alcohol and Drug Use Monitoring Survey.

Contacts: HECSB: Jocelyn Kula, Cheryl Tremblay, Brittany Sauvé  
HPFB-NHPD: Valerie Hurry, Robin Marles  
HPFB-MHPD: Scott Jordan (Draft Two only), Robert Leitch, Mano Murty

**Lisa MacKay/HC-SC/GC/CA**  
2009-12-23 02:12 PM

To Cheryl Tremblay/HC-SC/GC/CA@HWC  
cc Jocelyn Kula/HC-SC/GC/CA@HWC, Diane  
Allan/HC-SC/GC/CA@HWC, Kimberly  
Sorfleet/HC-SC/GC/CA@HWC, Jodi  
bcc  
Subject Fw: IYH on Salvia Divinorum

Hi Cheryl,

Here is the latest email approval from HPFB and here is the formal approval slip from way back:



Apps Slip DG&ADM HPFB Salvia May2009.wpd

Thanks

**Lisa Mackay**  
It's Your Health Project Manager/Gestionnaire du projet Votre santé et vous  
Public Affairs Division | Division des affaires publiques  
Public Affairs, Consultation and Communications Branch/ Direction générale des affaires publiques, de la  
consultation et des communications  
Health Canada | Santé Canada  
Tel 613.954.0105  
Fax 613.952.8644  
Lisa\_Mackay@hc-sc.gc.ca

— Forwarded by Lisa MacKay/HC-SC/GC/CA on 2009-12-23 02:10 PM —

**Elizabeth**  
Keeping/HC-SC/GC/CA  
2009-12-18 02:59 PM

To Lisa MacKay/HC-SC/GC/CA@HWC  
cc Jennifer Peddle/HC-SC/GC/CA@HWC  
Subject Fw: IYH on Salvia Divinorum

Hi Lisa,

Just got the okay on this one.

Cheers,  
Beth

— Forwarded by Elizabeth Keeping/HC-SC/GC/CA on 2009-12-18 02:58 PM —

**Brook**  
Bertrand/HC-SC/GC/CA  
2009-12-18 02:56 PM

To Elizabeth Keeping/HC-SC/GC/CA@HWC  
cc  
Subject Fw: IYH on Salvia Divinorum



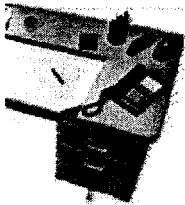
Hi Beth:

NHPD is ok with the proposed modifications to the IYH on Salvia

Thanks

Brook Bertrand  
Natural Health Products Directorate /  
Direction des produits de santé naturels  
Health Canada / Santé Canada  
613-948-3537

----- Forwarded by Brook Bertrand/HC-SC/GC/CA on 2009-12-18 02:54 PM -----



Robin Marles/HC-SC/GC/CA

2009-12-18 02:47 PM

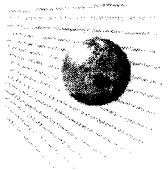
To Brook Bertrand/HC-SC/GC/CA@HWC

cc

Subject Re: Fw: IYH on Salvia Divinorum

That would be fine.

Robin  
Brook Bertrand/HC-SC/GC/CA



Brook  
Bertrand/HC-SC/GC/CA

2009-12-18 01:12 PM

To Robin Marles/HC-SC/GC/CA@HWC

cc Laura Cooney/HC-SC/GC/CA@HWC

Subject Fw: IYH on Salvia Divinorum

Hi Robin:

Would you be comfortable with the following modification to an *It's Your Health* article on Salvia:

### **Background**

*S. divinorum* is a species of sage that belongs to the mint family. It is known to have psychotropic effects, which means it affects the mind and mental processes.

The leaves of this plant have been used traditionally for spiritual and medicinal purposes by the Mazatec Indians in Mexico for many years. ~~Traditional use involves chewing the leaves or using them to make a tea for medicinal purposes (e.g., to treat such conditions as headache or stomach upset), or to induce a "mystical" or hallucinogenic experience for spiritual purposes.~~

Brook Bertrand  
Natural Health Products Directorate /  
Direction des produits de santé naturels  
Health Canada / Santé Canada  
613-948-3537

----- Forwarded by Brook Bertrand/HC-SC/GC/CA on 2009-12-18 01:11 PM -----

Elizabeth  
Keeping/HC-SC/GC/CA  
2009-12-17 04:08 PM

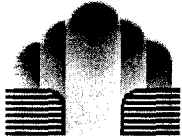
To Brook Bertrand/HC-SC/GC/CA@HWC  
cc Jennifer Piercey/HC-SC/GC/CA@HWC  
Subject Fw: IYH on Salvia Divinorum

Hi Brook,

Can you take a look at this.

Thanks,  
Beth

----- Forwarded by Elizabeth Keeping/HC-SC/GC/CA on 2009-12-17 04:07 PM -----



Jennifer  
Peddle/HC-SC/GC/CA  
2009-12-17 04:03 PM

To Elizabeth Keeping/HC-SC/GC/CA@HWC  
cc Blossom Leung/HC-SC/GC/CA@HWC  
Subject Fw: IYH on Salvia Divinorum

See below.

Jennifer Peddle  
A/Chief, Corporate Communications Services  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques de la  
consultation et des communications  
Health Canada | Santé Canada  
613.868.5835 (cell/portable)

----- Forwarded by Jennifer Peddle/HC-SC/GC/CA on 2009-12-17 04:03 PM -----

Lisa MacKay/HC-SC/GC/CA  
2009-12-17 03:27 PM

To Jennifer Peddle/HC-SC/GC/CA@HWC  
cc Blossom Leung/HC-SC/GC/CA@HWC  
Subject Re: IYH on Salvia Divinorum

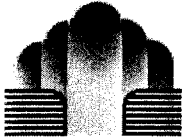
Hi,

I think we're getting close on the Salvia article. HECSB would like to know if they make this change will it need to be re-approved in HPFB:

## Background

*S. divinorum* is a species of sage that belongs to the mint family. It is known to have psychotropic effects, which means it affects the mind and mental processes.

The leaves of this plant have been used traditionally for spiritual and medicinal purposes by the Mazatec Indians in Mexico for many years. ~~Traditional use involves chewing the leaves or using them to make a tea for medicinal purposes (e.g., to treat such conditions as headache or stomach-upset), or to induce a "mystical" or hallucinogenic experience for spiritual purposes.~~  
Jennifer Peddle/HC-SC/GC/CA



Jennifer  
Peddle/HC-SC/GC/CA  
2009-10-05 09:52 AM

To Lisa MacKay/HC-SC/GC/CA@HWC  
cc Blossom Leung/HC-SC/GC/CA@HWC  
Subject IYH on Salvia Divinorum

Hi Lisa,  
Do you know if the IYH on Salvia Divinorum was published? If not, would you be able to send me the latest draft? Thanks!

Jennifer Peddle  
Senior Communications Advisor -HPFB | Conseillère principale en communications - DGPSA  
Strategic Communications Directorate | Direction des communications stratégique  
Public Affairs, Consultations and Regions Branch (PACRB) | Direction générale des affaires publiques, de  
la consultation et des régions (DGAPCR)  
Health Canada | Santé Canada  
613.957.8483 (office/bureau)  
613.957.8805 (fax/télécopieur)  
613.868.5835 (cell/portable)

## ***It's Your Health***

***(A Health Canada/Public Health Agency Publication)***

**Comments ♦ Commentaires**

It's Your Health articles answer frequently asked questions from the general public and provide health protection and promotion advice. The articles are distributed to: doctors and their clients, teachers and students, magazine editors and their subscribers, other federal and provincial departments, private firms, and Health Canada/Public Health Agency of Canada employees. This publication is also posted on the Health Canada and Public Health Agency Web sites.

<b>Subject ♦ Sujet:</b>	<b>Approval deadline Échéance d'approbation</b>
<b>Salvia divinorum</b>	<b>June 12, 2009</b>

<b>Branch: HPFB</b>	<b>Comm Contact: Blossom Leung 948-7799</b>
<b>Coordinator: Lisa Mackay 954-0105</b>	<b>Writer: Sue Lumsden</b>
<b>Program Contact: Valerie Hurry (NHPD), and Robert Leitch and Mano Murty (MHPD)</b>	

Approvals Approbations	Signing Authority Autorisé par	Signature	Date
1. Programme Director	Robin Marles	Approved	June 1, 2009
2. Programme Director	Duc Vu	Approved	June 1, 2009
3. Programme DG	Michelle Boudreau	Approved	June 1, 2009
4. Programme DG	Chris Turner	Approved	June 4, 2009
4. Communications Executive	Jennifer Peddle for Ken Polk	Approved	June 4, 2009
5. ADM	Meena Ballentyne	Approved	June 5, 2009
6. Risk/Crisis Communications	Kathy Howard		

Please return to ♦ Veuillez retourner à : Lisa Mackay 954-0105	Room ♦ Pièce: 1277D BC FAX: 952-8644
--	--

000586

**Salvia divinorum (Redline) – CSTD Proposed Revisions - December 23, 2000**

**The Issue**

Recently there have been reports suggesting that Canadian teens and young adults are using a substance called *Salvia divinorum* (*S. divinorum*) for its ability to produce hallucinations. Certain Web sites are also promoting the use of *S. divinorum* as a “legal” alternative to street drugs.

Street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastra, ska Maria pastora, ska pastora, diviner’s sage, magic mint, puff encens special, and salvia.

Health Canada recommends that you avoid using this substance because very little is known about the damage it may cause to the body, including the brain. There is also no way to predict how it will affect you with each use.

**Background**

*S. divinorum* is a species of sage that belongs to the mint family. It is known to have psychotropic effects, which means it affects the mind and mental processes.

The leaves of this plant have been used traditionally for spiritual and medicinal purposes by the Mazatec Indians in Mexico for many years.

Products that claim to contain *S. divinorum* – or its main active ingredient, salvinorin A – are widely available on the Internet and are sold in various “head shops” and natural food stores. The products are sold in a number of formats, including seeds and plant cuttings for growing purposes. Fresh or dried leaves are intended to be chewed, swallowed or smoked. Liquid preparations are also available.

**Deleted:** Traditional use involves chewing the leaves or using them to make a tea for medicinal purposes (e.g., to treat such conditions as headache or stomach upset), or to induce a “mystical” or hallucinogenic experience for spiritual purposes.

### Risks of Using *Salvia divinorum*

*S. divinorum*'s effects, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations;
- dysphoria (feeling unwell, uneasy or unhappy);
- out-of-body experiences;
- uncontrollable laughter;
- loss of consciousness;
- short-term memory loss;
- lack of physical coordination;
- slurred speech and awkward sentence patterns.

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product;
- how much is used;
- the purity of the product (it may be mixed with other substances);
- how it is taken (e.g., chewed, swallowed or smoked);
- the user's mood and expectations.

A major concern about *S. divinorum* is that there have only been a few scientific studies about the way it affects the body and the brain. Scientists know which brain receptors are targeted by the active ingredient, salvinorin A, but very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or permanent damage;
- how it interacts with other substances, including other drugs, natural health products and alcohol.

**Deleted:** the fact

The information regarding physical dependence or addiction to *S. divinorum* is unclear, although it appears the potential for either is low.

### Minimizing Your Risk

Health Canada recommends that you avoid using *S. divinorum*. Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs and other substances that distort

reality. (See the "Need More Info?" section below for links to resources that can help you with this.)

Also, remember that just because a drug is plant-based or "natural," it does not mean it is safe. Under certain conditions of use, *S. divinorum* meets the definition of a "natural health product" (NHP) under Health Canada's *Natural Health Products Regulations*. However, no NHPs containing this substance have been approved for sale in Canada. This means that products claiming to contain *S. divinorum* have not been reviewed by Health Canada for safety, efficacy or quality. As such, they may be counterfeit or contain other ingredients that pose risks to health, and consumers should apply the "buyer beware" principle.

Deleted: heed

Natural health products that have been reviewed and approved by Health Canada are labelled with one of the following:

- a Natural Product Number (NPN); or
- a Drug Identification Number - Homeopathic Medicine (DIN-HM).

### The Legal Status of *Salvia divinorum*

#### In Canada

Neither *S. divinorum* nor salvinorin A is currently regulated under the *Controlled Drugs and Substances Act* (CDSA). When assessing whether to add a substance to one of the Schedules to the CDSA, Health Canada considers the following factors:

- international requirements and trends in controlling the substance;
- similarity to other substances already regulated under the CDSA;
- whether there may be legitimate uses of the substance (e.g., potential health benefits, use in manufacturing, etc.);
- the potential for abuse and the risk of addiction associated with the substance;
- the extent of actual abuse of the substance in Canada and elsewhere;
- overall risk to public health and safety posed by the substance.

In the case of *S. divinorum*, there is simply not enough information available to determine whether regulation under the CDSA is the best option to manage the potential risks. Questions about the use of *S. divinorum* have been included in the 2008-2009 Youth Smoking Survey, the 2009 Canadian Alcohol and Drug Use Monitoring Survey, and the 2009 Ontario Student Drug Use and Health Survey (OSDUHS). The results from the 2009 OSDUHS were published on November 18, 2009 and indicate that among responding students in Ontario, 4.4% reported using *Salvia divinorum* at least once in the past year. Further data from the two national surveys will be available in 2010. It is anticipated that such data will help address some of the information gaps about this substance and contribute to future decisions that Health Canada may make about this plant and its active ingredient. See the Need More Info? section below for more information on the surveys that are collecting information about *Salvia divinorum* use in Canada and for more detailed findings from the 2009 OSDUHS.

Deleted: and

Deleted: ,

Deleted: these survey results

Deleted: fill

Deleted: The data, however, will not likely be available until 2010.

#### In Other Countries

Several countries (e.g., Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) have placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on their sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution (e.g., no sales to anyone under the age of 18).

Deleted: Sweden  
Deleted: Spain.  
Deleted: Finland and  
Comment [C1]: Alphabetize?

### Health Canada's Role

Health Canada continues to collect and consider information regarding *S. divinorum* and continues to consult with key stakeholders, including health officials in other countries, and law enforcement officials here at home. This will assist in determining the most appropriate strategy to manage the risks associated with the use of *S. divinorum*.

### Reporting Adverse Reactions

You can report any adverse reactions to the Canada Vigilance Program by one of the following three ways:

- Report online at the MedEffect™ Canada Web site
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and either:
- Fax toll-free to 1-866-678-6789
- Mail to: Canada Vigilance Program  
Health Canada  
AL 0701C

Ottawa, ON K1A 0K9

To have postage pre-paid, download the postage paid label from the MedEffect™ Canada Web site. The Canada Vigilance Reporting Form and the adverse reaction reporting guidelines may also be obtained via this Web site.

### Need More Info?

For information about the Government of Canada's Anti-Drug Strategy, go to: <http://www.nationalantidrugstrategy.gc.ca/>. The Prevention section on this site has a number of helpful resources for parents, including "Tips on Talking to Your Teenager" and "What to Do if Your Teen is Using Drugs."

Information on natural health products and the *Natural Health Products Regulations* can be found at: <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php>



For more on the surveys that are collecting information about *Salvia divinorum* use in Canada,  
see:

The 2008-2009 Youth Smoking Survey, at:  
[http://www.yss.uwaterloo.ca/ysss/site\\_app/controller/index.cfm](http://www.yss.uwaterloo.ca/ysss/site_app/controller/index.cfm) and

The 2009 Canadian Alcohol and Drug Use Monitoring Survey, at: <http://www.hc-sc.gc.ca/hl-vs/drug-drogués/cadums-escad-eng.php>

The 2009 Ontario Student Drug Use and Health Survey, at:  
<http://www.camh.net/Research/osdus.htm>

**Additional Resources:**

U.S. Drug Enforcement Administration: Drugs and Chemicals of Concern: *Salvia divinorum* and  
Salvinorin A at: [http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)

U.S. Department of Health & Human Services, National Survey on Drug Use and Health: Use of  
Specific Hallucinogens: 2006 at:  
<http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf>

For additional articles on health and safety issues go to the *It's Your Health* Web section at:

<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/index-eng.php>

<http://www.hc-sc.gc.ca/english/iyh/index.htm>

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

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Writer: Sue Lumsden [REDACTED]

Version/date: Draft Seven. May 27, 2009. Removes highlighter marking changes in Draft Six,  
which have been agreed to by the Program Contacts. Replaces reference (and link)  
to the Ontario Student Drug Use and Health Survey with a reference (and link) to  
the (national) Canadian Alcohol and Drug Use Monitoring Survey.

Contacts: HECSB: Jocelyn Kula, Cheryl Tremblay, Brittany Sauvé  
HPFB-NHPD: Valerie Hurry, Robin Marles  
HPFB-MHPD: Scott Jordan (Draft Two only), Robert Leitch, Mano Murty

## **CESAR – Centre for Substance Abuse Research – University of Maryland**

### **Salvia Divinorum**

#### **Profile**

Salvia divinorum, also known as *S. divinorum* or Salvia, is a hallucinogenic plant native to the northeastern Sierra Mazateca mountain region of Mexico where the native Mazatecs have used it for centuries as a healing and divining tool. Though this is the only known location where this perennial herb grows naturally, Salvia is cultivated in some areas of the United States.<sup>1</sup> Salvia divinorum is not likely to be found at a local nursery although it is one among many of the cooking and medicinal herbs in the mint family. It is also one among many that share the genus name Salvia; for example, Salvia officinalis, is also known as common sage.<sup>2</sup> The psychoactive component (that which produces the hallucinogenic effects) of Salvia divinorum, Salvinorin A, is the most potent naturally occurring hallucinogen.<sup>3</sup> Currently, neither Salvia divinorum nor its active ingredient Salvinorin A are listed as controlled substances in the United States, though there are efforts to criminalize Salvia and its active ingredients and classify them as Schedule I controlled substances.<sup>4</sup> To date, Australia is the only country that has criminalized Salvia divinorum and its active ingredients.<sup>5</sup>

#### **History**

The first recorded mention of Salvia was made in 1938 by Jean B. Johnson, who heard of Mazatecs making a tea from the leaves of "hierba Maria," which induced visions in users. In 1952, Roberto G. Weitlaner, Johnson's father-in-law, reported the preparation of "yerba de Maria."<sup>6</sup> R. Gordon Wasson and Albert Hofmann acquired the first specimen of Salvia divinorum from the Mazatecs in 1962; they described it as "a less desirable substitute" for hallucinogenic mushrooms.<sup>7</sup>

It was not until August 2002 that researchers discovered that Salvia divinorum acts at the kappa opiate receptor (KOR) site, where much of human perception is regulated. This puts Salvia divinorum in a class of drugs known as KOR agonists, which are thought to play psychotherapeutic roles in perception altering diseases such as schizophrenia and Alzheimer's disease.<sup>8</sup>

#### **Back to Top**

#### **Methods of Use**

Only when enough of Salvia's highly active compound, Salvinorin A, is absorbed through the oral mucosa and into the blood stream can a psychoactive effect be produced.<sup>9</sup> There are several methods of ingesting Salvia with varying durations of hallucinogenic effects.

- Dried leaves of Salvia can be smoked like marijuana, in a bong, pipe, or as a joint, with effects lasting up to 15 minutes. Fresh leaves of Salvia can be chewed and swallowed or chewed as a quid.<sup>10</sup>
- When chewed as a quid, the leaves of Salvia produce extractions of Salvinorin A before the leaves are removed from the mouth. The extractions are absorbed through the oral mucosa and produce visual hallucinations, lasting 1 to 2 hours; the longer the herb remains in the mouth, the stronger the effect will be.<sup>11</sup>
- Salvinorin A extracts can be mixed in a drink or vaporized and inhaled
- When Salvia's leaves are crushed and the extracted Salvinorin A can be mixed with water to make a drink. Since Salvinorin A is deactivated by the gastrointestinal system before entering the blood stream this method may produce a more moderate effect than other methods.<sup>12</sup>
- Salvinorin A can also be vaporized and inhaled-Salvinorin A is heated on a piece of tin foil and the vapors are inhaled through a glass pipe.<sup>13</sup>

#### **Psychological and Physical Effects**

Recent research suggests that Salvia divinorum acts at the kappa opiate receptor (KOR) site of the brain where much of human perception is regulated.<sup>14</sup> Although the Mazatec Indians have been using this herb for centuries with no obvious ill effects, it is still unclear whether Salvia divinorum causes long-term effects on the brain or on the rest of the body. There have been no reports of health problems or hospitalizations as a result of Salvia use, few dangers related to its use have been identified, and no evidence exists that it is addictive.<sup>15</sup>

Although the dosage ingested and the method of ingestion affects the user's experience, some common effects include:

- Intense hallucinations, such as sensations of traveling through time and space, of floating or flying; sensations of twisting and spinning, heaviness or lightness of the body, and "soreness."<sup>16</sup>
- Less intense effects (that occur only when the eyes are closed) include visual hallucinations of various patterns and shapes. The hallucinogenic visions produced by this herb terminate when interrupted by noise or light.<sup>17</sup>

Physical effects include:<sup>18</sup>

- Dizziness
- Nausea
- Lack of coordination
- Slurred speech and awkward sentence patterns
- Decreased heart rate
- Chills

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### Terminology

Many of the names used for Salvia divinorum indicate how the Mazatecs honor this herb for its healing and divination qualities; they believe it is the incarnation of the Virgin Mary. It has also been reported that visions of a woman are common during hallucinations. The genus name, Salvia, comes from the Latin word, salvare-meaning "to save," while the specific name, divinorum, means "of the seers."

### English

- Leaves (or herb) of the Shepherdess
- Leaves of Mary, the Shepherdess
- The Female
- Sage of the Seers
- Magic Mint
- Diviner's Mint
- Diviner's Sage

### Spanish

- Hojas de la Pastora
- Hojas de Maria Pastora
- La hembra
- Hierba (yerba) Maria
- La Maria

### Mazatec

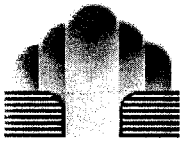
- Ska Pastora
- Ska Maria Pastora

**Links**

DEA: Drugs and Chemicals of Concern: Salvia Divinorum, ska Maria Pastora, Salvia  
(Salvinorin A, Divinorin A)  
NDIC Information Bulletin: Salvia Divinorum

**Footnotes**

- <sup>1</sup> Rovinsky, S.A., and Cizadlo, G.R., 1998, Salvia divinorum Epling et Jativa-M. (Labiatae): An Ethnopharmacological Investigation, The McNair Scholarly Review, 3: 142-156.
- <sup>2</sup> Boire, R.G., Russo, E., Fish, A.R., Bowman, J., 2001, Salvia divinorum: Information concerning the plant and its active principle, The Center for Cognitive Liberty & Ethic (CCLE); Valdes, L.J., Diaz, J.L., and Paul, A.G., 1983, Ethnopharmacology of Ska Maria Pastora (Salvia Divinorum, Epling and Jativa-M.), Journal of Ethnopharmacology, 7: 287-312.
- <sup>3</sup> Ott, J., 1996, Salvia divinorum Epling et Jativa, Eleusis, 4: 31-39; Valdes, L.J., 1994, Salvia divinorum and the Unique Diterpene Hallucinogen, Salvinorin (Divinorin) A, Journal of Psychoactive Drugs, 26(3): 277-283.
- <sup>4</sup> Boire, R.G., Russo, E., Fish, A.R., Bowman, J., 2001.
- <sup>5</sup> Epstein, R.J., 2002, Mexican Plant is Used as Legal Marijuana Alternative, Wisconsin State Journal, A1.
- <sup>6</sup> Rovinsky, S.A., and Cizadlo, G.R., 1998; Valdes, L.J., Diaz, J.L., and Paul, A.G., 1983.
- <sup>7</sup> Wasson, R. Gordon, 1962, A new Mexican psychotropic drug from the mint family, Botanical Museum Leaflets Harvard University, 20(3): 77-84.
- <sup>8</sup> Boire, R.G., Russo, E., Fish, A.R., Bowman, J., 2001; Roth, B.L., Baner, K., Westkaemper, R., Siebert, D., Rice, K.C., Steinberg, S., Ernsberger P., Rothman, R.B., 2002, Salvinorin A: A potent naturally occurring nonnitrogenous kappa opioid selective agonist. Proc Natl Acad Sci.: 99(18): 11934-11939.
- <sup>9</sup> Siebert, D.J., 1994, Salvia divinorum and Salvinorin A: new pharmacological findings, Journal of Ethnopharmacology, 34: 53-56.
- <sup>10</sup> Halpern, J.H., 2004, Hallucinogens and dissociative agents naturally growing in the United States, Pharmacology & Therapeutics: 102(2):131-138; Ott, J., 1996; Valdes, L.J., 1994.
- <sup>11</sup> Ott, J., 1996; Siebert, D.J., 1994.
- <sup>12</sup> Ibid.
- <sup>13</sup> Ott, J., 1996; Siebert, D.J., 1994; Valdes, L.J., 1994.
- <sup>14</sup> Roth, B.L., Baner, K., Westkaemper, R., Siebert, D., Rice, K.C., Steinberg, S., Ernsberger P., Rothman, R.B., 2002.
- <sup>15</sup> Boire, R.G., Russo, E., Fish, A.R., Bowman, J., 2001.
- <sup>16</sup> Rovinsky, S.A., and Cizadlo, G.R., 1998; Valdes, L.J., 1994; Valdes, L.J., Diaz, J.L., and Paul, A.G., 1983.
- <sup>17</sup> Valdes, L.J., Diaz, J.L., and Paul, A.G., 1983.
- <sup>18</sup> Valdes, L.J., 1994; Valdes, L.J., Diaz, J.L., and Paul, A.G., 1983.
- <sup>19</sup> Boire, R.G., Russo, E., Fish, A.R., Bowman, J., 2001; Ott, J., 1996; Rovinsky, S.A., and Cizadlo, G.R., 1998; Valdes, L.J., 2001, The Early History of Salvia divinorum, The Entheogen Review, 10(3): 73-75; Valdes, L.J., Diaz, J.L., and Paul, A.G., 1983; Wasson, R. Gordon, 1962.



Jocelyn Kula/HC-SC/GC/CA  
2010-01-04 07:22 AM

To Cheryl Tremblay/HC-SC/GC/CA@HWC  
cc  
bcc  
Subject Fw: Paul's comment on Salvia IYH

same

---

Jocelyn Kula  
Manager/ Gestionnaire  
Policy and Regulatory Affairs Division/ Division des politiques et affaires réglementaires  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
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----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2010-01-01 04:17 PM -----



Stephanie  
Szick/HC-SC/GC/CA  
2009-11-27 04:21 PM

To Jocelyn Kula/HC-SC/GC/CA@HWC  
cc  
Subject Fw: Paul's comment on Salvia IYH

as per our conversation

----- Forwarded by Stephanie Szick/HC-SC/GC/CA on 2009-11-27 04:20 PM -----



Stephanie  
Szick/HC-SC/GC/CA  
2009-11-27 04:16 PM

To Cathy A Sabiston/HC-SC/GC/CA, Jodi  
Brown/HC-SC/GC/CA, Diane Allan/HC-SC/GC/CA  
cc Kimberly Sorfleet/HC-SC/GC/CA@HWC  
Subject Fw: Paul's comment on Salvia IYH

the reply provide to Hayden in June.

----- Forwarded by Stephanie Szick/HC-SC/GC/CA on 2009-11-27 04:15 PM -----

Jay Khosla/HC-SC/GC/CA  
2009-06-23 07:45 PM

To Hayden Lansdell/HC-SC/GC/CA@HWC  
cc Stephanie Szick/HC-SC/GC/CA@HWC, Diane  
Allan/HC-SC/GC/CA@HWC, Paula  
Robert/HC-SC/GC/CA@HWC, Tacha  
Lehouillier/HC-SC/GC/CA@HWC

Subject Fw: Paul's comment on Salvia IYH

Hayden,

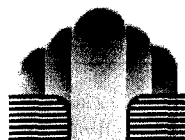
See responses in the string below.

Essentially, the answer to question #1 is not considered a controlled substance. Regarding question #2, info was provided for context and can be removed; however, we would have to "negotiate" w HPFB as this is their product.

Let us know if you need anything further

Jay Khosla  
Associate Director General /Directeur générale associé  
Controlled Substances & Tobacco Directorate (CSTD)  
Direction des substances contrôllées et de la lutte au tabagisme (DSCLT)  
Health Canada / Santé Canada  
Tel: (613) 952-4064 / Fax: (613) 954-2288  
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[www.hc-sc.gc.ca](http://www.hc-sc.gc.ca)

----- Forwarded by Jay Khosla/HC-SC/GC/CA on 2009-06-23 07:41 PM -----




Jocelyn Kula/HC-SC/GC/CA

2009-06-23 04:14 PM

To Jay Khosla/HC-SC/GC/CA@HWC

cc Cheryl Tremblay/HC-SC/GC/CA@HWC, Diane Allan/HC-SC/GC/CA@HWC, Stephanie Szick/HC-SC/GC/CA@HWC, Tacha Lehouillier/HC-SC/GC/CA@HWC

Subject Re: Paul's comment on Salvia IYH 

Jay,

Cheryl and I have come up with a response to Paul's questions and Diane has approved the following. Please advise if you would like us to make any changes.

Jocelyn

**Re. the issue of not including standard lines around drug prevention**

The standard lines on drug prevention were not incorporated in this IYH because the wording of those lines is oriented around illicit drugs which are already regulated as controlled substances. They do not translate well to *Salvia divinorum* in light of the fact that neither this plant nor its active ingredient are regulated as controlled substances at this time. The preliminary findings of our scheduling assessment are that information about the different factors considered, e.g., the potential for abuse and risk of addiction associated with the substance, the extent of actual abuse of the substance in Canada and internationally and the overall risk to public health and safety posed by the substance, is either missing or anecdotal in nature and thus, the controls imposed by the CDSA are likely not warranted. It is because of these

preliminary findings that this IYH was contemplated. *Salvia Divinorum* continues to attract moderate media attention and it was thought that it would be beneficial to have information available on the internet that would better inform the general public about the issue, i.e., health effects and what they can do to safe guard their own health. In this regard, the language used in the article is focused on the fact that Health Canada does not know very much about how *Salvia* acts on the brain and the body and thus we do not recommend that people use it.

**Re. the inclusion of information regarding he status in other countries**


The information regarding the status of *Salvia divinorum* and its active ingredient salvinorin A in other countries was included as it pertains to one of the factors that Health Canada considers when assessing whether to add a substance to one of the schedules to the CDSA, i.e., international requirements and trends in controlling the substance. This information could however be removed from the document without disrupting the flow of the article if there are concerns with its inclusion. We would however likely have to go back to HPFB if we make this type of change, as the content of the article has already been approved in that Branch.

---

Jocelyn Kula  
Manager/ Gestionnaire  
Policy and Regulatory Affairs Division/ Division des politiques et affaires réglementaires  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la  
sécurité des consommateurs  
Health Canada/ Santé Canada  
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Jay Khosla/HC-SC/GC/CA

Jay Khosla/HC-SC/GC/CA  
2009-06-22 02:31 PM

To Jocelyn Kula/HC-SC/GC/CA@HWC  
cc Cheryl Tremblay/HC-SC/GC/CA@HWC, Diane  
Allan/HC-SC/GC/CA@HWC, Stephanie  
Szick/HC-SC/GC/CA@HWC, Tacha  
Lehouillier/HC-SC/GC/CA@HWC  
Subject Re: Paul's comment on *Salvia* IYH 

Thanks. Based on this, I think a plainly worded explanation on why standard text is not being used would be helpful so let's tackle it from that perspective. Also, a few lines addressing other questions and a comment on the issue of approvals should assist in putting it to rest.

Clid you please craft a response to this effect for Diane's review and we'll go from there.

Thanks much.

Jay Khosla  
Associate Director General /Directeur générale associé  
Controlled Substances & Tobacco Directorate (CSTD)  
Direction des substances contrôllées et de la lutte au tabagisme (DSCLT)  
Health Canada / Santé Canada  
Tel: (613) 952-4064 / Fax: (613) 954-2288

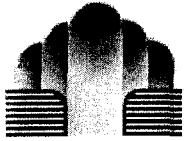
E-mail/courriel :

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Jocelyn Kula/HC-SC/GC/CA



Jocelyn Kula/HC-SC/GC/CA

2009-06-22 01:34 PM

To Jay\_Khosla/HC-SC/GC/CA@HWC

cc Diane Allan/HC-SC/GC/CA@HWC, Stephanie  
Szick/HC-SC/GC/CA@HWC, Tacha  
Lehouillier/HC-SC/GC/CA@HWC, Cheryl  
Tremblay/HC-SC/GC/CA@HWC

Subject Re: Paul's comment on Salvia IYH 

We can look at the wording but I am not sure the standard lines on drug prevention really work here because they are really oriented around illicit drugs (which are regulated as controlled substances) and the whole point of doing this IYH is that salvia is not yet regulated as a controlled substance and the preliminary findings of our scheduling assessment are that it does not warrant these types of controls. Hence the language about not knowing very much about how it acts on the brain and the body, and that we don't recommend that people use it.....

Cheryl (analyst responsible) is away today but we will get something back to DGO as soon as possible. That said, if Paul really wants changes, we are going to have to go all the way back through approvals in HPFB as this IYH has been a co-production if you will, and it is my understanding from Comms that Meena has already signed off.

JK

---

Jocelyn Kula

Manager/ Gestionnaire

Policy and Regulatory Affairs Division/ Division des politiques et affaires réglementaires

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs

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Tel: (613) 946-0125 Fax: (613) 946-4224


Jay\_Khosla/HC-SC/GC/CA

Jay\_Khosla/HC-SC/GC/CA

2009-06-22 12:04 PM

To Stephanie\_Szick/HC-SC/GC/CA@HWC

cc Diane Allan/HC-SC/GC/CA@HWC, Jocelyn  
Kula/HC-SC/GC/CA@HWC, Tacha  
Lehouillier/HC-SC/GC/CA@HWC

Subject Re: Paul's comment on Salvia IYH 

Diane,

Let me know if you'd like to discuss. Think we should insert standard lines on prevention if warranted. Also, need to add context about "status" in other countries.



Thanks

Jay Khosla  
Associate Director General /Directeur générale associé  
Controlled Substances & Tobacco Directorate (CSTD)  
Direction des substances contrôlées et de la lutte au tabagisme (DSCLT)  
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Website/Site web:  
**www.hc-sc.gc.ca**  
Stephanie Szick/HC-SC/GC/CA



Stephanie  
Szick/HC-SC/GC/CA  
2009-06-22 11:25 AM

To Diane Allan/HC-SC/GC/CA@HWC, Jocelyn  
Kula/HC-SC/GC/CA@HWC  
cc Jay Khosla/HC-SC/GC/CA@HWC  
Subject Paul's comment on Salvia IYH

Hi Diane and Jocelyn  
Please see attached - hand written comments from Paul on the Salvia IYH article. Can you send a  
response to his Q's early this afternoon?  
He writes that the piece raises some questions for him:  
1) Where are our standard lines around drug prevention?  
2) re: the Status in Other Countries section - is that normal to include this in an IYH article?  
Adding...  
As written, it seems to generate more questions than provide answers.

Thanks,

Stephanie Szick  
Controlled Substances & Tobacco Directorate (CSTD)  
Direction des substances contrôlées et de la lutte au tabagisme (DSCLT)  
Health Canada / Santé Canada  
Tel / Tél: (613) 952-3367

----- Forwarded by Stephanie Szick/HC-SC/GC/CA on 2009-06-22 11:20 AM -----

Hayden  
Lansdell/HC-SC/GC/CA  
2009-06-22 11:03 AM

To Jay Khosla/HC-SC/GC/CA@HWC  
cc Stephanie Szick/HC-SC/GC/CA@HWC  
Subject Fw: scan

PG has questions on this IYH. Can you please get Diane to take a look. An email response is all that is necessary at this point in time.

Hayden

----- Forwarded by Hayden Lansdell/HC-SC/GC/CA on 2009-06-22 10:58 AM -----



Julie  
Paquette/HC-SC/GC/CA  
2009-06-22 10:52 AM

To Hayden Lansdell/HC-SC/GC/CA@HWC  
cc  
Subject scan



salvia divinatorum.pdf

Julie Paquette  
Executive Assistant to the Director / Adjointe exécutive à la directrice  
Health Canada / Santé Canada  
Assistant Deputy Minister's Office / Bureau de la sous-ministre adjointe  
HECSB / DGSESC  
Tel: 613-946-6710  
Fax: 613-946-6666

Jay - this is raised some questions for me 1) where are our standards lines around drug prohibition in the states in other countries that normal in an It's your health? Happy to talk discuss. 21 Jan 08

## Salvia divinorum

### The Issue

Reports suggest that Canadian teens and young adults are using a substance called *Salvia divinorum* (*S. divinorum*) for its ability to produce hallucinations. Certain Web sites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs.

Street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastra, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff encens special, and salvia.

Health Canada recommends that you avoid using this substance because very little is known about the damage it may cause to the body, including the brain. There is also no way to predict how it will affect you with each use.

### Background

*S. divinorum* is a species of sage that belongs to the mint family. It is known to have psychotropic effects, which means it affects the mind and mental processes.

The leaves of this plant have been used traditionally by the Mazatec Indians in Mexico for many years. Traditional use involves chewing the leaves or using them to make a tea for medicinal purposes (e.g., to treat such conditions as headache or stomach upset), or to induce a "mystical" or hallucinogenic experience for spiritual purposes.

Products that claim to contain *S. divinorum* – or its main active ingredient, salvinorin A – are widely available on the Internet and are sold in various "head shops" and natural food stores. The products are sold in a number of formats, including seeds and plant cuttings for growing purposes. Fresh or dried leaves are intended to be chewed, swallowed or smoked. Liquid preparations are also available.

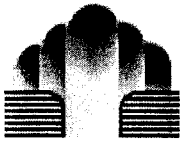
### Risks of Using *Salvia divinorum*

*S. divinorum*'s effects, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations;
- dysphoria (feeling unwell, uneasy or unhappy);
- out-of-body experiences;
- uncontrollable laughter;
- loss of consciousness;
- short-term memory loss;
- lack of physical coordination;
- slurred speech and awkward sentence patterns.

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

As written it seems to generate more questions than provide answers.



Jocelyn Kula/HC-SC/GC/CA

2010-01-08 12:35 PM

To Christine Roush/HC-SC/GC/CA@HWC

cc Brenda Paine/HC-SC/GC/CA@HWC, Bronwyn  
Cline/HC-SC/GC/CA@HWC, Cheryl  
Tremblay/HC-SC/GC/CA@HWC, Denis

bcc

Subject Re: FYI - Media interest in Quebec re: salvia divinorum 

Thanks Christine,

I think the TVA clip may be new but we are familiar with the YouTube one. Highlights the importance of getting our IYH out there.....

Jocelyn

---

Jocelyn Kula

Manager/ Gestionnaire

Policy and Regulatory Affairs Division/ Division des politiques et affaires réglementaires

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs

Health Canada/ Santé Canada

Tel: (613) 946-0125 Fax: (613) 946-4224

Christine Roush/HC-SC/GC/CA

Christine

Roush/HC-SC/GC/CA

2010-01-08 12:23 PM

To Jocelyn Kula/HC-SC/GC/CA@HWC

cc Cheryl Tremblay/HC-SC/GC/CA@HWC, Denis  
Arsenault/HC-SC/GC/CA@HWC, Stephanie  
Szick/HC-SC/GC/CA@HWC, Hayden  
Lansdell/HC-SC/GC/CA@HWC, Brenda  
Paine/HC-SC/GC/CA@HWC, Bronwyn  
Cline/HC-SC/GC/CA@HWC

Subject FYI - Media interest in Quebec re: salvia divinorum

FYI - in case you haven't seen this yet, it was sent to us from our Quebec comms office - print, TV, and U-Tube video showing youth using salvia divinorum.

Christine Roush

Senior Communications Advisor/

Marie-Annick

Gariepy/HC-SC/GC/CA

2010-01-08 09:53 AM

To Christine Roush/HC-SC/GC/CA@HWC, Bronwyn  
Cline/HC-SC/GC/CA@HWC

cc Jean Tessier/HC-SC/GC/CA@HWC, Paul  
Duchesne/HC-SC/GC/CA@HWC, Kathleen  
Malone/HC-SC/GC/CA@HWC, Alastair  
Sinclair/HC-SC/GC/CA@HWC, Jean-Christophe  
Senosier/HC-SC/GC/CA@HWC, Caroline  
Hares/HC-SC/GC/CA@HWC, Eric  
Delichy/HC-SC/GC/CA@HWC

Subject FYI - Media interest in Qc about salvia divinorum

Bonjour,

FYI - *Le Journal de Montréal*, des journaux hebdomadaires du Québec ainsi que le réseau de télévision TVA (la chaîne de nouvelles LCN et l'émission *Salut Bonjour!*) ont publié des articles aujourd'hui ou réalisé des reportages au sujet de la consommation de salvia divinorum par des adolescents du Québec.

Veillez trouver ci-joint des articles et un reportage de LCN à ce sujet.  
Bonne journée, Marie-Annick

---

**Vidéo LCN à TVA :**

<http://videos.lcn.canoe.ca/video/60824784001/drogue-legale-les-explications-de-patrick-rodrigue/>

Vidéos » En vedette » Drogue légale: les explications de Patrick Rodrigue...

Sur le site YouTube, on peut présentement voir dans une vidéo de deux minutes des jeunes en train d'inhaler de la salvia divinorum s'apparentant à la sauge.

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<b>SOURCETAG</b>	100108112723692
<b>PUBLICATION:</b>	Le Journal de Montréal
<b>DATE:</b>	2010.01.08
<b>EDITION:</b>	Final
<b>SECTION:</b>	Nouvelles
<b>PAGE:</b>	11
<b>BYLINE:</b>	AGENCE QMI
<b>DATELINE:</b>	ROUYN
<b>WORD COUNT:</b>	392
<b>CIRCULATION:</b>	222617

---

## **Filmés en train d'inhaler une drogue légale YOUTUBE -- ADOS**

---

ROUYN -- (Agence QMI) L'expérience est troublante. Une vidéo montre un groupe d'adolescents en train de consommer de la drogue dans une ruelle de Rouyn-Noranda. Plus troublante encore est la révélation voulant que cette substance, visiblement très puissante, soit tout à fait légale.

Sur le site YouTube, on peut présentement voir dans une vidéo de deux minutes des jeunes en train d'inhaler de la salvia divinorum, une herbe aux propriétés hallucinogènes s'apparentant à la sauge. La majeure partie de la vidéo s'at-tarde sur deux très jeunes adolescents complètement

euphoriques.

L'un d'eux est si intoxiqué qu'il n'arrive même pas à formuler une phrase complète et se contente de rire béatement, étant lui-même étonné de l'intensité de ce qu'il vit.

Légal au Canada

Si la vidéo est choquante, surtout en raison du très jeune âge de certains participants, sachez que personne n'y enfreint pas la loi. "Aucune disposition n'existe actuellement dans le Code criminel à l'égard de cette substance ", reconnaît Marie-Josée Ouellet, responsable des communications à la Sûreté du Québec. En cas d'arrestation, aucune accusation criminelle ne pourra donc être portée contre les consommateurs.

Selon le site Internet d'information sur les drogues Erowid.org, cette substance est pourtant contrôlée ou illégale dans certains pays : Allemagne, Australie, Belgique, Chili, Corée du Sud, Danemark, Finlande, Italie, Japon, Russie et Suède. Elle est aussi interdite aux États-Unis, mais pas dans tous les États.

Effets intenses

Les effets de la salvia sont pourtant intenses. "Cela se compare au LSD. Les effets sont cependant très brefs, durant rarement plus de cinq minutes. Et souvent, l'expérience s'apparente plus à un bad trip ", indique Joëlle Thouin, coordonnatrice du Centre Normand à Rouyn-Noranda.

D'ailleurs, à la Commission scolaire de Rouyn-Noranda (CSRN), en dépit de son statut légal, la salvia divinorum est considérée comme toutes les autres drogues.

"Si un élève se présente sous l'influence de la salvia ou qu'il y a échange entre élèves, les dispositions relatives à la drogue s'appliquent et on avertit ses parents", fait savoir Julie Roy, responsable des communications à la CSRN.

Il est possible de se procurer de la salvia dans certains commerces spécialisés de la région. Un des vendeurs reconnaît toutefois que la substance n'est pas très populaire.

"On n'a pas vraiment de consommateurs réguliers. Les gens l'essaient plus une fois par curiosité et ne recommencent pas. C'est souvent désagréable. J'ai même entendu parler d'un ou deux cas de gens qui prenaient régulièrement autre chose et qui ont carrément arrêté après avoir essayé la salvia parce que le buzz leur avait fait trop peur", mentionne-t-il.

=====  
Article :

<http://lafrontiere.canoe.ca/webapp/sitepages/content.asp?contentid=124356&id=162&classif=Derni%C3%A8re%20heure&catname=>

Galerie photos :

<http://lafrontiere.canoe.ca/webapp/sitepages/articleimages.asp?abID=124356&imgID=239807&catmainname=argalerie&catname=Salvia%20à%20Rouyn&dt=%20-%20Publi%E9%20le%2007%20janv.%202010>

## «C'est comme faire bouillir son cerveau au micro-ondes»

Journal La Frontière de Rouyn-Noranda

Raphael (nom fictif) a déjà consommé de la salvia divinorum à plusieurs reprises. Selon lui, il faut être extrêmement vigilant avec cette drogue, car elle peut produire une expérience qui altère la conscience.

«Une bouffée et tu pars complètement sur une autre planète, avertit-il. On perd entièrement le contact avec le monde extérieur. Par exemple, une fois j'ai eu le fixe sur une table et je me suis senti devenir la table.»

Les effets de la salvia sont relativement courts. Très rarement les hallucinations durent plus de cinq minutes. En revanche, celles-ci frappent le consommateur environ 30 secondes après inhalation de la fumée.

«Les effets sont nombreux. Chaque personne peut réagir de façon très différente et parfois, l'expérience peut être très douloureuse. On perd le contrôle complètement, on a des visions et nos sens se décuplent. C'est comme si on faisait bouillir son cerveau au micro-ondes», mentionne Raphael.

Ce dernier affirme avoir tenté l'expérience de la salvia après s'être renseigné. Selon lui, les amérindiens de l'Amérique latine auraient été les premiers consommateurs de cette plante lors de rituels religieux et c'est ce côté qui l'intriguait.

Beaucoup de précautions

«Je déconseille définitivement de consommer de la salvia. Les effets, quoique courts, sont trop puissants. Pour ma part, je ne compte plus en consommer, avoue-t-il.

Pourtant, c'est une drogue très facile à trouver et vraiment peu chère, entre 20 \$ et 40 \$ le gramme. Avec cette quantité, on peut facilement en avoir assez pour dix personnes.

Selon Raphael, il faut être très prudent lorsqu'on consomme de la salvia. «On reste chez soi, tranquille, et il doit y avoir quelqu'un avec soi qui reste sobre pour éviter que l'on tombe inconscient, ce qui est très dangereux. Ce que font les jeunes du video est totalement irresponsable», s'indigne-t-il.

---

<http://lafrontiere.canoe.ca/webapp/sitepages/content.asp?contentid=124359&id=162&classif=Demi%E8re+heure>

## La salvia divinorum: une drogue légale

Des jeunes de Rouyn-Noranda en plein délire sur YouTube

Une vidéo montre un groupe d'adolescents en train de consommer de la drogue dans une ruelle de Rouyn-Noranda. Plus que cette substance, visiblement très puissante, est tout à fait légale.

Sur le site YouTube, on peut présentement voir dans une vidéo de deux minutes des jeunes en train d'inhaler de la salvia hallucinogène s'apparentant à la sauge. La majeure partie de la vidéo s'attarde sur deux très jeunes adolescents complètement intoxiqués qu'il n'arrive même pas à formuler une phrase complète et se contente de rire béatement, étant lui-même étonné.

Légal au Canada

Si la vidéo est choquante, surtout en raison du très jeune âge de certains participants, sachez que personne n'y enfreint actuellement dans le Code criminel à l'égard de cette substance», reconnaît Marie-Josée Ouellet, responsable des communications, aucune accusation criminelle ne pourra donc être portée contre les consommateurs.

Selon le site internet d'information sur les drogues Erowid.org, cette substance est pourtant contrôlée ou illégale dans c Chili, Corée du Sud, Danemark, Finlande, Italie, Japon, Russie et Suède. Elle est aussi interdite aux États-Unis, mais pa

#### Effets intenses

Les effets de la salvia sont pourtant intenses. «Cela se compare au LSD. Les effets sont cependant très brefs, durant ra expérience s'apparente plus à un bad trip», indique Joëlle Thouin, coordonnatrice du Centre Normand à Rouyn-Norand:

D'ailleurs, à la Commission scolaire de Rouyn-Noranda (CSRN), en dépit de son statut légal, la salvia divinorum est cor un élève se présente sous l'influence de la salvia ou qu'il y a échange entre élèves, les dispositions relatives à la drogue savoir Julie Roy, responsable des communications à la CSRN.

#### Pas très populaire

Il est possible de se procurer de la salvia dans certains commerces spécialisés de la région. Un des vendeurs reconnaît populaire.

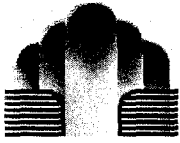
«On n'a pas vraiment de consommateurs réguliers. Les gens l'essaient plus une fois par curiosité et ne recommencent ; entendu parler d'un ou deux cas de gens qui prenaient régulièrement autre chose et qui ont carrément arrêté après avoi fait trop peur», mentionne-t-il.

=====

Marie-Annick Gariépy  
Conseillère en communications / Communications Advisor  
Direction des communications / Communications Directorate  
Santé Canada, région du Québec / Health Canada, Quebec Region  
Téléphone : 514 283-2046  
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Votre santé et votre sécurité... notre priorité / Your health and safety... our priority





Jocelyn Kula/HC-SC/GC/CA

2010-01-10 10:25 AM

To Cheryl Tremblay/HC-SC/GC/CA@HWC

cc Denis Arsenault/HC-SC/GC/CA@HWC, Diane  
Allan/HC-SC/GC/CA@HWC

bcc

Subject Fw: Global National - Salvia being used among young  
students in small Quebec town - Jan 9/10 5:50 PM

for the file pls

FYI, Hayden is following up with where the IYH is at; asked him when I saw him on Thurs; he thinks it is still in Paul's reading file....

---

Jocelyn Kula

Manager/ Gestionnaire

Policy and Regulatory Affairs Division/ Division des politiques et affaires réglementaires

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs

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----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2010-01-10 10:24 AM -----

HC\_Media\_SC/HC-SC/GC/C

A

Sent by: Henry Lau

2010-01-09 06:15 PM

To

cc

Subject Global National - Salvia being used among young students in  
small Quebec town - Jan 9/10 5:50 PM

Global National

Sat Jan 9 2010

5:50 PM

**Salvia being used among young students in small Quebec town**

Carolyn: IT'S CALLED MAGIC MINT, LADY "D" OR SALVIA. NO MATTER WHAT YOU CALL IT, EFFECTS ARE THE SAME. INTENSE HALLUCINATIONS. THERE ARE CONCERNS TEENS ARE GETTING THEIR HANDS ON IT AND PUTTING THEIR SAFETY AT RISK. DOMINIC FAZIOLI HAS MORE.

Dominic: THERE'S A NEW VIDEO BRINGING ATENSION TO AN OLD CONTROVERSY. A GROUP OF YOUNG STUDENTS SMOKING DRUGS IN A SMALL TOWN IN QUEBEC. THEY ARE HALLUCINATE ING AND UNCONSCIOUS. IT HAS A LESS TO DO WITH THE AGE OF THE CHILDREN THAN THE DRUG THEY'RE ON. IT'S CALLED SALVIA. IN CANADA YOU CAN BUY IT AND USE IT LEGALLY.

REALLY POPULAR FOR YOUNGER KIDS -- WELL, 18 TO 23.

Reporter: --

Dominic: SALVIA IS A BIG SELLER IN THIS DOWNTOWN SHOP. JENNY ROY SAYS MORE AND MORE TEENAGERS ARE FINDING OUT ABOUT THE DRUG.

IN A WEEK I CAN SELL ABOUT AT LEAST 50, 50 LITTLE VIALS A WEEK.

Dominic: VIALS START AT ABOUT \$25. USERS EXPERIENCE A HALLUCINOGENIC FEELING. THIS STUDENT SAYS SALVIA IS PLANT-BASED IS ONE OF THE REASONS MANY OF HIS 23RE7BDS HAVE TRIED IT.

BETTER THAT'S MY OPINION. BUT THIS IS NATURAL.

Dominic: SALVIA IS ILLEGAL IN OTHER PARTS OF THE WORLD. IN THE U.S. IT'S LABELLED AS A DRUG OF CONCERN. \*\*>HEALTH CANADA<\*\* HAS RULED IT TO BE NON-TOXIC AND NON-ADDICTIVE. OTHER PROFESSIONALS HAVE SERIOUS CONCERNS.

HIGH DOSE SOMEONE COULD HAVE TOO INTENSE OF AN EXPERIENCE AND HAVE A PANIC ATTACK AND END UP IN AN EMERGENCY ROOM OR END UP DOING SOMETHING, WALKING OUT INTO TRAFFIC OR SOMETHING LIKE THAT.

Dominic: HE SAYS THE ISSUE IS NOT LEGALITY BUT YOU INFORMING PARENTS WHAT THEIR RESPONSIBILITIES ARE.

THERE IS A LACK OF UNDERSTANDING BECAUSE THEY ARE NOT FULLY DEVELOPED PSYCHOLOGICALLY, EMOTIONALLY. THERE'S A LACK OF UNDERSTANDING OF WHAT BOUNDARIES ARE. OKAY. IF IT'S LEGAL, THERE'S NOTHING WRONG WITH IT.

Dominic: AT HIGH TIMES THEY TRY TO SET BOUNDARIES. YOU HAVE TO BE 18 YEARS OLD TO PURCHASE IT. BECAUSE IT'S ILLEGAL, TEENS CAN EASILY GET THEIR HANDS ON THE DRUG. DOMINIC FAZIOLI, GLOBAL NEWS, MONTREAL.

- END -

Media Monitoring Unit / Unité de surveillance des médias  
Health Canada / Santé Canada

s.19(1)



Cheryl  
Tremblay/HC-SC/GC/CA  
2010-01-11 01:46 PM

To [REDACTED]  
cc Denis Arsenault/HC-SC/GC/CA@HWC  
bcc Cheryl Tremblay/HC-SC/GC/CA  
Subject Salvia Divinorum

Hi Isabelle,

My colleague Denis Arsenault indicated to me that you were looking for information on Health Canada's position on and activities regarding *Salvia divinorum*. I trust that the following information will be helpful.

As you may be aware, *Salvia divinorum* is a species of sage which belongs to the mint family. It is found in a number of formats, including seeds, extract and plant cuttings for growing purposes. Fresh or dried leaves can be chewed, swallowed or smoked to induce psychotropic effects. Liquid preparations are also available. Products that claim to contain *S. divinorum* - or its main active ingredient, salvinorin A - are widely available on the Internet and sold in alternative lifestyle stores.

In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act*. *Salvia divinorum* is not listed under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these conventions.

Internationally, several countries (Australia, Belgium, Denmark, Sweden, Italy, Spain, Finland and South Korea) have however placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Although some individual states in the U.S. have implemented laws restricting its use, sale and/or distribution, *Salvia divinorum* and salvinorin A are not regulated under the federal *Controlled Substances Act*.

For its part, Health Canada considers several factors in determining whether scheduling a substance under the *Controlled Drugs and Substances Act* warranted. These include:

- international requirements and trends in regulatory status;
- chemical and pharmacological similarity to other substances already regulated under the *Controlled Drugs and Substances Act*,
- legitimate uses of the substance (i.e. therapeutic, industrial or commercial);
- potential for abuse and risk of addiction associated with the substance;
- extent of actual abuse of the substance in Canada and internationally; and,
- overall risk to public health and safety posed by the substance.

In the case of *Salvia divinorum*, information about these factors is either missing or anecdotal in nature. For example, very few scientific studies looking into the physical and psychotropic effects of *Salvia divinorum* on humans have been carried out. More systematic research in this area is needed. It should also be noted that, thus far, the Department has only received a limited number of communications indicating concern with respect to *Salvia divinorum* from law enforcement agencies, and none of these have advised that the use of *Salvia divinorum* poses any threat to public safety.

Thank you,

Cheryl Tremblay  
Policy and Regulatory Affairs Division / Division des politiques et affaires réglementaires  
Office of Controlled Substances / Bureau des substances contrôlées  
Controlled Substances and Tobacco Directorate / Direction des substances contrôlées et de la lutte au tabagisme  
Healthy Environments and Consumer Safety Branch / Direction générale de la santé environnementale et de la sécurité consommateurs

Health Canada / Santé Canada  
Tel: (613) 954-6527 Fax: (613) 946-4224



Jocelyn Kula/HC-SC/GC/CA  
2010-01-13 10:47 AM

To Cheryl Tremblay/HC-SC/GC/CA@HWC  
cc Denis Arsenault  
bcc  
Subject Fw: La Frontière (online) - Salvia: Lemay impuissant

Jocelyn Kula  
Manager/ Gestionnaire  
Policy and Regulatory Affairs Division/ Division des politiques et affaires réglementaires  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0125 Fax: (613) 946-4224  
----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2010-01-13 10:47 AM -----

HC\_Media\_SC/HC-SC/GC/C

A

To

Sent by: Jeremy  
Mesiano-Crookston

cc

Subject La Frontière (online) - Salvia: Lemay impuissant

2010-01-13 08:58 AM

Mardi le 12 janvier

**Salvia: Lemay impuissant**

Source: La Frontière

([lafrontiere.canoe.ca/webapp/sitepages/content.asp?contentid=124893&id=288](http://lafrontiere.canoe.ca/webapp/sitepages/content.asp?contentid=124893&id=288))

À la suite d'un reportage, révélé en primeur sur le site Internet de La Frontière, où l'on voit de jeunes adolescents consommer, en toute légalité, une drogue appelé salvia divinorum, le député fédéral, Marc Lemay a affirmé que cette substance ne devrait pas être bannie, du moins à court terme.

Rappelons que la salvia est une drogue aux effets intenses, qui provoque de puissantes hallucinations sur une très courte période. Officiellement, cette substance n'est pas illégale car elle ne causerait pas de dépendance, malgré ses effets comparable à ceux du LSD.

En vente libre dans certains commerces spécialisés, ici même en région, la salvia est toutefois considérée illégale dans de nombreux pays européens et états américains.

M. Lemay a avoué avoir appris l'existence de la salvia dans nos pages. «Je n'ai jamais eu de demande à ce sujet. Si quelqu'un venait me voir à propos de la salvia et souhaitait faire de la pression pour rendre cette drogue illégale, je lui conseillerais d'écrire au ministre de la Santé afin d'avoir davantage de précisions», indique-t-il.

#### Décision de Santé Canada

La procédure pour rendre une substance illégale passe moins par les parlementaires que par une recommandation du ministère de la Santé au ministère de la Justice, qui l'intègre ensuite au Code criminel.

«À terme, c'est au ministère de la Santé de prendre une décision à savoir si une substance doit, ou non, être considérée comme substance illicite. Le ministère de la Justice doit ensuite faire un règlement qui entre dans l'annexe des drogues, et donc, dans le Code criminel, sans avoir à passer par la Chambre, fait savoir l'avocat de formation.

C'est comme pour les substances dopantes, si l'Agence mondiale antidopage place un produit sur sa liste de produits interdits, automatiquement celui-ci est interdit au Canada, sans procédures supplémentaires.»

**Media Monitoring Unit / Unité de surveillance des médias**  
**Health Canada / Santé Canada**

# Issue Analysis Summary

DRAFT

## Scheduling *Salvia Divinorum* and/or *Salvinorin A* under the CDSA

Policy and Regulatory Affairs Division  
Office of Controlled Substances

Controlled Substances and Tobacco and Directorate

January 13, 2010

### CONTENTS

1. APPROVALS
2. ISSUE
3. PURPOSE
4. CONTEXT
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6. IDENTIFICATION AND ANALYSIS OF OPTIONS
7. CONSIDERATIONS
8. RECOMMENDATION(S)
9. CONSULTATIONS
10. IMPLEMENTATION AND EVALUATION

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### 1. APPROVALS

This Issue Analysis Summary is approved.

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Diane Allan, Director  
Office of Controlled Substances  
Tobacco and Drugs Directorate

---

[DD/MM/2009]

### 2. ISSUE

In Canada, neither the herb *Salvia divinorum* (*S. divinorum*) nor its main active ingredient, salvinorin A, are controlled under the *Controlled Drugs and Substances Act* (CDSA). Health Canada has received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *S. divinorum*, particularly given reports from scientific and media sources suggesting that *S. divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health

Canada has also noted an ongoing media interest regarding the availability of *S. divinorum* in Canada.

### 3. PURPOSE

To assess *Salvia divinorum* and/or salvinorin A against the criteria for the addition of a substance to one of the Schedules to the CDSA, in order to determine whether or not *S. divinorum*, and/or salvinorin A, should be regulated as controlled substances in Canada.

### 4. CONTEXT

*Salvia divinorum* is a species of sage which belongs to the mint family, and which is found in the form of dried leaves, extract and plant cuttings. Also known as "diviner's sage", the plant is known to induce illusions and hallucinations when chewed or smoked. Salvinorin A, the psychoactive ingredient in *S. divinorum*, which is also referred to chemically as a neoclerodane diterpene, is found primarily in the leaves, and to a lesser extent in the stems.<sup>1</sup>

*S. divinorum* is widely touted as a "legal" alternative to street drugs on the Internet, and has also been reported to be one of the most prevalently marketed herbal dietary supplements available for use as an alternative to illicit drugs of abuse among adolescents and young adults.<sup>2</sup> While very little is known about how and where *S. divinorum* is sold in Canada, it is suspected that it is mainly purchased over the Internet and/or bought at head shops, and alternative life style stores, etc.

A 2006 National Survey on Drug Use and Health Report, published in February 2008 by the Substance Abuse and Mental Health Administration in the United States, also estimated that:

- 1.8 million persons aged 12 or older used *Salvia divinorum* in their lifetime, with approximately 750,000 having done so in the past year;
- Use was more common among young adults (18 to 25 years old) as opposed to older adults (> 26 years of age);
- Young adults were nearly three times more likely than youths, aged 12 to 17, to have used *Salvia divinorum* in the past year; and
- Use was more common in males than in females.

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1 U.S. Department of Justice Drug Enforcement Administration. 2002. Drugs and Chemicals of Concern: *Salvia Divinorum* (salvinorin A, divinorin A) URL:

[http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm) Nov 2008

2 Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.



The use of *S. divinorum* as a psychotropic agent first came to Health Canada's attention in 2002. In 2004, Health Canada received four adverse drug reaction (ADR) reports associated with the use of *S. divinorum* as a hallucinogen, with three being considered non-serious (requiring no medical attention) and the fourth being considered serious (medical intervention was required) and involving the concomitant use of alcohol in a person diagnosed with Attention Deficit Disorder.

Further to the receipt of the aforementioned ADRs, the Marketed Health Products Directorate (MHPD) and the Natural Health Products Directorate (NHPD), of the Health Products and Food Branch (HPFB), prepared an issue analysis summary (IAS), which recommended that *S. divinorum* and its active ingredient salvinorin A be regulated as a controlled substance (a recommendation that was maintained when the IAS was updated in November 2006).

Later, in December 2005, MHPD and NHPD prepared a Signal Assessment (SA) (updated in June, 2007) that eventually led to the preparation of a Health Risk Assessment (HRA), which concluded that *S. divinorum* or salvinorin A-containing health products should be restricted from over-the-counter use. Should any such (unauthorized) health products be found on the Canadian market, they should be removed from sale. Such products would constitute a Type II Health Risk, defined as "A situation in which there is a reasonable probability that the use of, or exposure to, a product, will cause moderate or mild adverse health consequences.

Further to an ADM discussion in April 2007, DSCSD organized a meeting with MHPD, NHPD and the Inspectorate of HPFB (HPFBI) on May 16, 2007 to discuss *S. divinorum*. At that time, it was decided that *S. divinorum* would be classified by HPFB as a Type II substance. MHPD was to send the HRA and SA to DCSCD, look into preparing an adverse reaction case presentation in the ADR Newsletter, and explore the possibility of developing a product advisory. HPFBI was to determine compliance activities based on the HRA Type II classification and check with Canada Border Services Agency (CBSA) to determine if any further information regarding *S. divinorum* shipments was available. The Office of Research and Surveillance, DSCSD was to continue to work on the *S. divinorum* Fact Sheet and explore the feasibility of a health food/natural food store survey on *S. divinorum*. OCS was to gather information from Australia regarding its scheduling decision and to find out whether the DEA had any plans to schedule *S. divinorum* in the near future.

On September 13, 2007, a meeting was organized between DSCSD, MHDP, NHPD and HPFBI to discuss what is known about *S. divinorum* from a regulatory perspective and to reach consensus on next steps.

The following action items came out of this meeting:

- (1) DSCSD to submit a response to the MHPD/NHPD analytical documents and MHPD/NHPD to make changes accordingly;
- (2) DSCSD to finalize the latest version of the media lines on *S. divinorum* and put them forward, via Communications, for approval in HPFB;
- (3) DSCSD to find out the status of draft fact sheet that was being developed by its Office

of Research and Surveillance;

(4) HPFBI to discuss the potential allocation of additional resources, e.g., additional inspectors, etc. to the *S. divinorum* file; and

(5) DSCSD to explore the notion of scheduling, i.e., carry out a preliminary scheduling assessment, as part of a mid to long-term action plan.

The Director Generals of DSCSD, MHPD, TPD and the HPFBI also met on September 26, 2008 to discuss an update on issues relating to *S. divinorum* and to determine an agreed upon approach for subsequent steps.

The following action items came out of that meeting:

(1) Review and provide comments on *S. divinorum* IAS and SA and revise and re-issue IAS and SA, as needed;

(2) circulate draft Fact Sheet for comment and explore the possibility of developing a public-friendly communication;

(3) prepare draft media lines for *S. divinorum* and circulate for comment;

(4) contact DAS labs for any information on *S. divinorum*;

(5) prepare project charter for *S. divinorum* working group;

(6) contact Public Health Agency Canada (PHAC) for representation;

(7) continue work on scheduling assessment for *S. divinorum*; and

(8) continue sharing information relating to *S. divinorum* as it arises.

#### **4.1 Legislative Frameworks for Drug Control in Canada**

##### **4.1.1 Food and Drug Regulations**

The *Food and Drug Regulations* (F&DR) serve to ensure the safety, efficacy, and quality of health products offered for sale in Canada, including drugs and medical devices. Prior to being given market authorization, a manufacturer must present substantive scientific evidence of a product's safety, efficacy and quality and Health Canada reviews this information carefully. If the review is satisfactory, a Notice of Compliance (NOC) is issued and appropriate Drug Identification Numbers (DINs) are assigned.

A "drug" is defined under the F&DR as any substance or mixture of substances manufactured, sold or represented for use in

(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,

(b) restoring, correcting or modifying organic functions in human beings or animals, or

(c) disinfection in premises in which food is manufactured, prepared or kept;

##### **4.1.2 Natural Health Product Regulations**

The *Natural Health Products Regulations* (NHPR) came into force in January, 2004 to provide Canadians with ready access to natural health products (NHPs) that are safe, effective, and of high quality, while respecting freedom of choice and philosophical and cultural diversity. The NHPR contain a product licensing system that requires that all licensed products display a product identification number preceded by the prefix NPN, or, in the case of a homeopathic medicine, by the letters DIN-HM on their labels. The number is issued once a product is authorized for sale in Canada by the Natural Health Products Directorate. Product authorization requires either reference to a *natural health product monograph* or submission of other evidence of safety and health claim. A system of site licensing is also included in the NHPR which requires that all manufacturers, packagers, labellers, and importers be licensed; sites have procedures in place respecting distribution records and product recalls; where applicable, sites have procedures in place for the handling, storage and delivery of their products, and sites meet good manufacturing practice requirements.

The definition of an NHP under the NHPR has both a function and substance component. The function component refers to those substances that are manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
- (b) restoring or correcting organic functions in humans; or
- (c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

The substance component refers to whether the product or medicinal ingredient therein, is safe for consideration as an over-the-counter product, can be available for self-care and self-selection, and does not require a prescription to be sold.

#### **4.1.3 *Controlled Drugs and Substances Act and its Regulations***

The CDSA provides a legislative framework for the control of substances that can alter mental processes and that may produce harm to the health of an individual or to society when diverted or misused. Except as authorized under its regulations, activities such as possession, possession for the purposes of trafficking, trafficking, importation, exportation, possession for the purposes of exportation and production of controlled substances are prohibited under the CDSA.

The substances regulated under the CDSA are grouped into eight Schedules, and each Schedule is associated with particular penalties as described in Part I of the CDSA.

In determining whether a substance should be regulated as a controlled substance, and into which Schedule to the CDSA is should be placed, Health Canada considers the following factors:

- International requirements and trends in control/scheduling;
- Chemical and pharmacological similarity to other substances already scheduled under the CDSA;
- Legitimate uses of the substance (i.e. therapeutic, industrial or commercial);
- Potential for abuse and/or addiction liability of the substance;
- Extent of actual abuse in Canada and internationally; and
- Overall risk to public health and safety of Canadians.

## 4.2 Assessment of *Salvia Divinorum* for Scheduling Purposes

### 4.2.1 International Requirements and Trends in Control/Scheduling

At the present time, neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and therefore do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these conventions.

#### ***Australia***

In June, 2002, Australia became the first country to prohibit *S. divinorum* and salvinorin A. Although both *S. divinorum* and salvinorin A are listed on Schedule 9 of Australia's Standard for the Uniform Scheduling of Drugs and Poisons on the basis of "high potential for abuse and risk to public health and safety", no substantiation of this risk was provided at the time of this scheduling decision. Schedule 9 is Australia's most restrictive drug schedule, and includes "substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities."<sup>3</sup>

#### ***Belgium***

A decree was passed in Belgium on October 22, 2006 which added *S. divinorum* to the list of controlled substances.

#### ***Denmark***

Shortly after, in 2003, Denmark prohibited *S. divinorum* and salvinorin A by adding them to their list of "category B" controlled substances, a category which also includes psilocybin mushrooms, cocaine, amphetamine, and several others substances that are only legal for medicinal and scientific purposes. Illegal possession carries a penalty of up to two years in prison.

#### ***Germany***

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<sup>3</sup> [http://www.cognitiveliberty.org/news/salvia\\_australia.htm](http://www.cognitiveliberty.org/news/salvia_australia.htm)

*S. divinorum* (plant and plant parts) was added to Appendix I of the *Narcotics Act* in Germany on March 1, 2008, making it illegal to produce, traffic, or possess. The law does not specifically mention salvinorin A.

### ***Italy***

On June 25, 2004, the Italian Ministry of Health issued an ordinance prohibiting the sale of *S. divinorum*, and its active constituent salvinorin A. On January 11, 2005, the Ministry of Health made possession of *S. divinorum* and salvinorin A illegal by placing them in “*Tabella 1*” of the *Tabella Sostanze Stupefacenti o Psicotrope*.

### ***Japan***

On November 9, 2006, the Japanese government added a group of thirty-three drugs to its list of controlled substances, including salvinorin A. The drugs will be banned under a revised pharmaceutical law, under which persons involved in their illegal import, production, and sale i.e., that beyond medical treatment or research purposes, will be subject to up to five years imprisonment or to a fine of up to five million yen.

### ***Spain***

On January 28, 2004 the Spanish Ministry of Health and Consumption issued an order prohibiting the sale of *S. divinorum*, along with a long list of other alleged “toxic” herbs. The regulation went into effect on May 6, 2004 and only prohibits activities related to commerce. Possession and/or use are not considered to be criminal offences.

In Estonia, Finland, Iceland and Norway *S. divinorum* is treated as a medicinal herb and it is illegal to import it without a relevant prescription from a doctor.

### ***United States of America***

*S. divinorum* and salvinorin A are not included in the Schedules to the United States *Controlled Substances Act*, although some individual states have implemented laws restricting its use, sale and/or distribution. As of October 2009, fourteen states have enacted legislation placing regulatory controls on *S. divinorum* and/or salvinorin A. Delaware, Florida, Illinois, Kansas, Nebraska, North Dakota, Ohio, Oklahoma, and Virginia have placed *S. divinorum* and/or salvinorin A into Schedule I of state law.

California, Louisiana, Maine, North Carolina and Tennessee have enacted other forms of legislation restricting the distribution of the plant. Legislative bills proposing regulatory controls died in Alabama, Alaska, Georgia, Indiana, Maryland, South Carolina, Texas and West Virginia.

### ***California***

For example, effective January 1, 2009, the sale or distribution of *S. divinorum* or salvinorin A, or any substance or material containing *S. divinorum* or salvinorin A, to any person under 18 years of age became a misdemeanor in the state of California that is now punishable by imprisonment in a county jail for not more than six months, by a fine of no more than \$1,000, or both.

### ***Louisiana***

In 2005, Louisiana passed a bill which prohibits the possession, production, manufacture and distribution of a material, compound, mixture, or preparation intended for human consumption which contains a hallucinogenic plant. A "hallucinogenic plant" is defined as "any part or portion" of the forty plants listed, which includes *S. divinorum*.

### ***Maine***

In Maine, *S. divinorum* and salvinorin A are regulated similar to how tobacco products are controlled. Adults eighteen years of age or over can legally purchase and use the material, but selling or providing *S. divinorum* or salvinorin A to anyone under the age of eighteen is a criminal offence. Possession by a minor is a civil violation, punishable by a fine, community service, or both.

### ***North Carolina***

On February 11, 2009, Senate Bill 138 was introduced to the North Carolina State Legislature which sought to make *Salvia divinorum* and salvinorin A Schedule I controlled substances in that state. This bill was later amended to make possession of *S. divinorum* an infraction, a minor crime punishable by a maximum \$25 fine. A third possession offence would be charged as a misdemeanor. There are no separate penalties for manufacturing or sales. This bill includes two exemptions. One permits growing the plant for aesthetic, landscaping, or decorative purposes; the other allows for university-affiliated medical or pharmacological research. The amended version passed the Senate unanimously on May 14, 2009, the House approved it on August 5, 2009 and it was signed into law on August 28, 2009. The new law came into effect on December 1, 2009.

### ***Tennessee***

On July 1, 2006, Tennessee classified the deliberate production, manufacture, distribution, or possession of the active chemical ingredient in the hallucinogenic plant *S. divinorum* as a Class A misdemeanor. It is not however a criminal offence to possess, plant, cultivate, grow, or harvest *S. divinorum* for aesthetic, landscaping, or decorative purposes. The law also does not apply to any dosage that is legally obtainable from a

retail establishment without a prescription when it is recognized by the FDA as a homeopathic drug.

In addition, the U.S. Department of Justice Drug Enforcement Agency (DEA) has also placed *S. divinorum* and salvinorin A on a list of drugs and chemicals "of concern," without legal implication.

#### 4.2.2 Chemical and Pharmacological Similarity to Other Substances Listed in the CDSA

The psychoactive ingredient in *Salvia divinorum* is salvinorin A. Other plants which contain psychotropic terpenoids are *Artemisia absinthium* (wormwood) and *Cannabis sativa*. Salvinorin A is considered by some as the most potent natural hallucinogen ever isolated.<sup>4</sup>

Unlike all other hallucinogens, salvinorin A is structurally distinct and does not interact with the serotonin-2A receptor or any other molecular target of classical hallucinogens. It thus affects the brain in a way that is quite unique.<sup>5</sup> Recent pharmacological screenings of receptors have found it to be a highly potent and selective  $\kappa$ -opioid receptor (KOR) agonist.<sup>6</sup>

The psychomimetic effects of *S. divinorum* closely resemble schizophrenia symptoms induced by LSD or PCP.<sup>7</sup> Yet, it is said to have only weak influence on the prevailing mood of the user which differentiates it from other hallucinogens such as LSD and psilocybin.<sup>8</sup> Its strong dissociative effects are often compared to those of ketamine. Users have reported that the psychedelic effects of *S. divinorum* were most similar to those caused by psilocybin mushrooms.<sup>9</sup> However, users familiar with the effects of other hallucinogens agree that despite certain similarities to classical hallucinogens, the visions and overall experience is quite unique.<sup>10</sup> In addition, while the psychedelic effects of *S. divinorum* are similar to those of classical psychedelics regarding changes in perception and somatic sensations. *S. divinorum* causes an

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<sup>4</sup> Ott J. Ethnopharmacognosy and human pharmacology of *Salvia divinorum* and salvinorin A. *Curare*. 1995 18: 103-129. Unofficial transcription available online. URL <http://www.sagewisdom.org/ott2.html>

<sup>5</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>6</sup> Roth BL, Baner K, Westkaemper R, Siebert D, Rice KC, Steinberg S, Ernsberger P, Rothman RB. Salvinorin A: a potent naturally occurring nonnitrogenous kappa opioid selective agonist. *Proc Natl Acad Sci U S A*. 2002 Sep 3;99(18):11934-9.

<sup>7</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>8</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>9</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>10</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6 and González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

unusually high degree of sedation, weakness and fatigue, while the increased de-realization is not commonly reported for classical psychedelics.<sup>11</sup> The combination of these effects seems to correlate with that of other KOR agonists such as pentazocine.<sup>12</sup>

#### 4.2.3 Legitimate Uses of Salvia *Divinorum*

There are no legitimate medical or industrial uses for *S. divinorum* in Canada.

Although selective kappa receptor agonists have been shown to produce analgesic effects, adverse effects such as psychotomimesis, dysphoria and diuresis have been observed in studies investigating their therapeutic use.<sup>13</sup>

*Salvia divinorum* has traditionally been used for spiritual and medicinal purposes by the Mazatec Indians in Oaxaca, Mexico,<sup>14</sup> where an infusion of the leaves or ingestion of the leaves is used to treat gastrointestinal problems, headaches, rheumatism, anemia and swelling of the stomach.<sup>15</sup> Its main use is however for its psychoactive properties in the aid of producing “mystical” or hallucinogenic experiences as part of spiritual rituals.<sup>16</sup>

#### 4.2.4 Potential for Abuse Liability and/or Addiction Liability of the Substance

Most clinically used opioid analgesics (e.g. codeine, oxycodone, morphine) are selective for the  $\mu$ -opioid receptor (MOR) and can be habit-forming<sup>17</sup> because activation of the MORs causes euphoria, which makes the user want to take them. As previously mentioned, salvinorin A is a potent, selective agonist of the  $\kappa$ -opioid receptor (KOR), and in contrast to the euphoria produced by MOR agonists, the KOR agonists are negatively reinforcing and aversive.<sup>18</sup> In addition, KOR

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<sup>11</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>12</sup> Arasteh K, Poudevida S, Farre M, Roset PN, Cami J. Response patterns of the Spanish version of the 49-item short form of the Addiction Research Center Inventory after the use of sedatives, stimulants, and opioids. *Drug Alcohol Depend.* 1999 Jun 1;55(1-2):117-25.

<sup>13</sup> Barker RL, Fawcett J, Barkin SJ. 2002. Chronic pain management with a focus on the role of newer antidepressants and centrally acting agents. In: *Pain Management: A Practical Guide for Clinicians*, 6th edition, Weiner RS ed. CRC Press, Boca Raton, FL. pp. 415-34 and **Error! Main Document Only.** Tidgewell et al., 2004. A facile method for the preparation of deuterium labelled salvinorin A: *Biorganic & Medicinal Chemistry Letters*, 14: 5099-5102.

<sup>14</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>15</sup> Munro, T. The Chemistry of *Salvia divinorum*. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

<sup>16</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage *Salvia divinorum*. *Life Sci.* 2005 Dec 22;78(5):527-31.

<sup>17</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.

<sup>18</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590, Cooper S. Interactions between endogenous opioids and dopamine: Implications for reward and aversion. In:



agonists have analgesic properties but are not associated with respiratory depression like MOR agonists. Initially, these effects provided hope for the development of an analgesic absent of addiction liability and respiratory depression, however, it was soon discovered that KOR agonists produced dysphoria and psychomimetic effects such as confusion, hallucinations and depersonalization.<sup>19</sup> Finally, while MOR increases the release of dopamine, the activation of KOR decreases dopamine release in the nucleus accumbens.<sup>20</sup>

The onset and intensity of the effects of *Salvia divinorum* appear to be related to the route of administration by which it is taken. Traditional uses generally produce mild effects because the leaves are rolled and chewed or crushed and prepared as a foamy infusion whereby the salvinorin A is degraded in the gastrointestinal system before being absorbed into the bloodstream. These methods rely on contact with the oral mucosa for absorption and the level of effect relates quite closely to the length of time the material spends in the mouth. Onset of effect generally takes 5-10 minutes which build over the next hour and last for another hour before the effects begin to subside.<sup>21</sup>

Routes that avoid the hepatic first-pass effect are the quickest and most intense.<sup>22</sup> Salvinorin A can be isolated from the plant to make a powder which can be vaporized and inhaled. This method of administration is the most powerful and only requires 200-500µg of salvinorin A powder to produce the same effects as those of fresh leaves. The onset of effect felt from vaporizing salvinorin A powder is about 30 seconds and effects last for about 5-10 minutes and subside over the next 30 minutes.<sup>23</sup>

Smoking is by far the most popular method of administration<sup>24</sup> and this is accomplished by smoking the dried leaves or a concentrated extract using a pipe or bong. Dried leaves may also be fortified with a concentrated extract of salvinorin A and/or a concentrated extract can also be

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*The Mesolimbic Dopamine System: From Motivation to Action.* Willner P and Scheel-Kruger J (editors) Wiley, Chester, England, 1991, pp. 331-366, and Shippenberg TS, Herz A, Spanagel R, Bals-Kubik R, Stein C. Conditioning of opioid reinforcement: neuroanatomical and neurochemical substrates. *Ann N Y Acad Sci.* 1992 Jun 28;654:347-56.

<sup>19</sup> Pfeiffer A, Brantl V, Herz A, Emrich HM. Psychotomimesis mediated by kappa opiate receptors. *Science.* 1986 Aug 15;233(4765):774-6, Rimoy GH, Wright DM, Bhaskar NK, Rubin PC. The cardiovascular and central nervous system effects in the human of U-62066E. A selective opioid receptor agonist. *Eur J Clin Pharmacol.* 1994;46(3):203-7, and Walsh SL, Strain EC, Abreu ME, Bigelow GE. Enadoline, a selective kappa opioid agonist: comparison with butorphanol and hydromorphone in humans. *Psychopharmacology (Berl).* 2001 Sep;157(2):151-62.

<sup>20</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.

<sup>21</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>22</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.

<sup>23</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>24</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62 and Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

used sublingually. *S. divinorum* nor salvinorin A are not injected because the powder is insoluble in water.<sup>25</sup>

Although the various modes of administration lead to variable onset and duration of the effects, the effects of *S. divinorum* are generally accepted to be: becoming objects, visions of various two-dimensional surfaces, films and membranes, revisiting places of the past (particularly childhood), loss of the body and/or identity, various sensations of motion (being pulled or twisted by a force of some kind), uncontrollable hysterical laughter, and overlapping realities (perceptions of being in more than one place).<sup>26</sup> Laughter, happiness, sense of well-being and dissociative effects were deemed the best aspects of *S. divinorum* by users, second only to the "trip" that the drug elicits.<sup>27</sup> Depersonalization, speaking gibberish, widening of consciousness, subjective illusions of rapid movement, flying or hovering however have also been reported.<sup>28</sup>

The aversive effects of previously studied KOR agonists would predict that the risk of addiction to *S. divinorum* is negligible, however, very few controlled scientific studies of the physical and psychotropic effects of *Salvia divinorum* on humans have been carried out and, therefore, using these studies to predict its potential for addiction and abuse is difficult. In addition, in the studies that have been conducted, there is conflicting information around the addiction liability of *S. divinorum* in both animals and humans. More controlled systematic research in this area is needed. Further studies on the mediated decrease of dopamine as well as the impact of dose on the reward and aversive effects are also warranted.

Another aspect of *S. divinorum*'s abuse potential stems from its availability. As previously mentioned it is widely available for purchase on the Internet through drug promotional sites and is also sold in various "head shops" and corner stores. In addition, the potential for high yields and ease of extraction may make buying and selling the drug quite affordable and attractive. Originally the concerns for the abuse potential were minimal since it was concluded that 1 kg of dried leaves yielded only 3 to 6 human doses of salvinorin A. However, it was discovered that vaporizing and inhaling 200-500 µg had profound hallucinogenic effects.<sup>29</sup> The extraction of salvinorin A from the plant is very easy and with care, approximately 1.5 grams of pure salvinorin A per kilogram of dried leaves (8kg of fresh leaves) can be isolated. Therefore, even poor yields of a gram per kilograms of dried leaves would provide a dose for 2000 human

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<sup>25</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs*. 1994 Jul-Sep;26(3):277-83.

<sup>26</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>27</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>28</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5 and Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>29</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

doses.<sup>30</sup> This easy isolation makes buying the drug quite affordable. *S. divinorum* leaves sell for \$0.50-7 per gram, plants for \$20-45 and the liquid extract for \$4-10 per millilitre.<sup>31</sup>

#### 4.2.5 Extent of Actual Abuse in Canada and Internationally

Very limited data exists regarding the actual population use of *Salvia divinorum* across the Canadian population. To address this lack of data, questions about the use of *S. divinorum* were included in the 2008-2009 Youth Smoking Survey, the 2009 Canadian Alcohol and Drug Use Monitoring Survey and the 2009 Ontario Student Drug Use and Health Survey.

The results from the 2009 Ontario Student Drug Use and Health Survey were published on November 18, 2009 and indicate that:

- Among all responding students in Ontario, 4.4% report using *Salvia divinorum* at least once in the past year;
- Males (6.2%) are significantly more likely than females (2.3%) to use *Salvia divinorum*;
- There is significant grade variation, with *Salvia divinorum* use most likely among 11<sup>th</sup> graders (8.6%) and 12<sup>th</sup> graders (8.4%); and
- There are significant regional variations, with students in the North (9.2%) most likely to use *Salvia divinorum*.

Further data from the two national surveys, i.e., the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey, will be available in 2010.

As far as law enforcement is concerned, the Department has only received a limited number of communications indicating concern with respect to *S. divinorum* and none of these have advised that the use of *S. divinorum* poses any threat to public safety.

Health Canada's Drug Analysis Services (DAS) has collected some raw data regarding the number of samples identified as containing salvinorin A in the DAS labs, however, as the plant and/or substance is not in the CDSO druglist, it is not possible to have records of any seizures of it in the database.

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<sup>30</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs*. 1994 Jul-Sep;26(3):277-83.

<sup>31</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

**NUMBER OF SAMPLES FOUND TO CONTAIN SALVINORIN A**

Year Return Completed	Count
2006	6
2007	8
2008	6
2009	To be updated

In addition, the National Forensic Laboratory Information System (NFLIS) and the System to Retrieve Information from Drug Evidence (STRIDE) in the United States is a Drug Enforcement Agency (DEA) database that collects scientifically verified data on analyzed samples in state and local forensic labs. It also includes data from STRIDE, which are analyzed samples from DEA labs. The following table shows *Salvia divinorum* items seized from 2000 through 2008.

**ANALYZED SALVIA DIVINORUM or SALVINORIN A SEIZURES**

(Number of items/Exhibits)

Source	2000	2001	2002	2003	2004	2005	2006	2007	2008*
NFLIS-State/Local <sup>1</sup>	0	0	0	0	1	8	12	12	32
STRIDE <sup>2</sup>	0	0	1	1	1	0	0	0	0
<b>TOTAL</b>	0	0	1	1	2	8	12	12	32

Data Source: NFLIS & STRIDE, 2008 data queried 11/24/2008

<sup>1</sup> NFLIS reported items of salvinorin A

<sup>2</sup> STRIDE reported items of *Salvia divinorum*.

\* Includes only January – September data in 2008.

Two reports regarding the abuse of *S. divinorum* have been published in the academic literature. The first was an international case report in which a young man (19 years of age) described his perceptions after inhaling the smoke from *S. divinorum*. The peak psychotropic effects, including prickling of the skin, fever-like hot flashes, muscular tremor, and depersonalization, were reached in less than five minutes after inhalation of an unknown amount of dried leaves.<sup>32</sup> The second case involved a 15-year-old male who presented to psychiatric emergency services with acute onset of paranoia, déjà vu, blunted affect, thought blocking and slowed speech, after smoking *Salvia divinorum* over an unknown period of time. During his hospitalization all symptoms improved significantly except the feeling of déjà vu. Based on this case presentation, the author suggested that the feelings of déjà vu may be considered long-term effects of *Salvia* use.<sup>33</sup> However, given that this is the only case report in which déjà vu was associated with the use of *S. divinorum*, more reports are needed to substantiate this finding.

In addition to the above-mentioned case reports, in 2006, a case was reported in the U.S. in which a 17-year-old boy committed suicide after smoking *S. divinorum* for unknown period

<sup>32</sup> **Error! Main Document Only.** Bucheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>33</sup> **Error! Main Document Only.** Singh S. (2007) Adolescent salvia substance abuse. *Addiction*. 102, 823-824.

of time.<sup>34</sup> It should be noted that alcohol and general depression were the main confounders in this case. This case did, however, result in the state of Delaware passing a law outlawing *S. divinorum*, and classifying it as a Schedule I controlled substance with other hallucinogenic substances.

It is difficult to determine the extent of actual abuse of *S. divinorum* as there appear to be inconsistencies in the literature regarding risk aversion. For example, one author states: "Many who have used salvinorin A find the experience extremely unnerving, frightening and overly intense and most have no desire to repeat the experience."<sup>35</sup>, however, this aversion to the drug is not an effect being echoed in other studies and reports.<sup>36</sup> Moreover, over eighty percent of users surveyed on a web-based questionnaire about their *S. divinorum* use said they would probably or definitely use *S. divinorum* again.<sup>37</sup> Therefore, despite the fact that users have reported the negative effects of *S. divinorum* as: the short duration of action, lack of control over the experience, persisting negative effects (most often anxiety)<sup>38</sup> sweating, chills, increased diuresis, impaired vigilance,<sup>39</sup> and negative after-effects including tiredness, feeling head heavy, dizziness, physical exhaustion, and some degree of malaise or 'hangover' as they 'comedown' from the drug,<sup>40</sup> it is difficult to determine the influence these effects have on the use of *S. divinorum*.

#### 4.2.6 Overall Risk to Public Health and Safety of Canadians

The increase in the number of enquiries from various municipalities and members of the public and in the amount of media interest regarding the availability of *Salvia divinorum* in Canada may be an indication that the recreational use of *S. divinorum* as a hallucinogen may be on the rise in Canada. It is, however, premature to make this assumption as Health Canada presently does not have any viable statistics on the actual population use of *S. divinorum* across the Canadian population.

The potential for harm to the user and/or other individuals may be increased as users may get up and walk around without apparent awareness of their movements, behaviour or surroundings, distinction between self and surroundings is lost, and at doses greater than 1mg of salvinorin A,

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<sup>34</sup> <http://www.kvbc.com/Global/story.asp?S=4893692>

<sup>35</sup> Turner DM. Salvinorin - The Psychedelic Essence of Salvia Divinorum. Panther Press, San Francisco, CA 1996.

<sup>36</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62, Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5, and Valdès LJ 3rd. Salvia divinorum and the unique diterpene hallucinogen, Salvinorin (divinorin) A. J Psychoactive Drugs. 1994 Jul-Sep;26(3):277-83.

<sup>37</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>38</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>39</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5.

<sup>40</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

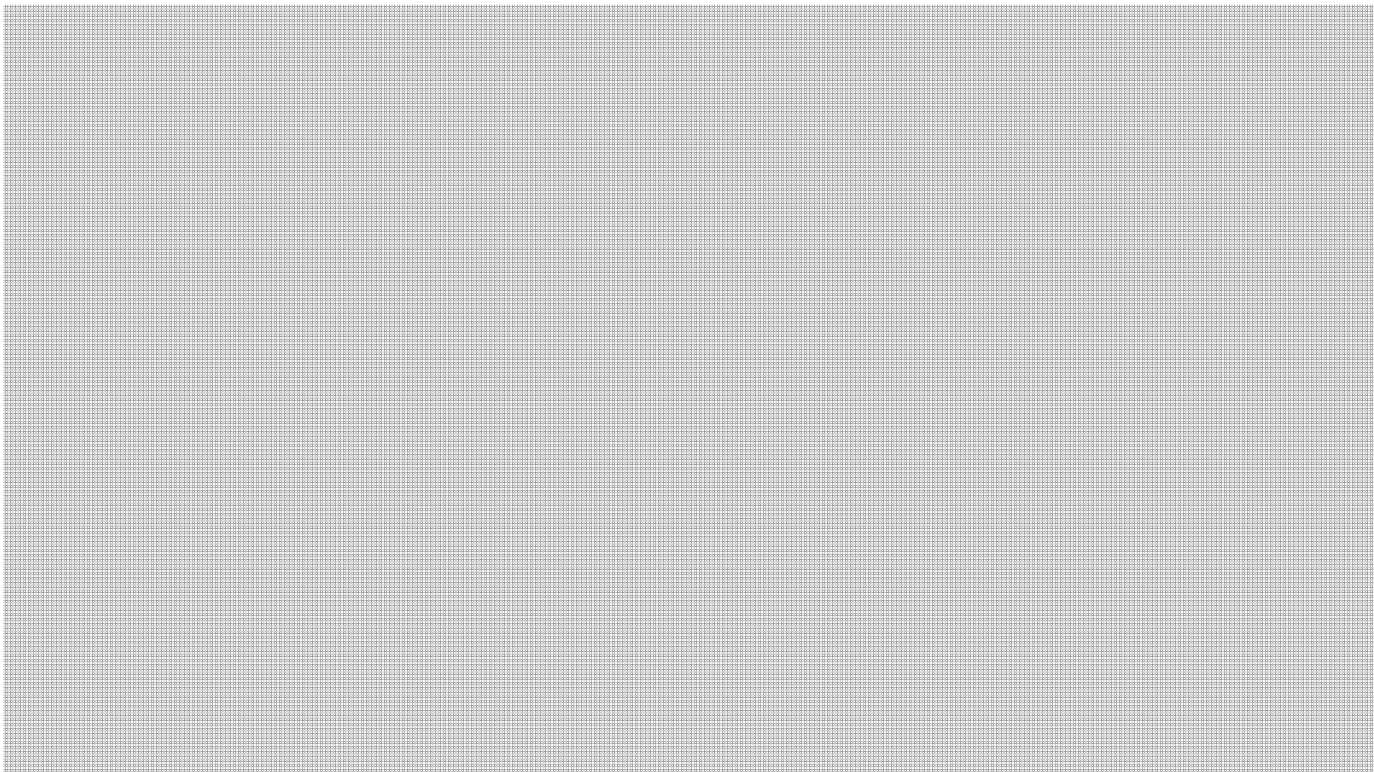
s.21(1)(a)  
s.21(1)(b)

out of body experiences are frequent and loss of consciousness has been reported.<sup>41</sup>

As stated earlier, there are no approved medical uses for *S. divinorum* in Canada. Health Canada has also not received nor approved any submissions for natural health products for sale in Canada. Therefore, products that claim to contain this substance have not been extensively reviewed by Health Canada and as such, may be counterfeit or may contain other ingredients that may pose risks to health. For example, like all drugs of abuse, the users are often unaware of the potency and adulterants in the products they are purchasing. A study by Wolowich *et al.* (2006)<sup>42</sup>, showed that the salvinorin A content in five out of five *S. divinorum* products were falsely indicated on the label and 4 out of 5 products contained unidentified adulterants (i.e. vitamin E, caffeine).

Health Canada has only anecdotal information about the use of *S. divinorum* in Canada and the risk of abuse and/or risk that *S. divinorum* poses to the health and safety of Canadians. Although reports of domestic adverse reactions related to the use of *S. divinorum* as a hallucinogen have been received through the Canada Vigilance database, it is important to note that the number of reports and the nature of reactions reported are not adequate to characterize the risk to the general population. These data cannot be used to determine incidence of use in the general population, as Health Canada does not have any information about the number of individuals using or who have used *S. divinorum*.

## 5. ASSESSMENT OF RISKS AND BENEFITS (OPTIONAL)



<sup>41</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>42</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five Salvia divinorum herbal products. Pharmacotherapy. 2006 Sep;26(9):1268-72.

**Page(s) 000629 to\à 000632**

**Is(Are) exempted pursuant to section(s)  
est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**

## 7. CONSIDERATIONS

*S. divinorum*'s KOR-mediated aversive and dysphoric effects do not appear to be hampering its use. Young adults have begun smoking the leaves and leaf extract recreationally.<sup>46</sup> It can be purchased through online botanical companies and other drug promotional sites and is often touted as a legal alternative to substances such as cannabis and mescaline.<sup>47</sup> Interestingly though, after being widely available for over a decade, the drug has not had any extreme social impact as did LSD or MDMA.<sup>48</sup>

The following points should be considered:

- Over the past few years, there has been an increase in the number of enquiries that Health Canada is receiving from various municipalities and members of the public regarding the availability of *Salvia divinorum* as a hallucinogen.

<sup>46</sup> Hazelden Foundation, 2004. Drug Abuse Trends. June 2004. URL: [www.research.hazelden.org](http://www.research.hazelden.org).

<sup>47</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

<sup>48</sup> Munro, T. The Chemistry of *Salvia divinorum*. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.



s.21(1)(a)

s.21(1)(b)

- Health Canada has also observed a steady increase in the amount of media interest regarding the availability of *S. divinorum* in Canada.

*Salvia divinorum* meets the definition of a natural health product (NHP) under the *Natural Health Product Regulations* (NHPR). This means that products containing *S. divinorum* must be approved by Health Canada prior to sale in Canada and that product's that are not in compliance with the NHPR may be subject to compliance and enforcement actions. As Health Canada has yet to receive and/or approve any applications for natural health products containing *S. divinorum* for sale on the Canadian market, it is difficult to ascertain how much *S. divinorum* is currently sold or consumed in Canada at the present time. Several challenges also arise with respect to the importation and domestic movement of such products as they are often declared as incense and therefore cannot be considered non-market natural health products. In addition, compliance and enforcement actions, such as voluntary stop-sales, forfeiture, destruction, and administrative seizure, cannot be implemented unless the labeling clearly indicates that the product is to be used for consumption and/or pharmacological effects (ie. statements regarding contraindications or restrictions on use) upon which the product will no longer meet the definition of a consumer product (i.e. incense) and will meet the definition of a NHP. The NHPR are therefore limited in their capacity to control the availability of *S. divinorum* beyond the scope of scenarios listed above.

- It is also hard to know because we have no way of tracking or counting

## 8. RECOMMENDATION

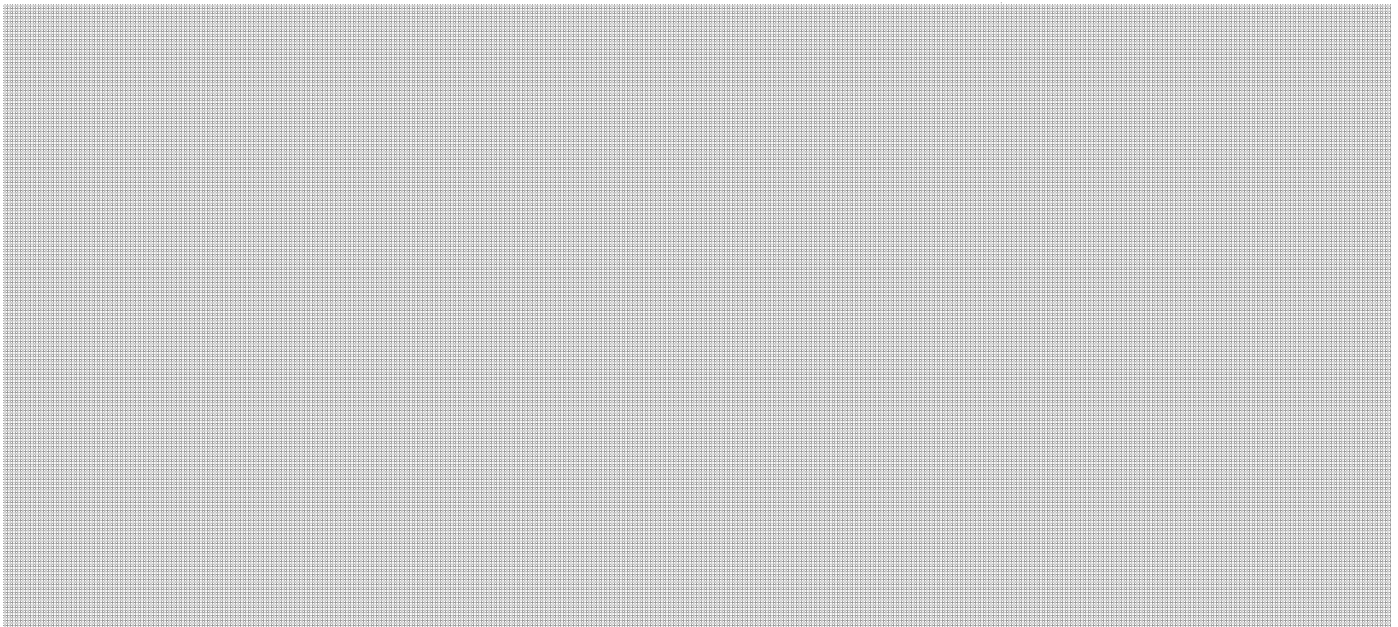
**9. CONSULTATIONS**

**s.21(1)(a)**

**s.21(1)(b)**

- Drug Analysis Services (DAS)
- Royal Canadian Mounted Police (RCMP)
- Canada Border Services Agency (CBSA)

**10. IMPLEMENTATION AND EVALUATION**



# Issue Analysis Summary

DRAFT

## Scheduling *Salvia Divinorum* and/or *Salvinorin A* under the CDSA

Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Controlled Substances and Tobacco and Directorate

January 13, 2010

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9. CONSULTATIONS
10. IMPLEMENTATION AND EVALUATION

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#### 1. APPROVALS

This Issue Analysis Summary is approved.

→ Where does our scheduling into law come into consideration in this assessment?

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Diane Allan, Director  
Office of Controlled Substances  
Tobacco and Drugs Directorate

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[DD/MM/2009]  
2010

#### 2. ISSUE

In Canada, neither the herb *Salvia divinorum* (*S. divinorum*) nor its main active ingredient, salvinorin A, are controlled under the *Controlled Drugs and Substances Act* (CDSA). Health Canada has received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *S. divinorum*, particularly given reports from scientific and media sources suggesting that *S. divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health

Canada has also noted an ongoing media interest regarding the availability of *S. divinorum* in Canada.

### 3. PURPOSE

To assess *Salvia divinorum* and/or salvinorin A against the criteria for the addition of a substance to one of the Schedules to the CDSA, in order to determine whether or not *S. divinorum*, and/or salvinorin A, should be regulated as controlled substances in Canada.

### 4. CONTEXT

*Salvia divinorum* is a species of sage which belongs to the mint family, and which is found in the form of dried leaves, extract and plant cuttings. Also known as "diviner's sage", the plant is known to induce illusions and hallucinations when chewed or smoked. Salvinorin A, the psychoactive ingredient in *S. divinorum*, which is also referred to chemically as a neoclerodane diterpene, is found primarily in the leaves, and to a lesser extent in the stems.<sup>1</sup>

*S. divinorum* is widely touted as a "legal" alternative to street drugs on the Internet, and has also been reported to be one of the most prevalently marketed herbal dietary supplements available for use as an alternative to illicit drugs of abuse among adolescents and young adults.<sup>2</sup> While very little is known about how and where *S. divinorum* is sold in Canada, it is suspected that it is mainly purchased over the Internet and/or bought at head shops, and alternative life style stores, etc.

A 2006 National Survey on Drug Use and Health Report, published in February 2008 by the Substance Abuse and Mental Health Administration in the United States, also estimated that:

- 1.8 million persons aged 12 or older used *Salvia divinorum* in their lifetime, with approximately 750,000 having done so in the past year;
- Use was more common among young adults (18 to 25 years old) as opposed to older adults (> 26 years of age);
- Young adults were nearly three times more likely than youths, aged 12 to 17, to have used *Salvia divinorum* in the past year; and
- Use was more common in males than in females.

1 U.S. Department of Justice Drug Enforcement Administration. 2002. Drugs and Chemicals of Concern: Salvia Divinorum (salvinorin A, divinorin A) URL:

[http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm) Nov 2008

2 Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.

some have  
no effect  
> (AD)?  
others  
causities?

The use of *S. divinorum* as a psychotropic agent first came to Health Canada's attention in 2002. In 2004, Health Canada received four adverse drug reaction (ADR) reports associated with the use of *S. divinorum* as a hallucinogen, with three being considered non-serious (requiring no medical attention) and the fourth being considered serious (medical intervention was required) and involving the concomitant use of alcohol in a person diagnosed with Attention Deficit Disorder.

Further to the receipt of the aforementioned ADRs, the Marketed Health Products Directorate (MHPD) and the Natural Health Products Directorate (NHPD), of the Health Products and Food Branch (HPFB), prepared an issue analysis summary (IAS), which recommended that *S. divinorum* and its active ingredient salvinorin A be regulated as a controlled substance (a recommendation that was maintained when the IAS was updated in November 2006).

Later, in December 2005, MHPD and NHPD prepared a Signal Assessment (SA) (updated in June, 2007) that eventually led to the preparation of a Health Risk Assessment (HRA), which concluded that *S. divinorum* or salvinorin A-containing health products should be restricted from over-the-counter use. Should any such (unauthorized) health products be found on the Canadian market, they should be removed from sale. Such products would constitute a Type II Health Risk, defined as "A situation in which there is a reasonable probability that the use of, or exposure to, a product, will cause moderate or mild adverse health consequences.

should have a description of what this means (regulation)

Further to an ADM discussion in April 2007, DSCSD organized a meeting with MHPD, NHPD and the Inspectorate of HPFB (HPFBI) on May 16, 2007 to discuss *S. divinorum*. At that time, it was decided that *S. divinorum* would be classified by HPFB as a Type II substance. MHPD was to send the HRA and SA to DCSCD, look into preparing an adverse reaction case presentation in the ADR Newsletter, and explore the possibility of developing a product advisory. HPFBI was to determine compliance activities based on the HRA Type II classification and check with Canada Border Services Agency (CBSA) to determine if any further information regarding *S. divinorum* shipments was available. The Office of Research and Surveillance, DSCSD was to continue to work on the *S. divinorum* Fact Sheet and explore the feasibility of a health food/natural food store survey on *S. divinorum*. OCS was to gather information from Australia regarding its scheduling decision and to find out whether the DEA had any plans to schedule *S. divinorum* in the near future.

On September 13, 2007, a meeting was organized between DSCSD, MHDP, NHPD and HPFBI to discuss what is known about *S. divinorum* from a regulatory perspective and to reach consensus on next steps.

The following action items came out of this meeting:

- (1) DSCSD to submit a response to the MHPD/NHPD analytical documents and MHPD/NHPD to make changes accordingly;
- (2) DSCSD to finalize the latest version of the media lines on *S. divinorum* and put them forward, via Communications, for approval in HPFB;
- (3) DSCSD to find out the status of draft fact sheet that was being developed by its Office

of Research and Surveillance;

(4) HPFBI to discuss the potential allocation of additional resources, e.g., additional inspectors, etc. to the *S. divinatorum* file; and

scheduling assessment →

(5) DSCSD to explore the notion of scheduling, i.e., carry out a preliminary scheduling assessment, as part of a mid to long-term action plan.

The Director Generals of DSCSD, MHPD, TPD and the HPFBI also met on September 26, 2008 to discuss an update on issues relating to *S. divinatorum* and to determine an agreed upon approach for subsequent steps.

The following action items came out of that meeting:

- (1) Review and provide comments on *S. divinatorum* IAS and SA and revise and re-issue IAS and SA, as needed;
- (2) circulate draft Fact Sheet for comment and explore the possibility of developing a public-friendly communication;
- (3) prepare draft media lines for *S. divinatorum* and circulate for comment;
- (4) contact DAS labs for any information on *S. divinatorum*;
- (5) prepare project charter for *S. divinatorum* working group;
- (6) contact Public Health Agency Canada (PHAC) for representation;
- (7) continue work on scheduling assessment for *S. divinatorum*; and
- (8) continue sharing information relating to *S. divinatorum* as it arises.

#### 4.1 **Legislative Frameworks for Drug Control in Canada**

##### 4.1.1 Food and Drug Regulations → under FDA

The *Food and Drug Regulations* (F&DR) serve to ensure the safety, efficacy, and quality of health products offered for sale in Canada, including drugs and medical devices. Prior to being given market authorization, a manufacturer must present substantive scientific evidence of a product's safety, efficacy and quality and Health Canada reviews this information carefully. If the review is satisfactory, a Notice of Compliance (NOC) is issued and appropriate Drug Identification Numbers (DINs) are assigned.

A "drug" is defined under the F&DR as any substance or mixture of substances manufactured, sold or represented for use in

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
- (b) restoring, correcting or modifying organic functions in human beings or animals, or
- (c) disinfection in premises in which food is manufactured, prepared or kept;

##### 4.1.2 Natural Health Product Regulations (under FDA)

→ 11-11-13  
100 TDA

The *Natural Health Products Regulations* (NHPR) came into force in January, 2004 to provide Canadians with ready access to natural health products (NHPs) that are safe, effective, and of high quality, while respecting freedom of choice and philosophical and cultural diversity. The NHPR contain a product licensing system that requires that all licensed products display a product identification number preceded by the prefix NPN, or, in the case of a homeopathic medicine, by the letters DIN-HM on their labels. The number is issued once a product is authorized for sale in Canada by the Natural Health Products Directorate. Product authorization requires either reference to a *natural health product monograph* or submission of other evidence of safety and health claim. A system of site licensing is also included in the NHPR which requires that all manufacturers, packagers, labellers, and importers be licensed; sites have procedures in place respecting distribution records and product recalls; where applicable, sites have procedures in place for the handling, storage and delivery of their products, and sites meet good manufacturing practice requirements.

The definition of an NHP under the NHPR has both a function and substance component. The function component refers to those substances that are manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
- (b) restoring or correcting organic functions in humans; or
- (c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

The substance component refers to whether the product or medicinal ingredient therein, is safe for consideration as an over-the-counter product, can be available for self-care and self-selection, and does not require a prescription to be sold.

#### **4.1.3 Controlled Drugs and Substances Act and its Regulations**

The CDSA provides a legislative framework for the control of substances that can alter mental processes and that may produce harm to the health of an individual or to society when diverted or misused. Except as authorized under its regulations, activities such as possession, possession for the purposes of trafficking, trafficking, importation, exportation, possession for the purposes of exportation and production of controlled substances are prohibited under the CDSA.

The substances regulated under the CDSA are grouped into eight Schedules, and each Schedule is associated with particular penalties as described in Part I of the CDSA.

In determining whether a substance should be regulated as a controlled substance, and into which Schedule to the CDSA is should be placed, Health Canada considers the following factors:

- International requirements and trends in control/scheduling;
- Chemical and pharmacological similarity to other substances already scheduled under the CDSA;
- Legitimate uses of the substance (i.e. therapeutic, industrial or commercial);
- Potential for abuse and/or addiction liability of the substance;
- Extent of actual abuse in Canada and internationally; and
- Overall risk to public health and safety of Canadians.

#### 4.2 Assessment of *Salvia Divinorum* for Scheduling Purposes

##### 4.2.1 International Requirements and Trends in Control/Scheduling

are they looking at it?  
with a memo?  
NO :\$

At the present time, neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and therefore do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these conventions.

##### *Australia*

In June, 2002, Australia became the first country to prohibit *S. divinorum* and salvinorin A. Although both *S. divinorum* and salvinorin A are listed on Schedule 9 of Australia's Standard for the Uniform Scheduling of Drugs and Poisons on the basis of "high potential for abuse and risk to public health and safety", no substantiation of this risk was provided at the time of this scheduling decision. Schedule 9 is Australia's most restrictive drug schedule, and includes "substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities."<sup>3</sup>

examples

##### *Belgium*

A decree was passed in Belgium on October 22, 2006 which added *S. divinorum* to the list of controlled substances.

no info of which class? NO. which includes hallucinogenic mushrooms, khat and peyote cactus.

##### *Denmark*

Shortly after, in 2003, Denmark prohibited *S. divinorum* and salvinorin A by adding them to their list of "category B" controlled substances, a category which also includes psilocybin mushrooms, cocaine, amphetamine, and several others substances that are only legal for medicinal and scientific purposes. Illegal possession carries a penalty of up to two years in prison.

##### *Germany*

<sup>3</sup> [http://www.cognitivefreedom.org/news/salvia\\_australia.htm](http://www.cognitivefreedom.org/news/salvia_australia.htm)



*S. divinorum* (plant and plant parts) was added to Appendix I of the *Narcotics Act* in Germany on March 1, 2008, making it illegal to produce, traffic, or possess. The law does not specifically mention salvinorin A.

### **Italy**

On June 25, 2004, the Italian Ministry of Health issued an ordinance prohibiting the sale of *S. divinorum*, and its active constituent salvinorin A. On January 11, 2005, the Ministry of Health made possession of *S. divinorum* and salvinorin A illegal by placing them in "Tabella I" of the *Tabelle Sostanze Stupefacenti o Psicotrope*.

### **Japan**

On November 9, 2006, the Japanese government added a group of thirty-three drugs to its list of controlled substances, including salvinorin A. The drugs will be banned under a revised pharmaceutical law, under which persons involved in their illegal import, production, and sale i.e., that beyond medical treatment or research purposes, will be subject to up to five years imprisonment or to a fine of up to five million yen.

### **Spain**

On January 28, 2004 the Spanish Ministry of Health and Consumption issued an order prohibiting the sale of *S. divinorum*, along with a long list of other alleged "toxic" herbs. The regulation went into effect on May 6, 2004 and only prohibits activities related to commerce. Possession and/or use are not considered to be criminal offences.

In Estonia, Finland, Iceland and Norway *S. divinorum* is treated as a medicinal herb and it is illegal to import it without a relevant prescription from a doctor.

### **United States of America**

*S. divinorum* and salvinorin A are not included in the Schedules to the United States *Controlled Substances Act*, although some individual states have implemented laws restricting its use, sale and/or distribution. As of October 2009, fourteen states have enacted legislation placing regulatory controls on *S. divinorum* and/or salvinorin A. Delaware, Florida, Illinois, Kansas, Nebraska, North Dakota, Ohio, Oklahoma, and Virginia have placed *S. divinorum* and/or salvinorin A into Schedule I of state law.

California, Louisiana, Maine, North Carolina and Tennessee have enacted other forms of legislation restricting the distribution of the plant. Legislative bills proposing regulatory controls died in Alabama, Alaska, Georgia, Indiana, Maryland, South Carolina, Texas and West Virginia.

### **California**

For example, effective January 1, 2009, the sale or distribution of *S. divinorum* or salvinorin A, or any substance or material containing *S. divinorum* or salvinorin A, to any person under 18 years of age became a misdemeanor in the state of California that is now punishable by imprisonment in a county jail for not more than six months, by a fine of no more than \$1,000, or both.

### ***Louisiana***

In 2005, Louisiana passed a bill which prohibits the possession, production, manufacture and distribution of a material, compound, mixture, or preparation intended for human consumption which contains a hallucinogenic plant. A "hallucinogenic plant" is defined as "any part or portion" of the forty plants listed, which includes *S. divinorum*.

### ***Maine***

In Maine, *S. divinorum* and salvinorin A are regulated similar to how tobacco products are controlled. Adults eighteen years of age or over can legally purchase and use the material, but selling or providing *S. divinorum* or salvinorin A to anyone under the age of eighteen is a criminal offence. Possession by a minor is a civil violation, punishable by a fine, community service, or both.

### ***North Carolina***

On February 11, 2009, Senate Bill 138 was introduced to the North Carolina State Legislature which sought to make *Salvia divinorum* and salvinorin A Schedule I controlled substances in that state. This bill was later amended to make possession of *S. divinorum* an infraction, a minor crime punishable by a maximum \$25 fine. A third possession offence would be charged as a misdemeanor. There are no separate penalties for manufacturing or sales. This bill includes two exemptions. One permits growing the plant for aesthetic, landscaping, or decorative purposes; the other allows for university-affiliated medical or pharmacological research. The amended version passed the Senate unanimously on May 14, 2009, the House approved it on August 5, 2009 and it was signed into law on August 28, 2009. The new law came into effect on December 1, 2009.

### ***Tennessee***

On July 1, 2006, Tennessee classified the deliberate production, manufacture, distribution, or possession of the active chemical ingredient in the hallucinogenic plant *S. divinorum* as a Class A misdemeanor. It is not however a criminal offence to possess, plant, cultivate, grow, or harvest *S. divinorum* for aesthetic, landscaping, or decorative purposes. The law also does not apply to any dosage that is legally obtainable from a

retail establishment without a prescription when it is recognized by the FDA as a homeopathic drug.

In addition, the U.S. Department of Justice Drug Enforcement Agency (DEA) has also placed *S. divinorum* and salvinorin A on a list of drugs and chemicals "of concern," without legal implication.

#### 4.2.2 Chemical and Pharmacological Similarity to Other Substances Listed in the CDSA

The psychoactive ingredient in *Salvia divinorum* is salvinorin A. Other plants which contain psychotropic terpenoids are *Artemisia absinthium* (wormwood) and *Cannabis sativa*. Salvinorin A is considered by some as the most potent natural hallucinogen ever isolated.<sup>4</sup>

Unlike all other hallucinogens, salvinorin A is structurally distinct and does not interact with the serotonin-2A receptor or any other molecular target of classical hallucinogens. It thus affects the brain in a way that is quite unique.<sup>5</sup> Recent pharmacological screenings of receptors have found it to be a highly potent and selective  $\kappa$ -opioid receptor (KOR) agonist.<sup>6</sup>

The psychomimetic effects of *S. divinorum* closely resemble schizophrenia symptoms induced by LSD or PCP.<sup>7</sup> Yet, it is said to have only weak influence on the prevailing mood of the user which differentiates it from other hallucinogens such as LSD and psilocybin.<sup>8</sup> Its strong dissociative effects are often compared to those of ketamine. Users have reported that the psychedelic effects of *S. divinorum* were most similar to those caused by psilocybin mushrooms.<sup>9</sup> However, users familiar with the effects of other hallucinogens agree that despite certain similarities to classical hallucinogens, the visions and overall experience is quite unique.<sup>10</sup> In addition, while the psychedelic effects of *S. divinorum* are similar to those of classical psychedelics regarding changes in perception and somatic sensations. *S. divinorum* causes an

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<sup>4</sup> Ott J. Ethnopharmacognosy and human pharmacology of *Salvia divinorum* and salvinorin A. *Curare*. 1995 18: 103-129. Unofficial transcription available online. URL <http://www.sagewisdom.org/ott2.html>

<sup>5</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>6</sup> Roth BL, Baner K, Westkaemper R, Siebert D, Rice KC, Steinberg S, Ernsberger P, Rothman RB. Salvinorin A: a potent naturally occurring nonnitrogenous kappa opioid selective agonist. *Proc Natl Acad Sci U S A*. 2002 Sep 3;99(18):11934-9.

<sup>7</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>8</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>9</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>10</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6 and González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

unusually high degree of sedation, weakness and fatigue, while the increased de-realization is not commonly reported for classical psychedelics.<sup>11</sup> The combination of these effects seems to correlate with that of other KOR agonists such as pentazocine.<sup>12</sup>

#### 4.2.3 Legitimate Uses of Salvia Divinorum

There are no legitimate medical or industrial uses for *S. divinorum* in Canada.

Although selective kappa receptor agonists have been shown to produce analgesic effects, adverse effects such as psychotomimesis, dysphoria and diuresis have been observed in studies investigating their therapeutic use.<sup>13</sup>

*Salvia divinorum* has traditionally been used for spiritual and medicinal purposes by the Mazatec Indians in Oaxaca, Mexico,<sup>14</sup> where an infusion of the leaves or ingestion of the leaves is used to treat gastrointestinal problems, headaches, rheumatism, anemia and swelling of the stomach.<sup>15</sup> Its main use is however for its psychoactive properties in the aid of producing “mystical” or hallucinogenic experiences as part of spiritual rituals.<sup>16</sup>

#### 4.2.4 Potential for Abuse Liability and/or Addiction Liability of the Substance

Most clinically used opioid analgesics (e.g. codeine, oxycodone, morphine) are selective for the  $\mu$ -opioid receptor (MOR) and can be habit-forming<sup>17</sup> because activation of the MORs causes euphoria, which makes the user want to take them. As previously mentioned, salvinorin A is a potent, selective agonist of the  $\kappa$ -opioid receptor (KOR), and in contrast to the euphoria produced by MOR agonists, the KOR agonists are negatively reinforcing and aversive.<sup>18</sup> In addition, KOR

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<sup>11</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>12</sup> Arasteh K, Poudevida S, Farre M, Roset PN, Cami J. Response patterns of the Spanish version of the 49-item short form of the Addiction Research Center Inventory after the use of sedatives, stimulants, and opioids. Drug Alcohol Depend. 1999 Jun 1;55(1-2):117-25.

<sup>13</sup> Barker RL, Fawcett J, Barkin SJ. 2002. Chronic pain management with a focus on the role of newer antidepressants and centrally acting agents. In: Pain Management: A Practical Guide for Clinicians, 6th edition, Weiner RS ed. CRC Press, Boca Raton, FL. pp. 415-34 and **Error! Main Document Only.** Tidgewell et al., 2004. A facile method for the preparation of deuterium labelled salvinorin A: Biorganic & Medicinal Chemistry Letters, 14: 5099-5102.

<sup>14</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>15</sup> Munro, T. The Chemistry of Salvia divinorum. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

<sup>16</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage Salvia divinorum. Life Sci. 2005 Dec 22;78(5):527-31.

<sup>17</sup> Gustein HB & Akil H. Opioid Analgesics. In: Goodman and Gilman's The Pharmacological Basis of Therapeutics 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.

<sup>18</sup> Gustein HB & Akil H. Opioid Analgesics. In: Goodman and Gilman's The Pharmacological Basis of Therapeutics 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590, Cooper S. Interactions between endogenous opioids and dopamine: Implications for reward and aversion. In:

agonists have analgesic properties but are not associated with respiratory depression like MOR agonists. Initially, these effects provided hope for the development of an analgesic absent of addiction liability and respiratory depression, however, it was soon discovered that KOR agonists produced dysphoria and psychomimetic effects such as confusion, hallucinations and depersonalization.<sup>19</sup> Finally, while MOR increases the release of dopamine, the activation of KOR decreases dopamine release in the nucleus accumbens.<sup>20</sup>

The onset and intensity of the effects of *Salvia divinorum* appear to be related to the route of administration by which it is taken. Traditional uses generally produce mild effects because the leaves are rolled and chewed or crushed and prepared as a foamy infusion whereby the salvinorin A is degraded in the gastrointestinal system before being absorbed into the bloodstream. These methods rely on contact with the oral mucosa for absorption and the level of effect relates quite closely to the length of time the material spends in the mouth. Onset of effect generally takes 5-10 minutes which build over the next hour and last for another hour before the effects begin to subside.<sup>21</sup>

Routes that avoid the hepatic first-pass effect are the quickest and most intense.<sup>22</sup> Salvinorin A can be isolated from the plant to make a powder which can be vaporized and inhaled. This method of administration is the most powerful and only requires 200-500µg of salvinorin A powder to produce the same effects as those of fresh leaves. The onset of effect felt from vaporizing salvinorin A powder is about 30 seconds and effects last for about 5-10 minutes and subside over the next 30 minutes.<sup>23</sup>

Smoking is by far the most popular method of administration<sup>24</sup> and this is accomplished by smoking the dried leaves or a concentrated extract using a pipe or bong. Dried leaves may also be fortified with a concentrated extract of salvinorin A and/or a concentrated extract can also be

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*The Mesolimbic Dopamine System: From Motivation to Action*. Willner P and Scheel-Kruger J (editors) Wiley, Chester, England, 1991, pp. 331-366, and Shippenberg TS, Herz A, Spanagel R, Bals-Kubik R, Stein C. Conditioning of opioid reinforcement: neuroanatomical and neurochemical substrates. *Ann N Y Acad Sci*. 1992 Jun 28;654:347-56.

<sup>19</sup> Pfeiffer A, Brantl V, Herz A, Emrich HM. Psychotomimesis mediated by kappa opiate receptors. *Science*. 1986 Aug 15;233(4765):774-6, Rimoy GH, Wright DM, Bhaskar NK, Rubin PC. The cardiovascular and central nervous system effects in the human of U-62066E. A selective opioid receptor agonist. *Eur J Clin Pharmacol*. 1994;46(3):203-7, and Walsh SL, Strain EC, Abreu ME, Bigelow GE. Enadoline, a selective kappa opioid agonist: comparison with butorphanol and hydromorphone in humans. *Psychopharmacology (Berl)*. 2001 Sep;157(2):151-62.

<sup>20</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.

<sup>21</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>22</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

<sup>23</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>24</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62 and Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

used sublingually. *S. divinorum* nor salvinorin A are not injected because the powder is insoluble in water.<sup>25</sup>

Although the various modes of administration lead to variable onset and duration of the effects, the effects of *S. divinorum* are generally accepted to be: becoming objects, visions of various two-dimensional surfaces, films and membranes, revisiting places of the past (particularly childhood), loss of the body and/or identity, various sensations of motion (being pulled or twisted by a force of some kind), uncontrollable hysterical laughter, and overlapping realities (perceptions of being in more than one place).<sup>26</sup> Laughter, happiness, sense of well-being and dissociative effects were deemed the best aspects of *S. divinorum* by users, second only to the "trip" that the drug elicits.<sup>27</sup> Depersonalization, speaking gibberish, widening of consciousness, subjective illusions of rapid movement, flying or hovering however have also been reported.<sup>28</sup>

The aversive effects of previously studied KOR agonists would predict that the risk of addiction to *S. divinorum* is negligible, however, very few controlled scientific studies of the physical and psychotropic effects of *Salvia divinorum* on humans have been carried out and, therefore, using these studies to predict its potential for addiction and abuse is difficult. In addition, in the studies that have been conducted, there is conflicting information around the addiction liability of *S. divinorum* in both animals and humans. More controlled systematic research in this area is needed. Further studies on the mediated decrease of dopamine as well as the impact of dose on the reward and aversive effects are also warranted.

Another aspect of *S. divinorum*'s abuse potential stems from its availability. As previously mentioned it is widely available for purchase on the Internet through drug promotional sites and is also sold in various "head shops" and corner stores. In addition, the potential for high yields and ease of extraction may make buying and selling the drug quite affordable and attractive. Originally the concerns for the abuse potential were minimal since it was concluded that 1 kg of dried leaves yielded only 3 to 6 human doses of salvinorin A. However, it was discovered that vaporizing and inhaling 200-500 µg had profound hallucinogenic effects.<sup>29</sup> The extraction of salvinorin A from the plant is very easy and with care, approximately 1.5 grams of pure salvinorin A per kilogram of dried leaves (8kg of fresh leaves) can be isolated. Therefore, even poor yields of a gram per kilograms of dried leaves would provide a dose for 2000 human

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<sup>25</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs*. 1994 Jul-Sep;26(3):277-83.

<sup>26</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>27</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>28</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5 and Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>29</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

in correctly cited remove.

doses.<sup>30</sup> This easy isolation makes buying the drug quite affordable. *S. divinorum* leaves sell for \$0.50-7 per gram, plants for \$20-45 and the liquid extract for \$4-10 per millilitre.<sup>31</sup>

↳ what is the [?] of Salvia [?]

#### 4.2.5 Extent of Actual Abuse in Canada and Internationally

Very limited data exists regarding the actual population use of *Salvia divinorum* across the Canadian population. To address this lack of data, questions about the use of *S. divinorum* were included in the 2008-2009 Youth Smoking Survey, the 2009 Canadian Alcohol and Drug Use Monitoring Survey and the 2009 Ontario Student Drug Use and Health Survey.

The results from the 2009 Ontario Student Drug Use and Health Survey were published on November 18, 2009 and indicate that:

- Among all responding students in Ontario, 4.4% report using *Salvia divinorum* at least once in the past year;
- Males (6.2%) are significantly more likely than females (2.3%) to use *Salvia divinorum*;
- There is significant grade variation, with *Salvia divinorum* use most likely among 11<sup>th</sup> graders (8.6%) and 12<sup>th</sup> graders (8.4%); and
- There are significant regional variations, with students in the North (9.2%) most likely to use *Salvia divinorum*.

↳ any explanation why this regional variation?

Further data from the two national surveys, i.e., the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey, will be available in 2010.

↳ when? do we

As far as law enforcement is concerned, the Department has only received a limited number of communications indicating concern with respect to *S. divinorum* and none of these have advised that the use of *S. divinorum* poses any threat to public safety.

have those?

Health Canada's Drug Analysis Services (DAS) has collected some raw data regarding the number of samples identified as containing salvinorin A in the DAS labs, however, as the plant and/or substance is not in the CDSO druglist, it is not possible to have records of any seizures of it in the database.

can we get those?

↳ ? table next page!

and compare to other drugs also?

<sup>30</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs*. 1994 Jul-Sep;26(3):277-83.

<sup>31</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

↳ maybe compare to other substances like marijuana and ecstasy etc... is this or are they deal? does it appear to be a one time experience for most?

is this from DAS?  
 also their text on previous page needs to be changed

**NUMBER OF SAMPLES FOUND TO CONTAIN SALVINORIN A**

Year Return Completed	Count
2006	6
2007	8
2008	6
2009	To be updated

explains

In addition, the National Forensic Laboratory Information System (NFLIS) and the System to Retrieve Information from Drug Evidence (STRIDE) in the United States is a Drug Enforcement Agency (DEA) database that collects scientifically verified data on analyzed samples in state and local forensic labs. It also includes data from STRIDE, which are analyzed samples from DEA labs. The following table shows *Salvia divinorum* items seized from 2000 through 2008.

**ANALYZED SALVIA DIVINORUM or SALVINORIN A SEIZURES**

(Number of items/Exhibits)

Source	2000	2001	2002	2003	2004	2005	2006	2007	2008*
NFLIS-State/Local <sup>1</sup>	0	0	0	0	1	8	12	12	32
STRIDE <sup>2</sup>	0	0	1	1	1	0	0	0	0
<b>TOTAL</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>1</b>	<b>2</b>	<b>8</b>	<b>12</b>	<b>12</b>	<b>32</b>

Data Source: NFLIS & STRIDE, 2008 data queried 11/24/2008

<sup>1</sup> NFLIS reported items of salvinorin A

<sup>2</sup> STRIDE reported items of *Salvia divinorum*.

\* Includes only January – September data in 2008.

Two reports regarding the abuse of *S. divinorum* have been published in the academic literature. The first was an international case report in which a young man (19 years of age) described his perceptions after inhaling the smoke from *S. divinorum*. The peak psychotropic effects, including prickling of the skin, fever-like hot flashes, muscular tremor, and depersonalization, were reached in less than five minutes after inhalation of an unknown amount of dried leaves.<sup>32</sup> The second case involved a 15-year-old male who presented to psychiatric emergency services with acute onset of paranoia, déjà vu, blunted affect, thought blocking and slowed speech, after smoking *Salvia divinorum* over an unknown period of time. During his hospitalization all symptoms improved significantly except the feeling of déjà vu. Based on this case presentation, the author suggested that the feelings of déjà vu may be considered long-term effects of *Salvia* use.<sup>33</sup> However, given that this is the only case report in which déjà vu was associated with the use of *S. divinorum*, more reports are needed to substantiate this finding.

In addition to the above-mentioned case reports, in 2006, a case was reported in the U.S. in which a 17-year-old boy committed suicide after smoking *S. divinorum* for unknown period

<sup>32</sup> **Error! Main Document Only.** Bucheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>33</sup> **Error! Main Document Only.** Singh S. (2007) Adolescent salvia substance abuse. *Addiction*. 102, 823-824.



of time.<sup>34</sup> It should be noted that alcohol and general depression were the main confounders in this case. This case did, however, result in the state of Delaware passing a law outlawing *S. divinorum*, and classifying it as a Schedule I controlled substance with other hallucinogenic substances.

It is difficult to determine the extent of actual abuse of *S. divinorum* as there appear to be inconsistencies in the literature regarding risk aversion. For example, one author states: "Many who have used salvinorin A find the experience extremely unnerving, frightening and overly intense and most have no desire to repeat the experience."<sup>35</sup>, however, this aversion to the drug is not an effect being echoed in other studies and reports.<sup>36</sup> Moreover, over eighty percent of users surveyed on a web-based questionnaire about their *S. divinorum* use said they would probably or definitely use *S. divinorum* again.<sup>37</sup> Therefore, despite the fact that users have reported the negative effects of *S. divinorum* as: the short duration of action, lack of control over the experience, persisting negative effects (most often anxiety)<sup>38</sup> sweating, chills, increased diuresis, impaired vigilance,<sup>39</sup> and negative after-effects including tiredness, feeling head heavy, dizziness, physical exhaustion, and some degree of malaise or 'hangover' as they 'comedown' from the drug,<sup>40</sup> it is difficult to determine the influence these effects have on the use of *S. divinorum*.

#### 4.2.6 Overall Risk to Public Health and Safety of Canadians

The increase in the number of enquiries from various municipalities and members of the public and in the amount of media interest regarding the availability of *Salvia divinorum* in Canada may be an indication that the recreational use of *S. divinorum* as a hallucinogen may be on the rise in Canada. It is, however, premature to make this assumption as Health Canada presently does not have any viable statistics on the actual population use of *S. divinorum* across the Canadian population.

The potential for harm to the user and/or other individuals may be increased as users may get up and walk around without apparent awareness of their movements, behaviour or surroundings, distinction between self and surroundings is lost, and at doses greater than 1mg of salvinorin A,

700  
we should  
have some  
info from  
studies

<sup>34</sup> <http://www.kvbc.com/Global/story.asp?S=4893692>

<sup>35</sup> Turner DM. Salvinorin - The Psychedelic Essence of Salvia Divinorum. Panther Press, San Francisco, CA 1996.

<sup>36</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62, Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5, and Valdès LJ 3rd. Salvia divinorum and the unique diterpene hallucinogen, Salvinorin (divinorin) A. J Psychoactive Drugs. 1994 Jul-Sep;26(3):277-83.

<sup>37</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>38</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>39</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5.

<sup>40</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

s.21(1)(a)

s.21(1)(b)

out of body experiences are frequent and loss of consciousness has been reported.<sup>41</sup>

As stated earlier, there are no approved medical uses for *S. divinorum* in Canada. Health Canada has also not received nor approved any submissions for natural health products for sale in Canada. Therefore, products that claim to contain this substance have not been extensively reviewed by Health Canada and as such, may be counterfeit or may contain other ingredients that may pose risks to health. For example, like all drugs of abuse, the users are often unaware of the potency and adulterants in the products they are purchasing. A study by Wolowich *et al.* (2006)<sup>42</sup>, showed that the salvinorin A content in five out of five *S. divinorum* products were falsely indicated on the label and 4 out of 5 products contained unidentified adulterants (i.e. vitamin E, caffeine).

Health Canada has only anecdotal information about the use of *S. divinorum* in Canada and the risk of abuse and/or risk that *S. divinorum* poses to the health and safety of Canadians. Although reports of domestic adverse reactions related to the use of *S. divinorum* as a hallucinogen have been received through the Canada Vigilance database, it is important to note that the number of reports and the nature of reactions reported are not adequate to characterize the risk to the general population. These data cannot be used to determine incidence of use in the general population, as Health Canada does not have any information about the number of individuals using or who have used *S. divinorum*.

## 5. ASSESSMENT OF RISKS AND BENEFITS (OPTIONAL)

<sup>41</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

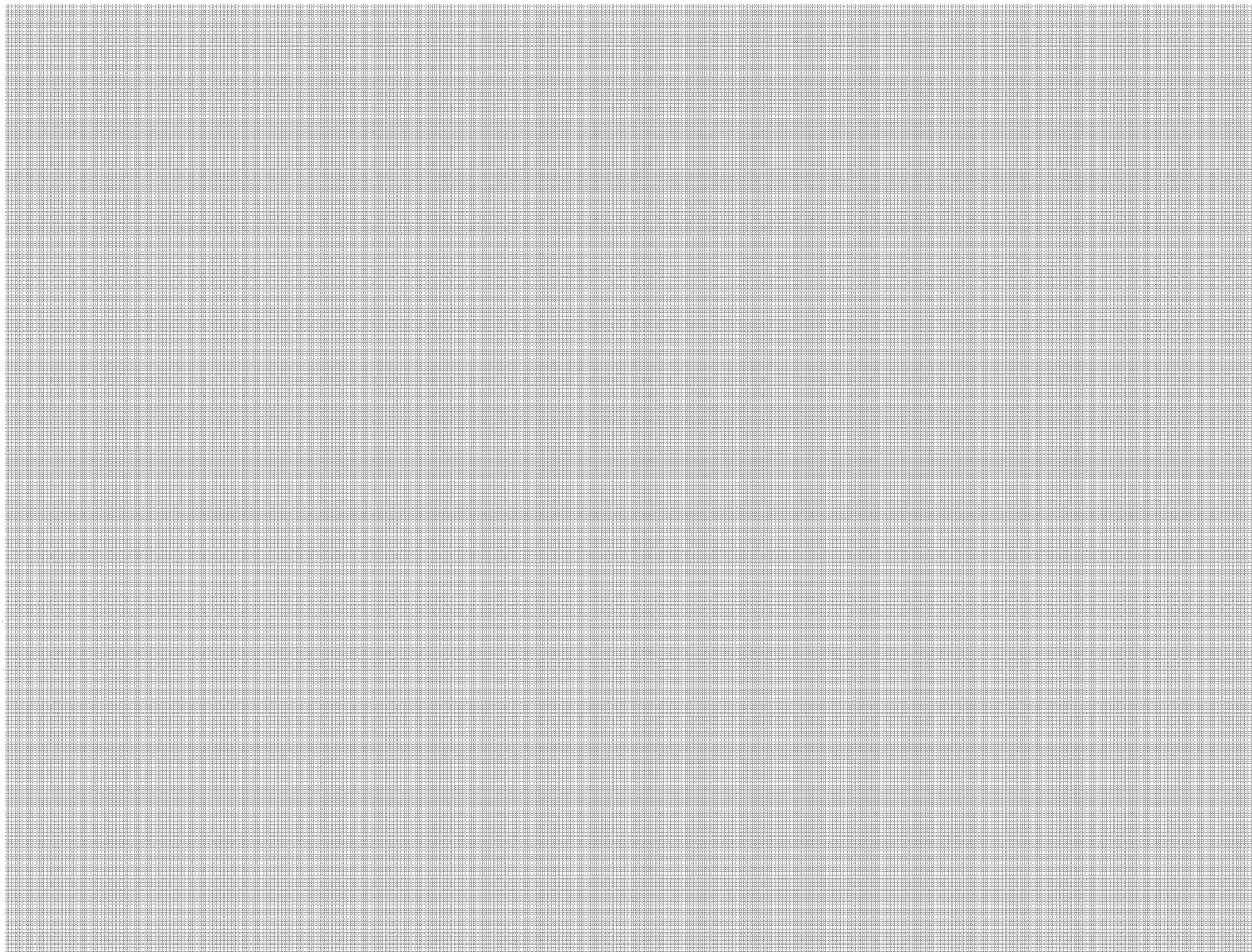
<sup>42</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.

**Page(s) 000652 to\à 000655**

**Is(Are) exempted pursuant to section(s)  
est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**



## 7. CONSIDERATIONS

s.21(1)(a) *S. divinorum*'s KOR-mediated aversive and dysphoric effects do not appear to be hampering its use.  
s.21(1)(b) Young adults have begun smoking the leaves and leaf extract recreationally.<sup>46</sup> It can be purchased through online botanical companies and other drug promotional sites and is often touted as a legal alternative to substances such as cannabis and mescaline.<sup>47</sup> Interestingly though, after being widely available for over a decade, the drug has not had any extreme social impact as did LSD or MDMA.<sup>48</sup>

The following points should be considered:

- Over the past few years, there has been an increase in the number of enquiries that Health Canada is receiving from various municipalities and members of the public regarding the availability of *Salvia divinorum* as a hallucinogen.

<sup>46</sup> Hazelden Foundation, 2004. Drug Abuse Trends. June 2004. URL: [www.research.hazelden.org](http://www.research.hazelden.org).

<sup>47</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

<sup>48</sup> Munro, T. The Chemistry of *Salvia divinorum*. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

So the negs work only for products intended to be marketed for human use. if labelled - increase when they basically fall outside the NHPR's

- Health Canada has also observed a steady increase in the amount of media interest regarding the availability of *S. divinorum* in Canada.

So it's controlled but not really implementable

what does this mean

*Salvia divinorum* meets the definition of a natural health product (NHP) under the *Natural Health Product Regulations* (NHPR). This means that products containing *S. divinorum* must be approved by Health Canada prior to sale in Canada and that product's that are not in compliance with the NHPR may be subject to compliance and enforcement actions. As Health Canada has yet to receive and/or approve any applications for natural health products containing *S. divinorum* for sale on the Canadian market, it is difficult to ascertain how much *S. divinorum* is currently sold or consumed in Canada at the present time. Several challenges also arise with respect to the importation and domestic movement of such products as they are often declared as incense and therefore cannot be considered non-market natural health products. In addition, compliance and enforcement actions, such as voluntary stop-sales, forfeiture, destruction, and administrative seizure, cannot be implemented unless the labeling clearly indicates that the product is to be used for consumption and/or pharmacological effects (ie. statements regarding contraindications or restrictions on use) upon which the product will no longer meet the definition of a consumer product (i.e. incense) and will meet the definition of a NHP. The NHPR are therefore limited in their capacity to control the availability of *S. divinorum* beyond the scope of scenarios listed above.

( - It is also hard to know because we have no way of tracking or counting ] what

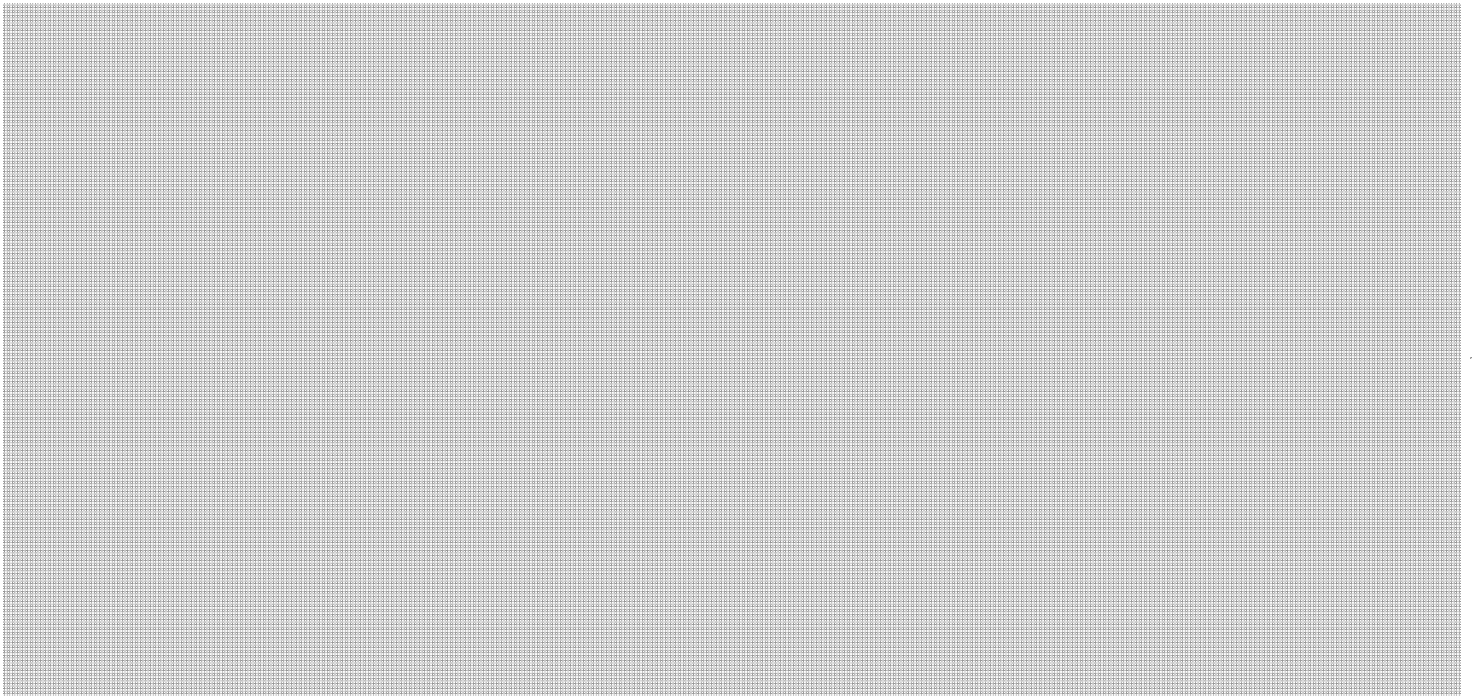
s.21(1)(a)  
s.21(1)(b)

**8. RECOMMENDATION**

**9. CONSULTATIONS**

- Drug Analysis Services (DAS)
- Royal Canadian Mounted Police (RCMP)
- Canada Border Services Agency (CBSA)

**10. IMPLEMENTATION AND EVALUATION**



**s.21(1)(a)**

**s.21(1)(b)**

**Page(s) 000659 to\à 000661**

**Is(Are) exempted pursuant to section(s)  
est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**

**Proposed Changes to Issue Analysis Summary for *Salvia divinorum***

- Template to be adjusted (based on IAS for BZP and TFMPP)

**CONTEXT**

- Too detailed
- Remove American statistics
- Remove meeting action items (re-work into a few sentences)

**Legislative Framework**

- Include how current FDR and NHPR are already controlling *S. divinorum*

**Assessment of *Salvia divinorum* for Scheduling Purposes**

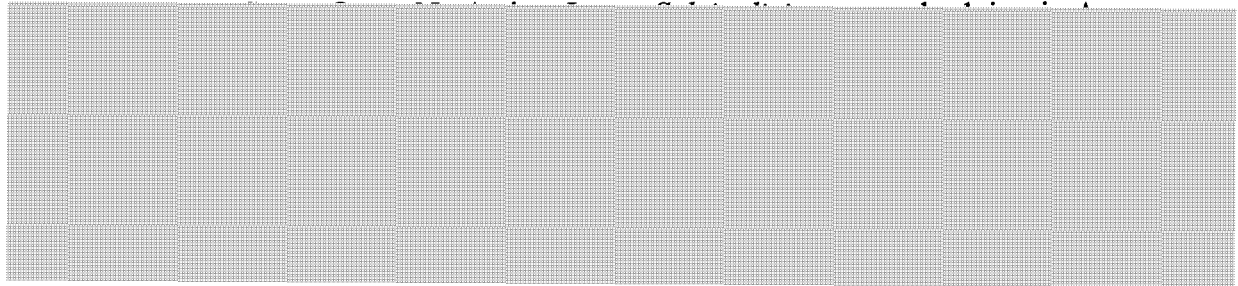
- Update international requirements, legitimate uses, potential for abuse and risk to public health sections

**ASSESSMENT OF RISKS AND BENEFITS**

- Re-work (in context of options)
- Add current controls in place (FDR, NHPR)

s.21(1)(a)  
s.21(1)(b)

**IDENTIFICATION AND ANALYSIS OF OPTIONS**



**CONSULTATIONS**

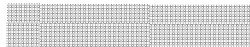
- Change to sentences instead of bullet points (and expand slightly)

**CONSIDERATIONS**

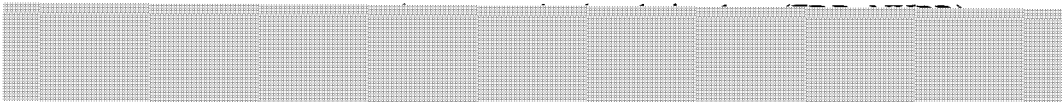
- Re-work (in context of options)
- [Redacted]
- Sentences instead of bullets

- short comingS of HPFB  
SA, IAS, HPA

**SELECTED STRATEGY**



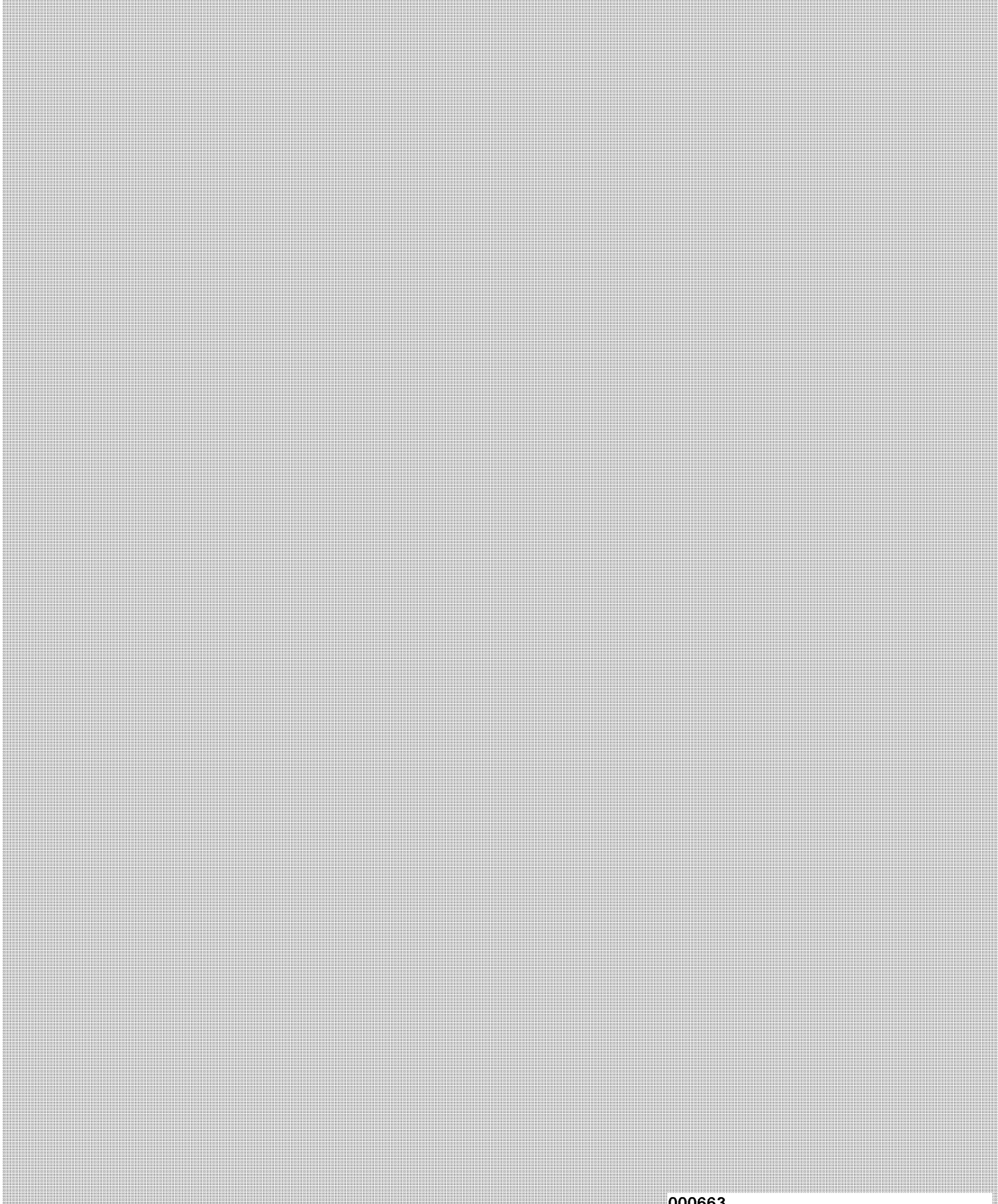
**IMPLEMENTATION AND EVALUATION**





s.21(1)(a)  
s.21(1)(b)

## 6. IDENTIFICATION AND ANALYSIS OF OPTIONS



**Page(s) 000664 to\à 000665**

**Is(Are) exempted pursuant to section(s)  
est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**

# Issue Analysis Summary

DRAFT

Scheduling - separate educational campaign & IYH? A

Policy and Office of Controlled Substances - compile CDSA schedules

- separate CDSA scheduling & FDRs?

CONTENTS - Option 3 - work w/ retailers? 13, 2010

- Option 4 - new regulatory scheme? - delete? +

1. APPF - Consultations? TFMPP

2. ISSU

3. PURP - Selected strategy vs. recommendations? - template

4. CONI

5. ASSE

-if Sd. is schedule 1, is it  
~~excluded from licensing as a NHP~~ such a license be sought? YES  
 - difference b/w scheduling under CDSA vs FDRs

## Time Frame

- criteria for CDSA scheduling.

- Type II Health Risk.

- citations & references.

~~analgesic effects therapeutic use?~~

~~target audience?~~

~~WP or MS?~~

- no studies on other effects, i.e.

teratogenicity & long-term effects.

- low acute & short-term toxicity, lack of evidence

- lack of data on influence of social behaviour &

eg. activities i.e. driving.

- impact of scheduling? - would usage ↓?

~~low risk to public health & safety??~~

- possibility of other mechanisms besides Salutarin A.

- criteria for CDSA scheduling.

- pharmacology or pharmacokinetics?  
 - subjective? (based on penalties?)

- target audience/use of IAS

- internal, not strictly scientific.

- citations / referencing.

- implications of only scheduling Salutarin A, not plant itself?

- Salutarin A encompasses plant

- excludes constituents that may

be found to have hallucinogenic properties.

# Issue Analysis Summary

DRAFT

## Scheduling *Salvia Divinorum* and/or *Salvinorin A* under the CDSA

Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Controlled Substances and Tobacco and Directorate

January 13, 2010

### CONTENTS

1. APPROVALS
2. ISSUE
3. PURPOSE
4. CONTEXT
5. ASSESSMENT OF RISKS AND BENEFITS
6. IDENTIFICATION AND ANALYSIS OF OPTIONS
7. CONSIDERATIONS
8. RECOMMENDATION(S)
9. CONSULTATIONS
10. IMPLEMENTATION AND EVALUATION

Template-adjust  
based on BZP & TFMP

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### 1. APPROVALS

This Issue Analysis Summary is approved.

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Diane Allan, Director  
Office of Controlled Substances  
Tobacco and Drugs Directorate

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[DD/MM/2009]

### 2. ISSUE

*regulated* In Canada, neither the herb *Salvia divinorum* (*S. divinorum*) nor its main active ingredient, salvinorin A, are controlled under the *Controlled Drugs and Substances Act* (CDSA). Health Canada has received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *S. divinorum*, particularly given reports from scientific and media sources suggesting that *S. divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health

Canada has also noted an ongoing media interest regarding the availability of *S. divinorum* in Canada.

### 3. PURPOSE

To assess *Salvia divinorum* and/or salvinorin A against the criteria for the addition of a substance to one of the Schedules <sup>of</sup> to the CDSA, in order to determine whether or not *S. divinorum*, and/or salvinorin A, should be regulated as controlled substances in Canada.

### 4. CONTEXT

*Salvia divinorum* is a species of sage which belongs to the mint family, and which is found in the form of dried leaves, extract and plant cuttings. Also known as "diviner's sage", the plant is known to induce illusions and hallucinations when chewed or smoked. Salvinorin A, the psychoactive ingredient in *S. divinorum*, which is also referred to chemically as a neoclerodane diterpene, is found primarily in the leaves, and to a lesser extent in the stems.<sup>1</sup>

*S. divinorum* is widely touted as a "legal" alternative to street drugs on the Internet, and has also been reported to be one of the most prevalently marketed herbal dietary supplements available for use as an alternative to illicit drugs of abuse among adolescents and young adults.<sup>2</sup> While very little is known about how and where *S. divinorum* is sold in Canada, it is suspected that it is mainly purchased over the Internet and/or bought at head shops, and alternative life style stores, etc.

A 2006 National Survey on Drug Use and Health Report, published in February 2008 by the Substance Abuse and Mental Health Administration in the United States, also estimated that:

- 1.8 million persons aged 12 or older <sup>have</sup> used *Salvia divinorum* in their lifetime, with approximately 750,000 having done so in the past year;
- Use was more common among young adults (18 to 25 years old) as opposed to older adults (> 26 years of age);
- Young adults were nearly three times more likely than youths, aged 12 to 17, to have used *Salvia divinorum* in the past year; and
- Use was more common in males than in females.

not needed.

1 U.S. Department of Justice Drug Enforcement Administration. 2002. Drugs and Chemicals of Concern: Salvia Divinorum (salvinorin A, divinorin A) URL:

[http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm) Nov 2008

2 Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.

too detailed.

The use of *S. divinorum* as a psychotropic agent first came to Health Canada's attention in 2002. In 2004, Health Canada received four adverse drug reaction (ADR) reports associated with the use of *S. divinorum* as a hallucinogen, with three being considered non-serious (requiring no medical attention) and the fourth being considered serious (medical intervention was required) and involving the concomitant use of alcohol in a person diagnosed with Attention Deficit Disorder.

↳ ADHD?

Further to the receipt of the aforementioned ADRs, the Marketed Health Products Directorate (MHPD) and the Natural Health Products Directorate (NHPD), of the Health Products and Food Branch (HPFB), prepared an issue analysis summary (IAS), which recommended that *S. divinorum* and its active ingredient salvinorin A be regulated as a controlled substance (a recommendation that was maintained when the IAS was updated in November 2006).

Later, in December 2005, MHPD and NHPD prepared a Signal Assessment (SA) (updated in June, 2007) that eventually led to the preparation of a Health Risk Assessment (HRA), which concluded that *S. divinorum* or salvinorin A-containing health products should be restricted from over-the-counter use. Should any such (unauthorized) health products be found on the Canadian market, they should be removed from sale. Such products would constitute a Type II Health Risk, defined as "A situation in which there is a reasonable probability that the use of, or exposure to, a product, will cause moderate or mild adverse health consequences."

what is this?

Drug Strategy & Controlled Substances Directorate.

Further to an ADM discussion in April 2007, (DSCSD) organized a meeting with MHPD, NHPD and the Inspectorate of HPFB (HPFBI) on May 16, 2007 to discuss *S. divinorum*. At that time, it was decided that *S. divinorum* would be classified by HPFB as a Type II substance. MHPD was to send the HRA and SA to DCSCD, look into preparing an adverse reaction case presentation in the ADR Newsletter, and explore the possibility of developing a product advisory. HPFBI was to determine compliance activities based on the HRA Type II classification and check with Canada Border Services Agency (CBSA) to determine if any further information regarding *S. divinorum* shipments was available. The Office of Research and Surveillance, DSCSD was to continue to work on the *S. divinorum* Fact Sheet and explore the feasibility of a health food/natural food store survey on *S. divinorum*. OCS was to gather information from Australia regarding its scheduling decision and to find out whether the DEA had any plans to schedule *S. divinorum* in the near future.

On September 13, 2007, a meeting was organized between DSCSD, MHPD, NHPD and HPFBI to discuss what is known about *S. divinorum* from a regulatory perspective and to reach consensus on next steps. It was determined that DSCSD would conduct a scheduling assessment of *S. d.* to explore the possibility of scheduling this substance under the CDSA.

The following action items came out of this meeting:

- (1) DSCSD to submit a response to the MHPD/NHPD analytical documents and MHPD/NHPD to make changes accordingly;
- (2) DSCSD to finalize the latest version of the media lines on *S. divinorum* and put them forward, via Communications, for approval in HPFB;
- (3) DSCSD to find out the status of draft fact sheet that was being developed by its Office

the

of Research and Surveillance;

(4) HPFBI to discuss the potential allocation of additional resources, e.g., additional inspectors, etc. to the *S. divinatorum* file; and

(5) DSCSD to explore the notion of scheduling, i.e., carry out a preliminary scheduling assessment, as part of a mid-to long-term action plan.

The Director Generals of DSCSD, MHPD, TPD and the HPFBI also met on September 26, 2008 to discuss an update on issues relating to *S. divinatorum* and to determine an agreed upon approach for subsequent steps.

The following action items came out of that meeting:

(1) Review and provide comments on *S. divinatorum* IAS and SA and revise and re-issue IAS and SA, as needed;

(2) circulate draft Fact Sheet for comment and explore the possibility of developing a public-friendly communication;

(3) prepare draft media lines for *S. divinatorum* and circulate for comment;

(4) contact DAS labs for any information on *S. divinatorum*;

(5) prepare project charter for *S. divinatorum* working group;

(6) contact Public Health Agency Canada (PHAC) for representation;

(7) continue work on scheduling assessment for *S. divinatorum*; and

(8) continue sharing information relating to *S. divinatorum* as it arises.

#### 4.1 Legislative Frameworks for Drug Control in Canada

##### 4.1.1 Food and Drug Regulations

The *Food and Drug Regulations* (F&DR) serve to ensure the safety, efficacy, and quality of health products offered for sale in Canada, including drugs and medical devices. Prior to being given market authorization, a manufacturer must present substantive scientific evidence of a product's safety, efficacy and quality and Health Canada reviews this information carefully. If the review is satisfactory, a Notice of Compliance (NOC) is issued and appropriate Drug Identification Numbers (DINs) are assigned.

A "drug" is defined under the F&DR as any substance or mixture of substances manufactured, sold or represented for use in

(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,

(b) restoring, correcting or modifying organic functions in human beings or animals, or

(c) disinfection in premises in which food is manufactured, prepared or kept;

##### 4.1.2 Natural Health Product Regulations

14H?

Salvia?

The *Natural Health Products Regulations* (NHPR) came into force in January 2004 to provide Canadians with ready access to natural health products (NHPs) that are safe, effective, and of high quality, while respecting freedom of choice and philosophical and cultural diversity. The NHPR contain a product licensing system that requires that all licensed products display a product identification number preceded by the prefix NPN, or, in the case of a homeopathic medicine, by the letters DIN-HM on their labels. The number is issued once a product is authorized for sale in Canada by the Natural Health Products Directorate. Product authorization requires either reference to a *natural health product monograph* or submission of other evidence of safety and health claim. A system of site licensing is also included in the NHPR which requires that all manufacturers, packagers, labellers, and importers be licensed; sites have procedures in place respecting distribution records and product recalls; where applicable, sites have procedures in place for the handling, storage and delivery of their products, and sites meet good manufacturing practice requirements.

The definition of an NHP under the NHPR has both a function and substance component. The function component refers to those substances that are manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
- (b) restoring or correcting organic functions in humans; or
- (c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

Salvia?  
↓

The substance component refers to whether the product or medicinal ingredient therein is safe for consideration as an over-the-counter product, can be available for self-care and self-selection, and does not require a prescription to be sold.

#### 4.1.3 Controlled Drugs and Substances Act and its Regulations

The CDSA provides a legislative framework for the control of substances that can alter mental processes and that may produce harm to the health of an individual or to society when diverted or misused. Except as authorized under its regulations, activities such as possession, possession for the purposes of trafficking, trafficking, importation, exportation, possession for the purposes of exportation and production of controlled substances are prohibited under the CDSA.

The substances regulated under the CDSA are grouped into eight Schedules, and each Schedule is associated with particular penalties as described in Part I of the CDSA.

In determining whether a substance should be regulated as a controlled substance, and into which Schedule <sup>of</sup> the CDSA <sup>it</sup> should be placed, Health Canada considers the following factors:

of it



- International requirements and trends in control/scheduling;
- Chemical and pharmacological similarity to other substances already scheduled under the CDSA;
- Legitimate uses of the substance (i.e. therapeutic, industrial or commercial);
- Potential for abuse and/or addiction liability of the substance;
- Extent of actual abuse in Canada and internationally; and
- Overall risk to public health and safety of Canadians.

## 4.2 Assessment of *Salvia Divinorum* for Scheduling Purposes

### 4.2.1 International Requirements and Trends in Control/Scheduling

At the present time, neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and therefore do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these conventions.

#### ***Australia***

In June, 2002, Australia became the first country to prohibit *S. divinorum* and salvinorin A. Although both *S. divinorum* and salvinorin A are listed on Schedule 9 of Australia's Standard for the Uniform Scheduling of Drugs and Poisons on the basis of "high potential for abuse and risk to public health and safety", no substantiation of this risk was provided at the time of this scheduling decision. Schedule 9 is Australia's most restrictive drug schedule, and includes "substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities."<sup>3</sup>

#### ***Belgium***

A decree was passed in Belgium on October 22, 2006 which added *S. divinorum* to the list of controlled substances.

#### ***Denmark***

Shortly after, in 2003, Denmark prohibited *S. divinorum* and salvinorin A by adding them to their list of "category B" controlled substances, a category which also includes psilocybin mushrooms, cocaine, amphetamine, and several others substances that are only legal for medicinal and scientific purposes. Illegal possession carries a penalty of up to two years in prison.

#### ***Germany***

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<sup>3</sup> [http://www.cognitiveliberty.org/news/salvia\\_australia.htm](http://www.cognitiveliberty.org/news/salvia_australia.htm)

*S. divinorum* (plant and plant parts) was added to Appendix I of the *Narcotics Act* in Germany on March 1, 2008, making it illegal to produce, traffic, or possess. The law does not specifically mention salvinorin A.

### ***Italy***

On June 25, 2004, the Italian Ministry of Health issued an ordinance prohibiting the sale of *S. divinorum*, and its active constituent salvinorin A. On January 11, 2005, the Ministry of Health made possession of *S. divinorum* and salvinorin A illegal by placing them in "Tabella 1" of the *Tabella Sostanze Stupefacenti o Psicotrope*.

### ***Japan***

On November 9, 2006, the Japanese government added a group of thirty-three drugs to its list of controlled substances, including salvinorin A. The drugs will be banned under a revised pharmaceutical law, under which persons involved in their illegal import, production, and sale i.e., that beyond medical treatment or research purposes, will be subject to up to five years imprisonment or to a fine of up to five million yen.

### ***Spain***

On January 28, 2004, the Spanish Ministry of Health and Consumption issued an order prohibiting the sale of *S. divinorum*, along with a long list of other alleged "toxic" herbs. The regulation went into effect on May 6, 2004 and only prohibits activities related to commerce. Possession and/or use are not considered to be criminal offences.

In Estonia, Finland, Iceland and Norway *S. divinorum* is treated as a medicinal herb and it is illegal to import it without a relevant prescription from a doctor.

### ***United States of America***

*S. divinorum* and salvinorin A are not included in the Schedules to the United States *Controlled Substances Act*, although some individual states have implemented laws restricting its use, sale and/or distribution. As of October 2009, fourteen states have enacted legislation placing regulatory controls on *S. divinorum* and/or salvinorin A. Delaware, Florida, Illinois, Kansas, Nebraska, North Dakota, Ohio, Oklahoma, and Virginia have placed *S. divinorum* and/or salvinorin A into Schedule I of state law.

California, Louisiana, Maine, North Carolina and Tennessee have enacted other forms of legislation restricting the distribution of the plant. Legislative bills proposing regulatory controls died in Alabama, Alaska, Georgia, Indiana, Maryland, South Carolina, Texas and West Virginia.

### ***California***

as of  
For example, effective January 1, 2009, the sale or distribution of *S. divinorum* or salvinorin A, or any substance or material containing *S. divinorum* or salvinorin A, to any person under 18 years of age became a misdemeanor in the state of California that is now punishable by imprisonment in a county jail for not more than six months, by a fine of no more than \$1,000, or both.

### **Louisiana**

In 2005, Louisiana passed a bill which prohibits the possession, production, manufacture and distribution of a material, compound, mixture, or preparation intended for human consumption which contains a hallucinogenic plant. A "hallucinogenic plant" is defined as "any part or portion" of the forty plants listed, which includes *S. divinorum*.

### **Maine**

In Maine, *S. divinorum* and salvinorin A are regulated similarly to how tobacco products are controlled. Adults eighteen years of age or over can legally purchase and use the material, but selling or providing *S. divinorum* or salvinorin A to anyone under the age of eighteen is a criminal offence. Possession by a minor is a civil violation, punishable by a fine, community service, or both.

### **North Carolina**

On February 11, 2009, Senate Bill 138 was introduced to the North Carolina State Legislature which sought to make *Salvia divinorum* and salvinorin A Schedule I controlled substances in that state. This bill was later amended to make possession of *S. divinorum* an infraction, a minor crime punishable by a maximum \$25 fine. A third possession offence would be charged as a misdemeanor. There are no separate penalties for manufacturing or sales. This bill includes two exemptions. One permits growing the plant for aesthetic, landscaping, or decorative purposes; the other allows for university-affiliated medical or pharmacological research. The amended version passed the Senate unanimously on May 14, 2009, the House approved it on August 5, 2009 and it was signed into law on August 28, 2009. The new law came into effect on December 1, 2009.

### **Tennessee**

On July 1, 2006, Tennessee classified the deliberate production, manufacture, distribution, or possession of the active chemical ingredient in the hallucinogenic plant *S. divinorum* as a Class A misdemeanor. It is not however a criminal offence to possess, plant, cultivate, grow, or harvest *S. divinorum* for aesthetic, landscaping, or decorative purposes. The law also does not apply to any dosage that is legally obtainable from a

retail establishment without a prescription when it is recognized by the FDA as a homeopathic drug.

In addition, the U.S. Department of Justice Drug Enforcement Agency (DEA) has also placed *S. divinorum* and salvinorin A on a list of drugs and chemicals "of concern," without legal implication.

#### 4.2.2 Chemical and Pharmacological Similarity to Other Substances Listed in the CDSA

The psychoactive ingredient in *Salvia divinorum* is salvinorin A. Other plants which contain psychotropic terpenoids are *Artemisia absinthium* (wormwood) and *Cannabis sativa*. Salvinorin A is considered by some as the most potent natural hallucinogen ever isolated.<sup>4</sup>

Unlike all other hallucinogens, salvinorin A is structurally distinct and does not interact with the serotonin-2A receptor or any other molecular target of classical hallucinogens. It thus affects the brain in a way that is quite unique.<sup>5</sup> Recent pharmacological screenings of receptors have found it to be a highly potent and selective  $\kappa$ -opioid receptor (KOR) agonist.<sup>6</sup>

The psychomimetic effects of *S. divinorum* closely resemble schizophrenia symptoms induced by LSD or PCP.<sup>7</sup> Yet, it is said to have only weak influence on the prevailing mood of the user which differentiates it from other hallucinogens such as LSD and psilocybin.<sup>8</sup> Its strong dissociative effects are often compared to those of ketamine. Users have reported that the psychedelic effects of *S. divinorum* were most similar to those caused by psilocybin mushrooms.<sup>9</sup> However, users familiar with the effects of other hallucinogens agree that despite certain similarities to classical hallucinogens, the visions and overall experience is quite unique.<sup>10</sup> In addition, ~~while~~ the psychedelic effects of *S. divinorum* are similar to those of classical psychedelics regarding changes in perception and somatic sensations. *S. divinorum* causes an

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<sup>4</sup> Ott J. Ethnopharmacognosy and human pharmacology of *Salvia divinorum* and salvinorin A. *Curare*. 1995 18: 103-129. Unofficial transcription available online. URL <http://www.sagewisdom.org/ott2.html>

<sup>5</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>6</sup> Roth BL, Baner K, Westkaemper R, Siebert D, Rice KC, Steinberg S, Ernsberger P, Rothman RB. Salvinorin A: a potent naturally occurring nonnitrogenous kappa opioid selective agonist. *Proc Natl Acad Sci U S A*. 2002 Sep 3;99(18):11934-9.

<sup>7</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>8</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>9</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>10</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6 and González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

unusually high degree of sedation, weakness and fatigue, while the increased de-realization is not commonly reported for classical psychedelics.<sup>11</sup> The combination of these effects seems to correlate with that of other KOR agonists such as pentazocine.<sup>12</sup>

#### 4.2.3 Legitimate Uses of *Salvia Divinorum*

There are no legitimate medical or industrial uses for *S. divinorum* in Canada.

→ potential as antipsychotic & psych drug? Sheffler & Roth, 2003

→ Although selective kappa receptor agonists have been shown to produce analgesic effects, adverse effects such as psychotomimesis, dysphoria and diuresis have been observed in studies investigating their therapeutic use.<sup>13</sup>

→ potential as addiction treatment (Prisinzano 2005)

→ 1/4 known selective kappa agonist

*Salvia divinorum* has traditionally been used for spiritual and medicinal purposes by the Mazatec Indians in Oaxaca, Mexico,<sup>14</sup> where an infusion of the leaves or ingestion of the leaves is used to treat gastrointestinal problems, headaches, rheumatism, anemia and swelling of the stomach.<sup>15</sup> Its main use is however for its psychoactive properties in the aid of producing "mystical" or hallucinogenic experiences as part of spiritual rituals.<sup>16</sup>

→ the leaves themselves are ingested to

#### 4.2.4 Potential for Abuse Liability and/or Addiction Liability of the Substance

Most clinically used opioid analgesics (e.g. codeine, oxycodone, morphine) are selective for the  $\mu$ -opioid receptor (MOR) and can be habit-forming<sup>17</sup> because activation of the MORs causes euphoria, which makes the user want to take them.<sup>18</sup> As previously mentioned, salvinorin A is a potent, selective agonist of the  $\kappa$ -opioid receptor (KOR); and in contrast to the euphoria produced by MOR agonists, the KOR agonists are negatively reinforcing and aversive.<sup>18</sup> In addition, KOR

<sup>11</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>12</sup> Arasteh K, Poudevida S, Farre M, Roset PN, Cami J. Response patterns of the Spanish version of the 49-item short form of the Addiction Research Center Inventory after the use of sedatives, stimulants, and opioids. *Drug Alcohol Depend.* 1999 Jun 1;55(1-2):117-25.

<sup>13</sup> Barker RL, Fawcett J, Barkin SJ. 2002. Chronic pain management with a focus on the role of newer antidepressants and centrally acting agents. In: *Pain Management: A Practical Guide for Clinicians*, 6th edition, Weiner RS ed. CRC Press, Boca Raton, FL. pp. 415-34 and **Error! Main Document Only.** Tidgewell et al., 2004. A facile method for the preparation of deuterium labelled salvinorin A: *Biorganic & Medicinal Chemistry Letters*, 14: 5099-5102.

<sup>14</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>15</sup> Munro, T. The Chemistry of *Salvia divinorum*. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

<sup>16</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage *Salvia divinorum*. *Life Sci.* 2005 Dec 22;78(5):527-31.

<sup>17</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.

<sup>18</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590, Cooper S. Interactions between endogenous opioids and dopamine: Implications for reward and aversion. In:

agonists have analgesic properties but are not associated with respiratory depression like MOR agonists. Initially, these effects provided hope for the development of an analgesic absent of addiction liability and respiratory depression, however, it was soon discovered that KOR agonists produced dysphoria and psychomimetic effects such as confusion, hallucinations and depersonalization.<sup>19</sup> Finally, while MOR increases the release of dopamine, the activation of KOR decreases dopamine release in the nucleus accumbens.<sup>20</sup>

The onset and intensity of the effects of *Salvia divinorum* appear to be related to the route of administration by which it is taken. Traditional uses generally produce mild effects because the leaves are rolled and chewed or crushed and prepared as a foamy infusion whereby the salvinorin A is degraded in the gastrointestinal system before being absorbed into the bloodstream. These methods rely on contact with the oral mucosa for absorption and the level of effect relates quite closely to the length of time the material spends in the mouth. Onset of effect generally takes 5-10 minutes, which build over the next hour and last for another hour before the effects begin to subside.<sup>21</sup>

Routes that avoid the hepatic first-pass effect are the quickest and most intense.<sup>22</sup> Salvinorin A can be isolated from the plant to make a powder which can be vaporized and inhaled. This method of administration is the most powerful and only requires 200-500µg of salvinorin A powder to produce the same effects as those of fresh leaves. The onset of effect felt from vaporizing salvinorin A powder is about 30 seconds and effects last for about 5-10 minutes and subside over the next 30 minutes.<sup>23</sup>

Smoking is by far the most popular method of administration<sup>24</sup> and this is accomplished by smoking the dried leaves or a concentrated extract using a pipe or bong. Dried leaves may also be fortified with a concentrated extract of salvinorin A and/or a concentrated extract can also be

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*The Mesolimbic Dopamine System: From Motivation to Action.* Willner P and Scheel-Kruger J (editors) Wiley, Chester, England, 1991, pp. 331-366, and Shippenberg TS, Herz A, Spanagel R, Bals-Kubik R, Stein C. Conditioning of opioid reinforcement: neuroanatomical and neurochemical substrates. *Ann N Y Acad Sci.* 1992 Jun 28;654:347-56.

<sup>19</sup> Pfeiffer A, Brantl V, Herz A, Emrich HM. Psychotomimesis mediated by kappa opiate receptors. *Science.* 1986 Aug 15;233(4765):774-6, Rimoy GH, Wright DM, Bhaskar NK, Rubin PC. The cardiovascular and central nervous system effects in the human of U-62066E. A selective opioid receptor agonist. *Eur J Clin Pharmacol.* 1994;46(3):203-7, and Walsh SL, Strain EC, Abreu ME, Bigelow GE. Enadoline, a selective kappa opioid agonist: comparison with butorphanol and hydromorphone in humans. *Psychopharmacology (Berl).* 2001 Sep;157(2):151-62.

<sup>20</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.

<sup>21</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>22</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.

<sup>23</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>24</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62 and Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

used sublingually. <sup>Neither</sup> *S. divinorum* nor salvinorin A are ~~not~~ injected because the powder is insoluble in water.<sup>25</sup>

However, Although the various modes of administration lead to variable onset and duration of the effects, <sup>of S.d.</sup> the effects of *S. divinorum* are generally accepted to be: <sup>inhalation of an</sup> becoming objects, visions of various two-dimensional surfaces, films and membranes, revisiting places of the past (particularly childhood), loss of the body and/or identity, various sensations of motion (being pulled or twisted by a force of some kind), uncontrollable hysterical laughter, and overlapping realities (perceptions of being in more than one place).<sup>26</sup> Laughter, happiness, sense of well-being and dissociative effects were deemed the best aspects of *S. divinorum* by users, second only to the "trip" that the drug elicits.<sup>27</sup> Depersonalization, speaking gibberish, widening of consciousness, subjective illusions of rapid movement, flying or hovering ~~however~~ have also been reported.<sup>28</sup>

The aversive effects of previously studied KOR agonists would predict that the risk of addiction to *S. divinorum* is negligible. However, very few controlled scientific studies of the physical and psychotropic effects of *Salvia divinorum* on humans have been carried out, and, therefore, using these studies to predict its potential for addiction and abuse is difficult. In addition, in the studies that have been conducted, there is conflicting information around the addiction liability of *S. divinorum* in both animals and humans. More controlled systematic research in this area is needed. Further studies on the mediated decrease of dopamine as well as the impact of dose on the reward and aversive effects are also warranted.

Another aspect of <sup>the</sup> *S. divinorum*'s abuse potential stems from its availability. As previously mentioned, it is widely available for purchase on the Internet through drug promotional sites and is also sold in various "head shops" and corner stores. In addition, the potential for high yields and ease of extraction may make buying and selling the drug quite affordable and attractive. Originally the concerns for the abuse potential were minimal since it was concluded that 1 kg of dried leaves yielded only 3 to 6 human doses of salvinorin A. However, it was discovered that vaporizing and inhaling 200-500 µg had profound hallucinogenic effects.<sup>29</sup> The extraction of salvinorin A from the plant is very easy and, ~~with care~~, approximately 1.5 grams of pure salvinorin A per kilogram of dried leaves (8kg of fresh leaves) can be isolated. Therefore, even poor yields of a gram per kilograms of dried leaves would provide ~~a dose~~ <sup>enough</sup> for 2000 human ~~doses~~ Salvinorin A

<sup>25</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs*. 1994 Jul-Sep;26(3):277-83.

<sup>26</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>27</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>28</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5 and Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>29</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

need to  
dose  
↓  
poss. mech. of  
tolerance  
(Bücheler 2004)  
↑  
easier to  
extract  
than LSD or  
produce  
phenylethylamine  
derivatives  
(Bücheler 2004)

doses.<sup>30</sup> This easy isolation makes buying the drug quite affordable. *S. divinorum* leaves sell for \$0.50-7 per gram, plants, for \$20-45 and the liquid extract for \$4-10 per millilitre.<sup>31</sup>

7.00

sell

sells

#### 4.2.5 Extent of Actual Abuse in Canada and Internationally

Very limited data exists regarding the actual population use of *Salvia divinorum* across the Canadian population. To address this lack of data, questions about the use of *S. divinorum* were included in the 2008-2009 Youth Smoking Survey, the 2009 Canadian Alcohol and Drug Use Monitoring Survey and the 2009 Ontario Student Drug Use and Health Survey.

The results from the 2009 Ontario Student Drug Use and Health Survey were published on November 18, 2009 and indicate that:

- Among all responding students in Ontario, 4.4% report using *Salvia divinorum* at least once in the past year;
- Males (6.2%) are significantly more likely than females (2.3%) to use *Salvia divinorum*;
- There is significant grade variation, with *Salvia divinorum* use most likely among 11<sup>th</sup> graders (8.6%) and 12<sup>th</sup> graders (8.4%); and
- There are significant regional variations, with students in the North (9.2%) most likely to use *Salvia divinorum*.

Further data from the two national surveys, i.e., the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey, will be available in 2010.

→ now available.

the spring/summer of

As far as law enforcement is concerned, the Department has only received a limited number of communications indicating concern with respect to *S. divinorum* and none of these have advised that the use of *S. divinorum* poses any threat to public safety.

Health Canada's Drug Analysis Services (DAS) has collected some raw data regarding the number of samples identified as containing salvinorin A in the DAS labs, however, as the plant and/or substance is not in the CDSO druglist, it is not possible to have records of any seizures of it in the database.

<sup>30</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs*. 1994 Jul-Sep;26(3):277-83.

<sup>31</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.



**NUMBER OF SAMPLES FOUND TO CONTAIN SALVINORIN A**

Year Return Completed	Count
2006	6
2007	8
2008	6
2009	To be updated ← ?

In addition, the National Forensic Laboratory Information System (NFLIS) and the System to Retrieve Information from Drug Evidence (STRIDE) in the United States is a Drug Enforcement Agency (DEA) database that collects scientifically verified data on analyzed samples in state and local forensic labs. It also includes data from STRIDE, which are analyzed samples from DEA labs. The following table shows *Salvia divinorum* items seized from 2000 through 2008.

**ANALYZED SALVIA DIVINORUM or SALVINORIN A SEIZURES**

(Number of items/Exhibits)

Source	2000	2001	2002	2003	2004	2005	2006	2007	2008*
NFLIS-State/Local <sup>1</sup>	0	0	0	0	1	8	12	12	32
STRIDE <sup>2</sup>	0	0	1	1	1	0	0	0	0
<b>TOTAL</b>	0	0	1	1	2	8	12	12	32

Data Source: NFLIS & STRIDE, 2008 data queried 11/24/2008

<sup>1</sup> NFLIS reported items of salvinorin A

<sup>2</sup> STRIDE reported items of *Salvia divinorum*.

\* Includes only January – September data in 2008.

Two reports regarding the abuse of *S. divinorum* have been published in the academic literature. The first was an international case report in which a young man (19 years of age) described his perceptions after inhaling the smoke from *S. divinorum*. The peak psychotropic effects, including prickling of the skin, fever-like hot flashes, muscular tremor, and depersonalization, were reached in less than five minutes after inhalation of an unknown amount of dried leaves.<sup>32</sup> The second case involved a 15-year-old male who presented to psychiatric emergency services with acute onset of paranoia, déjà vu, blunted affect, thought blocking and slowed speech, after smoking *Salvia divinorum* over an unknown period of time. During his hospitalization all symptoms improved significantly except the feeling of déjà vu. Based on this case presentation, the author suggested that the feelings of déjà vu may be considered long-term effects of Salvia use.<sup>33</sup> However, given that this is the only case report in which déjà vu was associated with the use of *S. divinorum*, more reports are needed to substantiate this finding.

In addition to the above-mentioned case reports, in 2006, a case was reported in the U.S. in which a 17-year-old boy committed suicide after smoking *S. divinorum* for unknown period

<sup>32</sup> Error! Main Document Only. Bucheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>33</sup> Error! Main Document Only. Singh S. (2007) Adolescent salvia substance abuse. *Addiction*. 102, 823-824.

of time.<sup>34</sup> It should be noted that alcohol and general depression were the main confounders in this case. This case did, however, result in the state of Delaware passing a law outlawing *S. divinorum*, and classifying it as a Schedule I controlled substance with other hallucinogenic substances.

It is difficult to determine the extent of actual abuse of *S. divinorum* as there appear to be inconsistencies in the literature regarding risk aversion. For example, one author states: "Many who have used salvinorin A find the experience extremely unnerving, frightening and overly intense and most have no desire to repeat the experience."<sup>35</sup> However, this aversion to the drug is not an effect being echoed in other studies and reports.<sup>36</sup> Moreover, over eighty percent of users surveyed on a web-based questionnaire about their *S. divinorum* use said they would probably or definitely use *S. divinorum* again.<sup>37</sup> ~~Therefore, despite the fact that users have reported the negative effects of *S. divinorum* as: the short duration of action, lack of control over the experience, persisting negative effects (most often anxiety)<sup>38</sup> sweating, chills, increased diuresis, impaired vigilance,<sup>39</sup> and negative after-effects including tiredness, feeling head heavy, dizziness, physical exhaustion, and some degree of malaise or 'hangover' as they 'comedown' from the drug,~~ it is difficult to determine the influence these effects have on the use of *S. divinorum*.

However,

#### 4.2.6 Overall Risk to Public Health and Safety of Canadians

The increase in the number of enquiries from various municipalities and members of the public and ~~by~~ the amount of media interest regarding the availability of *Salvia divinorum* in Canada may be an indication that the recreational use of *S. divinorum* as a hallucinogen ~~may be~~ on the rise in Canada. It is, however, premature to make this assumption as Health Canada presently does not have any viable statistics on the actual ~~population~~ use of *S. divinorum* across the Canadian population.

The potential for harm to the user and/or other individuals may be increased as users may get up and walk around without apparent awareness of their movements, behaviour or surroundings, distinction between self and surroundings is lost, and at doses greater than 1mg of salvinorin A,

<sup>34</sup> <http://www.kvbc.com/Global/story.asp?S=4893692>

<sup>35</sup> Turner DM. Salvinorin - The Psychedelic Essence of Salvia Divinorum. Panther Press, San Francisco, CA 1996.

<sup>36</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62, Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5, and Valdès LJ 3rd. Salvia divinorum and the unique diterpene hallucinogen, Salvinorin (divinorin) A. J Psychoactive Drugs. 1994 Jul-Sep;26(3):277-83.

<sup>37</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>38</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>39</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5.

<sup>40</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

- long-term effects  
- other effects  
- lack of data pertains to toxicity

however, this assumption may be premature

- lack of data re: social behavior & activities such as driving

out of body experiences are frequent and loss of consciousness has been reported.<sup>41</sup>

As stated earlier, there are no approved medical uses for *S. divinorum* in Canada. Health Canada has also ~~not~~ received nor approved any submissions for natural health products for sale in Canada. Therefore, products that claim to contain this substance have not been extensively reviewed by Health Canada and as such, may be counterfeit or may contain other ingredients that may pose risks to health. For example, like ~~all~~ drugs of abuse, the users are often unaware of the potency and adulterants in the products they are purchasing. A study by Wolowich *et al.* (2006)<sup>42</sup>, showed that the salvinorin A content in five out of five *S. divinorum* products were falsely indicated on the label and 4 out of 5 products contained unidentified adulterants (i.e. vitamin E, caffeine).

Health Canada has only anecdotal information about the use of *S. divinorum* in Canada and the risk of abuse and/or risk that *S. divinorum* poses to the health and safety of Canadians. Although reports of domestic adverse reactions related to the use of *S. divinorum* as a hallucinogen have been received through the Canada Vigilance database, it is important to note that the number of reports and the nature of reactions reported are not adequate to characterize the risk to the general population. These data cannot be used to determine incidence of use in the general population, as Health Canada does not have any information about the number of individuals using or who have used *S. divinorum*.

## 5. ASSESSMENT OF RISKS AND BENEFITS (~~OPTIONAL~~)

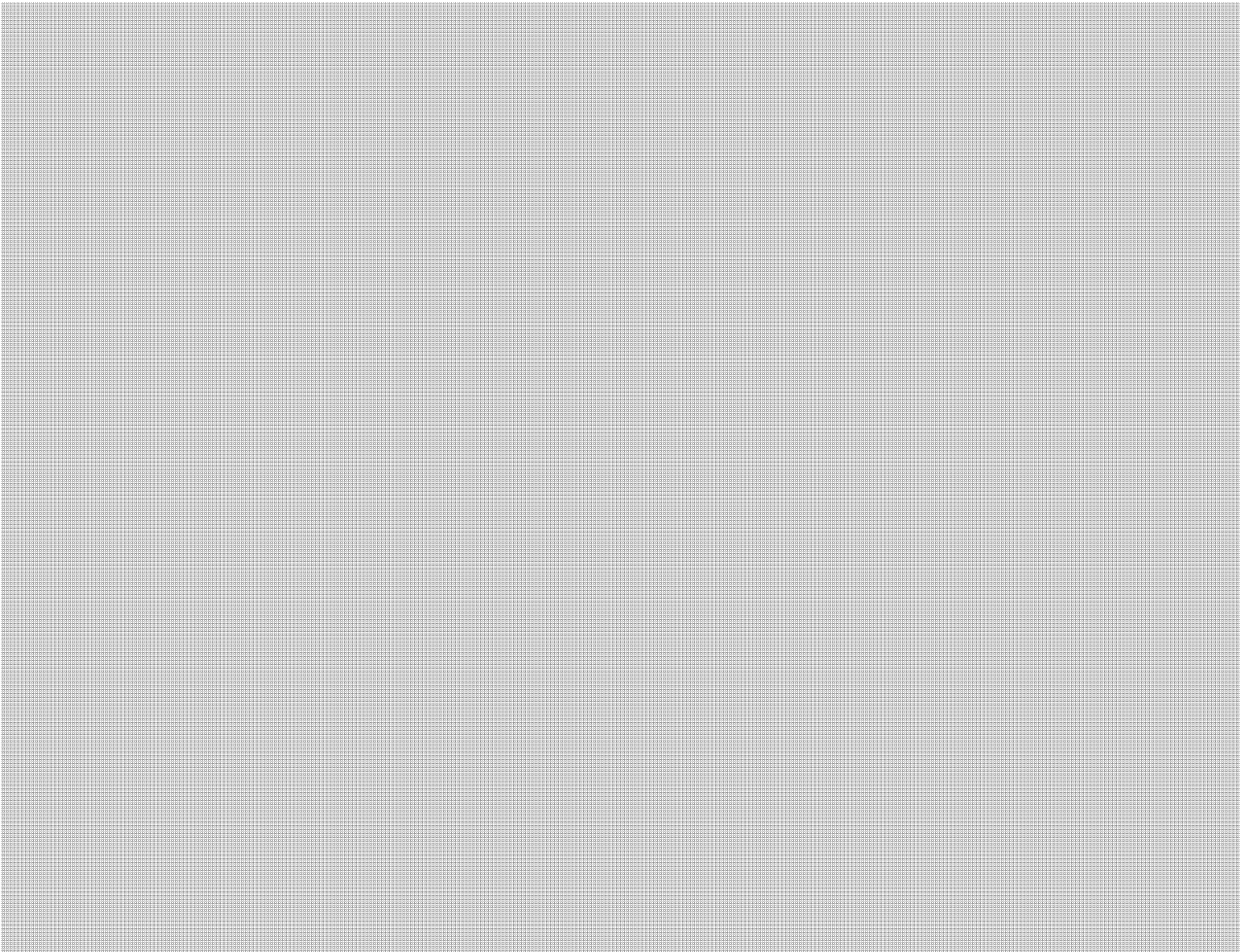
**Page(s) 000683 to\à 000686**

**Is(Are) exempted pursuant to section(s)  
est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**

s.21(1)(a)  
s.21(1)(b)



8.1. CONSIDERATIONS

*S. divinorum*'s KOR-mediated aversive and dysphoric effects do not appear to be hampering its use. Young adults have begun smoking the leaves and leaf extract recreationally.<sup>46</sup> It can be purchased through online botanical companies and other drug promotional sites and is often touted as a legal alternative to substances such as cannabis and mescaline.<sup>47</sup> Interestingly though, after being widely available for over a decade, the drug has not had any extreme social impact as did LSD or MDMA.<sup>48</sup>

The following points should be considered:

- Over the past few years, there has been an increase in the number of enquiries that Health Canada is receiving from various municipalities and members of the public regarding the availability of *Salvia divinorum* as a hallucinogen.

<sup>46</sup> Hazelden Foundation, 2004. Drug Abuse Trends. June 2004. URL: [www.research.hazelden.org](http://www.research.hazelden.org).

<sup>47</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

<sup>48</sup> Munro, T. The Chemistry of *Salvia divinorum*. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

s.21(1)(a)

s.21(1)(b)

- Health Canada has also observed a steady increase in the amount of media interest regarding the availability of *S. divinorum* in Canada.

*Salvia divinorum* meets the definition of a natural health product (NHP) under the *Natural Health Product Regulations* (NHPR). This means that products containing *S. divinorum* must be approved by Health Canada prior to sale in Canada and that product's that are not in compliance with the NHPR may be subject to compliance and enforcement actions. As Health Canada has yet to receive and/or approve any applications for natural health products containing *S. divinorum* for sale on the Canadian market, it is difficult to ascertain how much *S. divinorum* is currently sold or consumed in Canada at the present time. Several challenges also arise with respect to the importation and domestic movement of such products as they are often declared as incense and therefore cannot be considered non-market natural health products. In addition, compliance and enforcement actions, such as voluntary stop-sales, forfeiture, destruction, and administrative seizure, cannot be implemented unless the labeling clearly indicates that the product is to be used for consumption and/or pharmacological effects (ie. statements regarding contraindications or restrictions on use) upon which the product will no longer meet the definition of a consumer product (i.e. incense) and will meet the definition of a NHP. The NHPR are therefore limited in their capacity to control the availability of *S. divinorum* beyond the scope of scenarios listed above.

→ - It is also hard to know because we have no way of tracking or counting

9 8. ~~RECOMMENDATION~~ selected strategy (1 line?!)

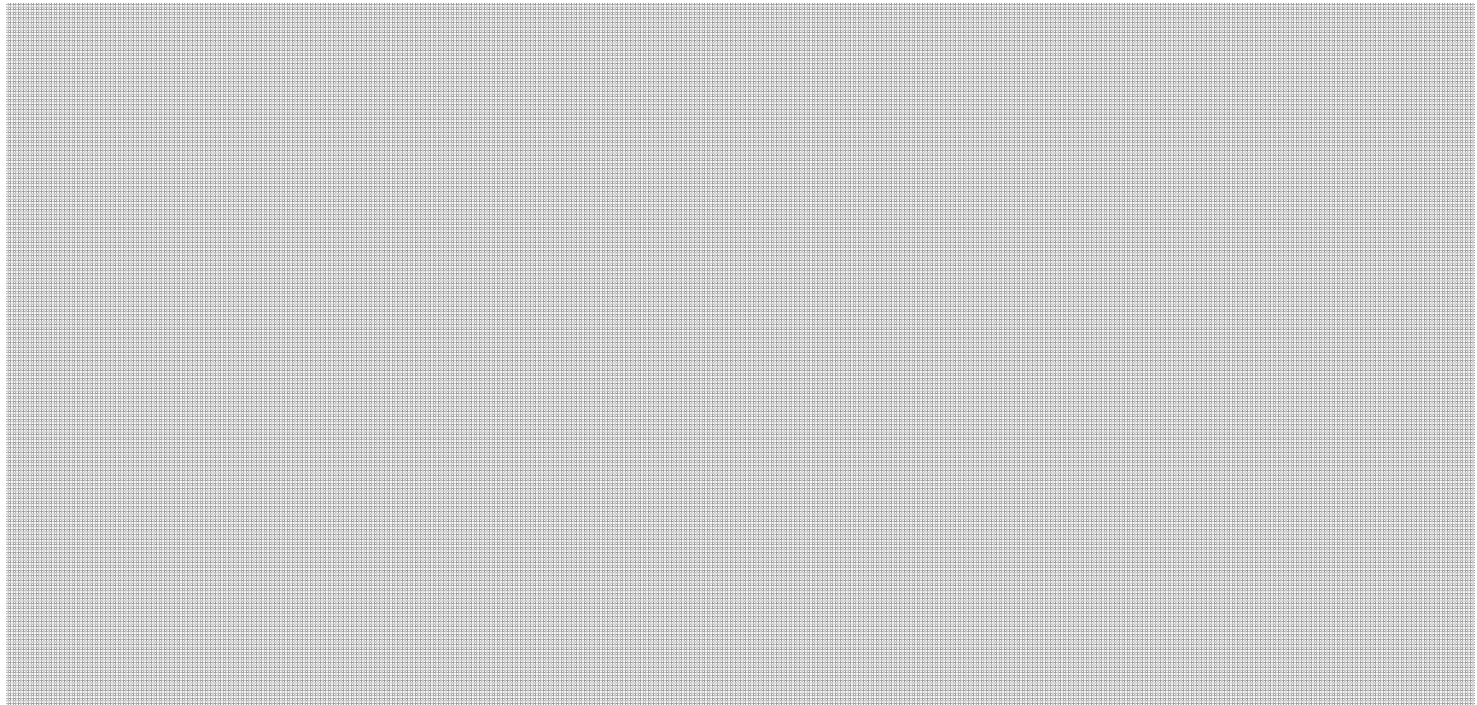
79. **CONSULTATIONS**

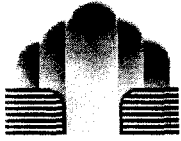
paragraphs ?

- Drug Analysis Services (DAS)
- Royal Canadian Mounted Police (RCMP)
- Canada Border Services Agency (CBSA)

**s.21(1)(a)**  
**s.21(1)(b)**

10. **IMPLEMENTATION AND EVALUATION**





Jocelyn Kula/HC-SC/GC/CA  
2010-03-14 08:49 PM

To denis.arsenault@hc-sc.gc.ca, Salha  
Jumbe/HC-SC/GC/CA@HWC

cc  
bcc

Subject Fw: CBC-radio Calgary - Concerns over controls on salvia -  
Mar 12 2010, 8:12AM

pls add to salvia file

Jocelyn Kula  
Manager/ Gestionnaire  
Policy and Regulatory Affairs Division/ Division des politiques et affaires réglementaires  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0125 Fax: (613) 946-4224  
----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2010-03-14 08:48 PM -----

HC\_Media\_SC/HC-SC/GC/C

A  
Sent by: Nicolas Frate

To  
cc

2010-03-12 03:14 PM

Subject CBC-radio Calgary - Concerns over controls on salvia - Mar  
12 2010, 8:12AM

STATION CBC Radio 1 (Calgary)  
DATE Fri 12 Mar 2010  
PROGRAM Calgary Eyeopener  
TIME 8:12 AM  
REPORTER Mary-Catherine McIntosh  
HEADLINE **Concerns over controls on salvia**  
MEDIA LOG ID 20100312R-1407

JUDY ALDOUS (Announcer): The man who killed Arcelie Laoagan says he was high on drugs and alcohol at the time. While testifying in his own defense this week, Christopher Watcheston said he had smoked salvia. It's a psychoactive plant, that's perfectly legal in Canada. With more on what this drug is, I'm joined in the studio by CBC Reporter Mary-Catherine McIntosh. Good morning.

MARY-CATHERINE MCINTOSH (Reporter): Good morning.

ALDOUS: So what is salvia?

MCINTOSH: Salvia is a green leafy plant, that's hallucinogenic. Um historically, it was used by healers in Mexico, as a tool for meditation and spirituality. Um it's also been used in the past to heal arthritis, headaches, and diarrhea. But today in Canada, it's mostly used as a recreational drug. And the high, or the hallucination period, uh typically lasts for just 2 to 5 minutes. And there are tons of videos on Youtube to um, that are called things like Hailey gets high on salvia. And uh, here's one, just to give you an idea about what I'm talking about.

UNIDENTIFIED PERSON: [unintelligible laughter or crying]



MCINTOSH: So, so in this video, a young woman sitting on a bed, and I don't know if she's laughing or crying, but it does not look fun. At times she kind of looks like she's choking. And uh, she holds out her arms and then looks at them as if they don't belong to her. And it's clear in the video there are friends watching her, or having a lot more fun than she is. Um this video's pretty typical for so many that are online. But for the drug, people who defend it, say that it's mostly an aid in meditation.

ALDOUS: So where do you find this drug, salvia?

MCINTOSH: At head shops. They're those shops that sell um, marijuana things, like bongos and rolling papers, and lighters. And I visited a couple, and that's where I met uh, Vlassis Duvas. Now again he runs one of these shops. Uh, it smells like tobacco, and incense, and there are bongos that run almost the entire length of the store. And he says he'd never try the stuff. He never has, and he never wants to because it sort of scares him. But he does sell 1 gram baggies of the, of salvia. And it looks like dried up tea. And he sells it in different strengths, and they sell for about \$30. He said he sells mostly to young adults, and um, here's part of our conversation.

MCINTOSH: What do you say to people when they come in, and say they'd like to buy it?

VLASSIS DUVAS (store owner): I would say I'll sell it to you. If they ask me my opinion, I'd point blank say hey, I haven't tried the stuff and never will. It's your choice, I'll give you the info that I have, and I usually try to keep all my customers safe, not just the ones that buy this one.

MCINTOSH: Do you give them a little warning?

DUVAS: Yes, I do.

MCINTOSH: What do you say?

DUVAS: I usually say, uh if you do it, do it in the company of someone else that will not do it. Take turns. Don't do it all together and hope that that's going to work. It is not a party drug. It is a personal thing.

MCINTOSH: So neither shop I visited sell that much of this stuff. Uh Duvas says that he sells just a couple grams a day.

ALDOUS: So you said that the high from salvia can be intense. What makes it different from so many illegal drugs?

MCINTOSH: That's a hard one to answer. Uh, I went to the greenhouse at the University of Calgary that actually, that actually grows these plants, and I spoke with researcher Dae-Kyun Ro, he said it's the gene sequence of salvia. And I asked him and just a note in this answer, uh salvinorin A is the active component of salvia.

DAE-KYUN RO (University of Calgary researcher): I'm not 100% sure why certain substances actually legal, and certain, salvinorin A is legal. It, was, uh, why some substances illegal, and salvinorin A is legal. I don't know exactly the reason why, but I suspect is that, um, salvinorin A is less addictive. And the um, the effect of salvinorin A is very quick, so less than, two to five minutes. So

even though it's a very potent compound, um, the effect is very short and it's less addictive.

MCINTOSH: So he says the drug's less addictive and the high is really short. But there's no real scientific reason, why it's legal and others aren't.

ALDOUS: So what does Health Canada say about this?

MCINTOSH: Well it's not studying salvia, and it never has. Basically, the department has a set of criteria, uh for controlling substances, and they include things like international requirements, chemical and pharmacological similarity to other substances that are controlled and regulated. Legitimate uses of the substance, potential for abuse, um, risk of addiction, overall risk to public health. And basically salvia doesn't meet those criteria. Uh but one interesting thing that um, the department also said was that the um, that there's not a lot know about the plant. And that's something that was backed up by Dr. Ro. He said just in the last five years, scientists have discovered that unlike some other drugs like LSD, salvia binds to one single receptor in the brain. And that makes it possible for some day down the line, for salvia to be adopted, and for things to be added to it, and for it to be used as a mood altering drug for things like depression.

ALDOUS: Huh. So, for, for good uses.

MCINTOSH: Yes, potentially.

ALDOUS: Thank you very much Mary-Catherine.

MCINTOSH: You're welcome.

ALDOUS: That's Mary-Catherine McIntosh, she is a reporter with CBC Radio here.

\*\*\* END OF STORY \*\*\*

Media Monitoring Unit / Unité de surveillance des médias  
Health Canada / Santé Canada

DRAFT  
December 23, 2009

**Media Lines  
Regulatory Control of Salvia Divinorum**

**Issue**

Since 2006, Health Canada has noted ongoing media interest regarding the availability of *Salvia divinorum* on the Canadian market. Health Canada has also received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum*, particularly given reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties.

**Key Messages:**

When r... .., <sup>Salvia</sup> ~~any~~ products are subject to NHPR

- ~~The Department has not yet decided whether to regulate *Salvia divinorum* or its active ingredient salvinorin A as controlled substances under the *Controlled Drugs and Substances Act (CDSA)*.~~
- ~~There is currently not enough scientific information available to determine whether regulation under the CDSA is the best option to manage the potential risks associated with the use of *Salvia divinorum*.~~ <sup>Reg. of *Salvia divinorum* and its active ingredient as controlled subst are warranted.</sup>
- Health Canada continues to collect and consider information regarding *Salvia divinorum* and to consult with key stakeholders, including health officials in other countries, and law enforcement here at home to determine the most appropriate strategy to manage the risks associated with the use of this substance.

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Comment [B1]: This language is closer to what is in the IYH article

Deleted: *Salvia divinorum*

**Supplementary Messages:**

**On the classification of *Salvia divinorum*:**

- In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act (CDSA)*.
- *Salvia divinorum* is not listed under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these conventions.
- Several countries (Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) have placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Although some individual U.S. states have implemented laws restricting its use, sale and/or distribution, *Salvia divinorum* and

salvinorin A are not federally regulated under the *Controlled Substances Act* in the United States.

①

When represented... substance and function components of the substance + function (aspects)

to 1st KM

*Salvia divinorum* meets the definition of a natural health product under the *Natural Health Product Regulations* (NHPR). This means that *Salvia* products that are not in compliance with the NHPR may be subject to compliance and enforcement actions.

- As of January 2009, Health Canada had not issued any Natural Product Numbers (NPN) or Drug Identification Numbers – Homeopathic Medicine (DIN-HM) for *Salvia divinorum* products.

If pressed on the lack of statistics on *Salvia divinorum* use in Canada:

- Health Canada is taking steps to address this lack of data. Questions about the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey, the 2009 Canadian Alcohol and Drug Use Monitoring Survey and the 2009 Ontario Student Drug Use and Health Survey. This data will be available in 2010.
- It is anticipated that the data from these surveys will help address some of the information gaps about this substance and contribute to future decisions that Health Canada may make about this plant and its active ingredient.

better detail → Suzanne

If pressed regarding the results of the 2009 Ontario Student Drug Use and Health Survey:

- The results from the 2009 Ontario Student Drug Use and Health Survey were published on November 18, 2009 and indicate that among responding students in Ontario, 4.4% reported using *Salvia divinorum* at least once in the past year. Health Canada will consider this data in its ongoing examination of *Salvia divinorum* and salvinorin A,

Deleted: asked for specifics on the survey data

**Questions and Answers**

**Q1 – If Health Canada is aware of *Salvia divinorum*'s ill-effects, why isn't it illegal?**

A1 – Very few controlled scientific studies of the physical and psychotropic effects of *Salvia divinorum* on humans have been carried out, and using these studies to predict the potential for addiction and abuse associated with *Salvia divinorum* is difficult. More controlled systematic research in this area is needed.

~~Health Canada has only received a limited number of communications indicating concern with respect to *Salvia divinorum* from law enforcement agencies, and none of these has advised that the use of *Salvia divinorum* poses any threat to public safety.~~

eland c Bronn wynn's stuff

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The sale for hallucinogenic purposes is illegal under... CTE actions are limited

What are the risks associated with the use of salvia purported to be

How is it available if we know what it does?

**Q2 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?**

A2 – The *Natural Health Product Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *Salvia divinorum*.

**Q3 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A3 – *Salvia divinorum* products that are not in compliance with the *Natural Health Product Regulations* and/or are found to pose a risk to the health of Canadians may be subject to compliance and enforcement action by Health Canada. An import target for products containing *Salvia divinorum* has already been placed with Canada Border Services Agency.

**Q4 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum*. What does that involve and what stage is it at?**

A4 - Health Canada considers several factors in determining whether scheduling a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in controlling the substance;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada has only anecdotal information about the last three of the above-mentioned factors, and thus is not yet convinced that the controls imposed by the CDSA are an appropriate strategy for managing the risks associated with the use of *Salvia divinorum*. It is anticipated that the data from the 2008-2009 Youth Smoking Survey, the 2009 Canadian Alcohol and Drug Use Monitoring Survey and the 2009 Ontario Student Drug Use and Health Survey will help address some of the information gaps about this substance and contribute to future decisions that Health Canada may make about this plant and its active ingredient. The data from the two national surveys will be available in 2010.

change to use wording from KI

**Comment [B2]:** Suggest replacing this sentence with this line from IYH article:  
  
there is simply not enough information available to determine whether regulation under the CDSA is the best option to manage the potential risks.

para 7

Health Canada will continue to collect and consider information regarding *Salvia divinorum* as it becomes available.

**Q5 – Didn't an internal report from Health Canada's Marketed Health Products Directorate recommend that *Salvia divinorum* be scheduled under the CDSA? Why has that recommendation not been acted upon?**

A5 – See A4

**Q6 – What is the significance of the adverse reaction reports that Health Canada has received with respect to the use of *Salvia divinorum*?**

A6 – Health Canada has received four domestic adverse reaction reports related to the use of *Salvia divinorum* as a hallucinogen through the Canada Vigilance database. The number of reports and the nature of reactions reported are not adequate to characterize the risk to the general population. These data cannot be used to determine incidence of use in the general population, as Health Canada does not have any information about the number of individuals using or who have used *Salvia divinorum*.

**If pressed: Q. Has Health Canada issued any kind of warning to Canadians about the use of *Salvia divinorum*?**

**A. Health Canada is developing an It's Your Health (IYH) article on *Salvia divinorum* to help inform the general public about the risks associated with the use of this substance.**

**Background**

*Salvia divinorum* is a species of sage belonging to the mint family that is chewed or smoked in order to induce its psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are often described as unpleasant.

The leaves of this plant have been used traditionally for spiritual and medicinal purposes by the Mazatec Indians in Mexico for many years,

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago.

**Data from a 2006 National Survey on Drug Use and Health Report, published by the U.S. Substance Abuse and Mental Health Services Administration has estimated that:**

- 1.8 million persons aged 12 or older have used *Salvia divinorum* at least once in their lifetime, and approximately 750,000 did so in the past year
- Use was more common among young adults (18 to 25 years old) as opposed to older adults (>26 years of age)
- Young adults were three times more likely than youths aged 12 to 17 to have used *Salvia divinorum* in the past year
- Use was more common in males than females

*Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

**Deleted:** The results from the 2009 Ontario Student Drug Use and Health Survey, which were published on November 18, 2009, indicate that among responding students in Ontario, 4.4% reported using *Salvia divinorum* at least once in the past year. Health Canada will consider this data in its ongoing examination of *Salvia divinorum* and salvinorin A.¶

¶ It is anticipated that the data from the 2008-2009 Youth Smoking Survey, the 2009 Canadian Alcohol and Drug Use Monitoring Survey and the 2009 Ontario Student Drug Use and Health Survey will help address some of the information gaps about the use of this substance and contribute to future decisions that Health Canada may make about this plant and its active ingredient. The data from the two national surveys will be available in 2010.¶

**Deleted:** While no validated data exist regarding usage in Canada, d

**Comment [C3]:** Leave in?

While some users have reported that the psychotropic effects of *Salvia divinorum* resemble those induced by other hallucinogens, such as LSD and phencyclidine, the overall experience appears to be quite unique.

**Prepared by:** Cheryl Tremblay, OCS, CSTD

**Approved by:**

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DMO (pending)  
MO (pending)  
PCO (pending)

input by COB wed

Discussed April 11/10

## Salvia divinorum

Deleted: (Redline) - CSTD Proposed Revisions - December 23, 2009

### The Issue

Recently there have been reports suggesting that Canadian teens and young adults are using a substance called *Salvia divinorum* (*S. divinorum*) for its ability to produce hallucinations. Certain Web sites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs.

Street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastra, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff encens special, and salvia.

Health Canada recommends that you avoid using this substance because very little is known about the damage it may cause to the body, including the brain. There is also no way to predict how it will affect you with each use.

### Background

*S. divinorum* is a species of sage that belongs to the mint family. It is known to have psychotropic effects, which means it affects the mind and mental processes. The leaves of this plant have been used traditionally for spiritual and medicinal purposes by the Mazatec Indians in Mexico for many years.

add back ←

Products that claim to contain *S. divinorum* – or its main active ingredient, salvinorin A – are widely available on the Internet and are sold in various "head shops" and natural food stores. The products are sold in a number of formats, including seeds and plant cuttings for growing purposes. Fresh or dried leaves are intended to be chewed, swallowed or smoked. Liquid preparations are also available.

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### Risks of Using *Salvia divinorum*

*S. divinorum*'s effects, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations;
- dysphoria (feeling unwell, uneasy or unhappy);
- out-of-body experiences;
- uncontrollable laughter;
- loss of consciousness;
- short-term memory loss;
- lack of physical coordination;
- slurred speech and awkward sentence patterns.

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product;
- how much is used;
- the purity of the product (it may be mixed with other substances);



- how it is taken (e.g., chewed, swallowed or smoked);
- the user's mood and expectations.

A major concern about *S. divinorum* is that there have only been a few scientific studies about the way it affects the body and the brain. Scientists know which brain receptors are targeted by the active ingredient, salvinorin A, but very little is known about the following:

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- how it affects the brain overall, including whether there are any long-term effects or permanent damage;
- how it interacts with other substances, including other drugs, natural health products and alcohol.

The information regarding physical dependence or addiction to *S. divinorum* is unclear, ~~although it appears the potential for either is low.~~

### Minimizing Your Risk

Health Canada recommends that you avoid using *S. divinorum*. Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs and other substances that distort reality. (See the "Need More Info?" section below for links to resources that can help you with this.)

Also, remember that just because a drug is plant-based or "natural," it does not mean it is safe. Under certain conditions of use, *S. divinorum* meets the definition of a "natural health product" (NHP) under Health Canada's *Natural Health Products Regulations*. However, no NHPs containing this substance have been approved for sale in Canada. This means that products claiming to contain *S. divinorum* have not been reviewed by Health Canada for safety, efficacy or quality. As such, they may be counterfeit or contain other ingredients that pose risks to health, and consumers should apply the "buyer beware" principle.

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Natural health products that have been reviewed and approved by Health Canada are labelled with one of the following:

- a Natural Product Number (NPN); or
- a Drug Identification Number - Homeopathic Medicine (DIN-HM).

### The Legal Status of *Salvia divinorum*

#### In Canada

Neither *S. divinorum* nor salvinorin A is currently regulated under the *Controlled Drugs and Substances Act* (CDSA). When assessing whether to add a substance to one of the Schedules to the CDSA, Health Canada considers the following factors:

- international requirements and trends in controlling the substance;
- similarity to other substances already regulated under the CDSA;
- whether there may be legitimate uses of the substance (e.g., potential health benefits, use in manufacturing, etc.);
- the potential for abuse and the risk of addiction associated with the substance;
- the extent of actual abuse of the substance in Canada and elsewhere;

- overall risk to public health and safety posed by the substance.

In the case of *S. divinorum*, there is simply not enough information available to determine whether regulation under the CDSA is the best option to manage the potential risks. Questions about the use of *S. divinorum* have been included in the 2008-2009 Youth Smoking Survey, the 2009 Canadian Alcohol and Drug Use Monitoring Survey, and the 2009 Ontario Student Drug Use and Health Survey (OSDUHS). The results from the 2009 OSDUHS were published on November 18, 2009 and indicate that among responding students in Ontario, 4.4% reported using *Salvia divinorum* at least once in the past year. Further data from the two national surveys will be available in 2010. It is anticipated that such data will help address some of the information gaps about this substance and contribute to future decisions that Health Canada may make about this plant and its active ingredient. See the Need More Info? section below for more information on the surveys that are collecting information about *Salvia divinorum* use in Canada and for more detailed findings from the 2009 OSDUHS.

**In Other Countries**

Several countries (e.g., Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) have placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on their sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution (e.g., no sales to anyone under the age of 18).

**Health Canada's Role**

Health Canada continues to collect and consider information regarding *S. divinorum* and continues to consult with key stakeholders, including health officials in other countries, and law enforcement officials here at home. This will assist in determining the most appropriate strategy to manage the risks associated with the use of *S. divinorum*.

**Reporting Adverse Reactions**

You can report any adverse reactions to the Canada Vigilance Program by one of the following three ways:

Report online at the MedEffect™ Canada Web site

Call toll-free at 1-866-234-2345

Complete a Canada Vigilance Reporting Form and either:

Fax toll-free to 1-866-678-6789

Mail to: \_\_\_\_\_ Canada Vigilance Program

\_\_\_\_\_ Health Canada

AL 0701C,

\_\_\_\_\_ Ottawa, ON K1A 0K9

To have postage pre-paid, download the postage paid label from the MedEffect™ Canada Web site. The Canada Vigilance Reporting Form and the adverse reaction reporting guidelines may also be obtained via this Web site.

*if this regulation as a controlled substance is warranted.*

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*PFBI complaints reporting*

**Need More Info?**

For information about the Government of Canada's Anti-Drug Strategy, go to: <http://www.nationalantidrugstrategy.gc.ca/>. The Prevention section on this site has a number of helpful resources for parents, including "Tips on Talking to Your Teenager" and "What to Do if Your Teen is Using Drugs."

Information on natural health products and the *Natural Health Products Regulations* can be found at: <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php>

For more on the surveys that are collecting information about *Salvia divinorum* use in Canada, see:

The 2008-2009 Youth Smoking Survey, at: [http://www.yss.uwaterloo.ca/ysss/site\\_app/controller/index.cfm](http://www.yss.uwaterloo.ca/ysss/site_app/controller/index.cfm) and

The 2009 Canadian Alcohol and Drug Use Monitoring Survey, at: <http://www.hc-sc.gc.ca/hl-vs/drug-drogues/cadums-esccad-eng.php>

The 2009 Ontario Student Drug Use and Health Survey, at: <http://www.camh.net/Research/osdus.html>

**Additional Resources:**

U.S. Drug Enforcement Administration: Drugs and Chemicals of Concern: *Salvia divinorum* and Salvinorin A at: [http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)

U.S. Department of Health & Human Services, National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006 at: <http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf>

For additional articles on health and safety issues go to the *It's Your Health* Web section at: [www.healthcanada.gc.ca/iyh](http://www.healthcanada.gc.ca/iyh)  
You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

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<http://www.hc-sc.gc.ca/english/iyh/index.html>

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Writer: Sue Lumsden  
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Deleted: Removes highlighter marking changes in Draft Six, which have been agreed to by the Program Contacts. Replaces reference (and link) to the Ontario Student Drug Use and Health Survey with a reference (and link) to the (national) Canadian Alcohol and Drug Use Monitoring Survey.

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Calendar Entry

# Meeting

- Notify me   Mark Private  Pencil In

<b>Subject</b>	Meeting to discuss Salvia It's Your Health			<b>Chair</b>	Lisa MacKay/HC-SC/GC/CA		
<b>When</b>	Starts	2010-04-01 Thu	09:30 AM	<b>Where</b>	Location	1234B Brooke Claxton Bldg	
	Ends	2010-04-01 Thu	10:30 AM		1 hour		
<b>Invitees</b>	Required (to)	Allison Lui/HC-SC/GC/CA@HWC, Angela Tonary/HC-SC/GC/CA@HWC, Christine Roush/HC-SC/GC/CA@HWC, Danika Courtney Leitch/HC-SC/GC/CA@HWC,					
	Optional (cc)	Jeff Devine/HC-SC/GC/CA@HWC, Kathy Howard/HC-SC/GC/CA@HWC, Kevan					
<b>Categorize</b>							

**Description**

### Documents for discussion:



Salvia D MLs Dec24 918.doc IYH - Salvia Divinorum\_v9 Mar2010.doc

### Teleconference Number:

NCR: [redacted]

s.16(2)(c)

Code: [redacted]

**Your Notes**

DRAFT  
April 20, 2010

### Media Lines Regulatory Control of *Salvia Divinorum*

#### Issue

Since 2006, Health Canada has noted ongoing media interest regarding the availability of *Salvia divinorum* on the Canadian market. Health Canada has also received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum*, particularly given reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties.

#### Key Messages:

- Health Canada advises Canadians not to use *S. divinorum* products because very little is known about the substance and its potential effects on the brain and/or body.
- Since it is used primarily for its hallucinogenic properties, *S. divinorum* products would meet the definition of a drug under the *Food and Drugs Act*. To date, no *S. divinorum* products have been licensed for sale in Canada. The illegal sale of these products would be subject to compliance and enforcement actions by Health Canada.
- Health Canada continues to collect and study information as it becomes available, and to consult with law and health officials domestically and internationally to determine the best way to manage the risks associated with the use of *Salvia divinorum* and whether it needs to be controlled under the *Controlled Drugs and Substances Act*.

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#### Supplementary Messages:

##### *On the classification of *Salvia divinorum*:*

- When *S. divinorum* is manufactured, sold or represented for use in modifying organic functions in humans, and hallucinogens such as *S. divinorum* work by modifying organic functions in the brain, it meets the definition of a Natural Health Product (NHP) in accordance with the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*. It is illegal to sell NHPs in Canada unless they have market authorization, and as of January 2010, no *S. divinorum* product has been licensed by Health Canada. All unauthorized drugs and NHPs are subject to compliance and enforcement actions by the Health Products and Food Branch Inspectorate.

- In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA).
- *Salvia divinorum* is not listed under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these conventions.
- Several countries (Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) have placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Although some individual U.S. states have implemented laws restricting its use, sale and/or distribution, *Salvia divinorum* and salvinorin A are not federally regulated under the *Controlled Substances Act* in the United States.
- As of January 2010, Health Canada had not issued any Natural Product Numbers (NPN) or Drug Identification Numbers – Homeopathic Medicine (DIN-HM) for *Salvia divinorum* products.

***If pressed on the lack of statistics on Salvia divinorum use in Canada:***

- Health Canada is taking steps to address this lack of data. Questions about the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey, the 2009 Canadian Alcohol and Drug Use Monitoring Survey. The results from these surveys are anticipated in the Spring/Summer of 2010.
- It is anticipated that the data from these surveys will help address some of the information gaps about this substance and contribute to future decisions that Health Canada may make about this plant and its active ingredient.

***If pressed regarding the results of the 2009 Ontario Student Drug Use and Health Survey:***

- The results from the 2009 Ontario Student Drug Use and Health Survey were published on November 18, 2009 and indicate that among responding students in Ontario, 4.4% reported using *Salvia divinorum* at least once in the past year. Health Canada will consider this data in its ongoing examination of *Salvia divinorum* and salvinorin A.

**Questions and Answers**

**Q1 – If Health Canada is aware of *Salvia divinorum*'s ill-effects, why isn't it illegal?**

A1 – When *S. divinorum* is manufactured, sold or represented for use as a hallucinogen it meets the definition of a drug under the *Food and Drugs Act*. No drug can be sold legally without a licence authorizing it to be marketed in Canada, and as of January 2010, no *S.*

*divinorum* product has been licensed. The illegal sale of *S. divinorum* is subject to compliance and enforcement actions by the Health Products and Food Branch Inspectorate.

With respect to the ill effects, an insufficient number of controlled scientific studies of the physical and psychotropic effects of *Salvia divinorum* on humans and animals have been carried out. As such, it is difficult to predict the potential for addiction and abuse of *Salvia divinorum*. More controlled systematic research in this area is needed.

**Q2 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?**

A2 – The *Natural Health Products Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *Salvia divinorum*.

**Q3 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A3 – *Salvia divinorum* products that are not in compliance with the *Natural Health Products Regulations* and/or are found to pose a risk to the health of Canadians may be subject to compliance and enforcement action by Health Canada. Complaints about illegal sale of drugs containing *S. divinorum* can be made to the Health Products and Food Branch Inspectorate at 1-800-267-9675. The Canada Border Services Agency has already targeted imports of products containing *Salvia divinorum*.

**Q4 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum*. What does that involve and what stage is it at?**

A4 - Health Canada considers several factors in determining whether scheduling a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in controlling the substance;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada has only limited information on the above-mentioned factors, and thus there is simply not enough information available to determine whether regulation of *Salvia divinorum* under the CDSA is warranted.

**Comment [D1]:** I think the term "import target" could be viewed as vague for the general public. See proposed alternate wording.

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**Comment [D2]:** Does the lack of information not extend to all of the factors identified?

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It is anticipated that the data from the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey in addition to 2009 Ontario Student Drug Use and Health Survey will help address some of the information gaps about this substance and contribute to future decisions that Health Canada may make about this plant and its active ingredient. The data from the two national surveys will be available in 2010.

Health Canada will continue to collect and consider information regarding *Salvia divinorum* as it becomes available.

**Q5 – Didn't an internal report from Health Canada's Marketed Health Products Directorate recommend that *Salvia divinorum* be scheduled under the CDSA? Why has that recommendation not been acted upon?**

A5 – See A4

**Q6 – What is the significance of the adverse reaction reports that Health Canada has received with respect to the use of *Salvia divinorum*?**

A6 – Health Canada has received four domestic adverse reaction reports related to the use of *Salvia divinorum* as a hallucinogen through the Canada Vigilance database. The number of reports and the nature of reactions reported are not adequate to characterize the risk to the general population. These data cannot be used to determine incidence of use in the general population, as Health Canada does not have any information about the number of individuals using or who have used *Salvia divinorum*.

**If pressed: Q. Has Health Canada issued any kind of warning to Canadians about the use of *Salvia divinorum*?**

A. Health Canada is developing an It's Your Health (IYH) article on *Salvia divinorum* to help inform the general public about the risks associated with the use of this substance.

#### **Background**

*Salvia divinorum* is a species of sage belonging to the mint family. (It's) leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are often described as unpleasant.

The leaves of this plant have been used traditionally for spiritual and medicinal purposes by the Mazatec Indians in Mexico.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago.



Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) estimated that:

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year.
- 5.4% of students (grades 7-12) ever used *S. divinorum*.
- Use of *S. divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

Data from the 2007 report on Alcohol and Other Drugs published by the Addictions Foundation of Manitoba estimated that:

- 3.7% of males vs. 2.2% of females (grades 7-12) used *S. divinorum* during that year.

Data from a 2006 National Survey on Drug Use and Health Report, published by the U.S. Substance Abuse and Mental Health Services Administration estimated that:

- 0.3% of persons aged 12 or older used *S. divinorum* in 2006.
- 0.6% of persons between the ages of 12 and 17 used *S. divinorum* in 2006.
- 1.7% of persons between the ages of 18 to 25 used *S. divinorum* in 2006.
- Young adults (18-25) were nearly three times more likely than youths aged 12-17 to have used *S. divinorum* in 2006.
- Males between the ages of 12-25 were three to four times more likely than females in the same age range to have used *S. divinorum* in 2006.

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*Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

While some users have reported that the psychotropic effects of *Salvia divinorum* resemble those induced by other hallucinogens, such as LSD and phencyclidine, the overall experience appears to be quite unique and generally is reported to be unpleasant.

Prepared by: Cheryl Tremblay, OCS, CSTD

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DMO (pending)  
MO (pending)  
PCO (pending)

## ***Salvia divinorum***

### **The Issue**

Recently there have been reports suggesting that Canadian teens and young adults are using a substance called *Salvia divinorum* (*S. divinorum*) for its ability to produce hallucinations. *S. divinorum* is a plant, some street names for which include: Sally D, Lady Sally, Maria pastora, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff, incense special, and salvia.

While certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs, when *S. divinorum* is manufactured, sold or represented for use as a hallucinogen it meets the definition of a drug under the *Food and Drugs Act*. No drug can be sold legally without a licence authorizing it to be marketed in Canada. As of January 2010, no *S. divinorum* product has been licensed.

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Health Canada recommends that you avoid using this plant because very little is known about the effects it may have on your body and/or brain. There is also no way to predict how it will affect you with each use.

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### **Background**

*S. divinorum* is a species of sage that belongs to the mint family. It is known to have psychotropic effects, which means it affects the mind and mental processes. The leaves of this plant have been traditionally used for spiritual and medicinal purposes by the Mazatec Indians. Traditional use involves chewing the leaves or using them to make a tea for medicinal purposes or to induce a "mystical" or hallucinogenic experience for spiritual purposes.

~~Oaxaca~~ Mexico

Products that claim to contain *S. divinorum* – or its main active ingredient, salvinorin A – are widely available on the Internet and are sold in various "head shops" and natural food stores. The products are sold in a number of forms, including fresh or dried leaves, liquids or seeds and plant cuttings for growing purposes. However, consumers have no way to know what these illegal products actually contain.

### **Risks of Using *Salvia divinorum***

*S. divinorum*'s effects, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations;
- dysphoria (feeling unwell, uneasy or unhappy);
- out-of-body experiences;
- uncontrollable laughter;
- loss of consciousness;
- short-term memory loss;
- lack of physical coordination;
- slurred speech and awkward sentence patterns.

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product;
- how much is used;
- the purity of the product (it may be mixed with other substances);
- how it is taken (e.g., chewed, swallowed or smoked);
- the user's mood and expectations.

→ Scientists know which brain receptors are targeted by the active ingredient, salvinorin A, but very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or permanent damage;
- how it interacts with other substances, including other drugs, natural health products and alcohol.

There is also insufficient information regarding *S. divinorum*'s potential to produce physical dependence and/or addiction.

Health Canada recommends that you avoid using *S. divinorum*. Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs and other substances that distort reality. (See the "Need More Info?" section below for links to resources that can help you with this.)

### The Legal Status of *Salvia divinorum*

#### In Canada

When *S. divinorum* is manufactured, sold or represented for use in modifying organic functions in humans, and hallucinogens work by modifying organic functions in the brain, it meets the definition of a Natural Health Product (NHP) in accordance with the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*. It is illegal to sell NHPs in Canada unless they have market authorization. Natural health products that have been reviewed and approved by Health Canada are labelled with one of the following:

- a Natural Product Number (NPN); or
- a Drug Identification Number - Homeopathic Medicine (DIN-HM).

As of January 2010 no *S. divinorum* product has been licensed by Health Canada. All unauthorized drugs and NHPs are subject to compliance and enforcement actions by the Health Products and Food Branch Inspectorate.

Neither *S. divinorum* nor salvinorin A are currently regulated under the *Controlled Drugs and Substances Act* (CDSA) as there is simply not enough information available to determine

#### **Deleted: Minimizing Your Risk!**

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**Deleted:** Natural health products that have been reviewed and approved by Health Canada are labelled with one of the following:¶  
<#>a Natural Product Number (NPN); or¶  
a Drug Identification Number - Homeopathic Medicine (DIN-HM).

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<#>international requirements and trends in controlling the substance:¶  
<#>similarity to other substances already regulated under the CDSA:¶  
<#>whether there may be legitimate uses of the substance (e.g., potential health benefits, use in manufacturing, etc.): ¶  
<#>the potential for abuse and the risk of addiction associated with the substance:¶  
<#>the extent of actual abuse of the substance in Canada and elsewhere:¶  
<#>overall risk to public health and safety posed by the substance.¶  
¶  
In the case of *S. divinorum*,

whether regulation under the CDSA is warranted. Questions about the use of *S. divinorum* have been included in the 2008-2009 Youth Smoking Survey, the 2009 Canadian Alcohol and Drug Use Monitoring Survey and the 2009 Ontario Student Drug Use and Health Survey (OSDUHS). The results from the 2009 OSDUHS were published on November 18, 2009 and indicate that among responding students in Ontario, 4.4% reported using *Salvia divinorum* at least once in the past year. Further data from the two national surveys will be available in 2010. It is anticipated that such data will help address some of the information gaps about this substance and contribute to future decisions that Health Canada may make about this plant and its active ingredient. See the Need More Info? section below for more information on the surveys that are collecting information about *Salvia divinorum* use in Canada and for more detailed findings from the 2009 OSDUHS.

**Comment [D1]:** If we do mention the CDSA in the IYH, do we need to explain the consequences of scheduling under the CDSA as opposed regulation under the FDA?

#### In Other Countries

Several countries have placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on their sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution (e.g., no sales to anyone under the age of 18).

#### **Health Canada's Role**

Health Canada continues to collect and consider information regarding *S. divinorum* and continues to consult with key stakeholders, including health officials in other countries, and law enforcement officials here at home. This will assist in determining whether Health Canada's approach to managing the risks associated with the use of *S. divinorum* should be modified.

Complaints about illegal sale of drugs containing *S. divinorum* can be made to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

#### **Reporting Adverse Reactions**

You can report any adverse reactions to the Canada Vigilance Program by one of the following three ways:

Report online at the MedEffect™ Canada Web site

Call toll-free at 1-866-234-2345

Complete a Canada Vigilance Reporting Form and either:

Fax toll-free to 1-866-678-6789

Mail to: Canada Vigilance Program  
Health Canada  
AL 0701C  
Ottawa, ON K1A 0K9

To have postage pre-paid, download the postage paid label from the MedEffect™ Canada Web site. The Canada Vigilance Reporting Form and the adverse reaction reporting guidelines may also be obtained via this Web site.

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*S. divinorum* is a species of sage that belongs to the mint family. It is known to have psychotropic effects, which means it affects the mind and mental processes. The leaves of this plant have been traditionally used for spiritual and medicinal purposes by the Mazatec Indians in. Traditional use involves chewing the leaves or using them to make a tea for medicinal purposes or to induce a "mystical" or hallucinogenic experience for spiritual purposes. ¶

¶  
Products that claim to contain *S. divinorum* – or its main active ingredient, salvinorin A – are widely available on the Internet and are sold in various "head shops" and natural food stores. The products are sold in a number of forms, including fresh or dried leaves, liquids or seeds and plant cuttings for growing purposes. However, consumers have no way to know what these illegal products actually contain. ¶

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### Need More Info?

- For information about the Government of Canada's **Anti-Drug Strategy**, go to:

[www.nationalantidrugstrategy.gc.ca/](http://www.nationalantidrugstrategy.gc.ca/)

The Prevention section on this site has a number of helpful resources for parents, including:

- **Tips on Talking to Your Teenager**, at: [www.hc-sc.gc.ca/hc-ps/pubs/adp-apd/talk-aborder/index-eng.php](http://www.hc-sc.gc.ca/hc-ps/pubs/adp-apd/talk-aborder/index-eng.php)

- **What to Do if Your Teen is Using Drugs**, at:

[www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html](http://www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html)

- Information on natural health products and the **Natural Health Products Regulations** can be found at: [www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php)

For more on the surveys that are collecting information about *Salvia divinorum* use in Canada, see:

- **The 2008-2009 Youth Smoking Survey**, at:

[www.yss.uwaterloo.ca/ysss/site\\_app/controller/index.cfm](http://www.yss.uwaterloo.ca/ysss/site_app/controller/index.cfm) and ←

- **The 2009 Canadian Alcohol and Drug Use Monitoring Survey**, at: [www.hc-sc.gc.ca/hl-vs/drug-drogués/cadums-escad-eng.php](http://www.hc-sc.gc.ca/hl-vs/drug-drogués/cadums-escad-eng.php)

- **The 2009 Ontario Student Drug Use and Health Survey**, at:

[www.camh.net/Research/osdus.html](http://www.camh.net/Research/osdus.html)

### Additional Resources:

- U.S. Drug Enforcement Administration: Drugs and Chemicals of Concern: ***Salvia divinorum*** and Salvinorin A at: [www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)

- U.S. Department of Health & Human Services, **National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006** at:

[www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf](http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf)

- For additional articles on health and safety issues go to the ***It's Your Health*** Web section at: [www.healthcanada.gc.ca/iyh](http://www.healthcanada.gc.ca/iyh) ← update url?

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

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May 10/10

## *Salvia divinorum*

### Issue

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Recently there have been reports suggesting that Canadian teens and young adults are using a substance called *Salvia divinorum* (*S. divinorum*) for its ability to produce hallucinations. *S. divinorum* is a plant, some street names for which include: Sally D, Lady Sally, Maria pastora, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff, incense special, and salvia.

Health Canada recommends that you avoid using this plant because very little is known about the effects it may have on your body and/or brain. There is also no way to predict how it will affect you with each use.

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### Background

*S. divinorum* is a species of sage that belongs to the mint family. It is known to have psychotropic effects, which means it affects the mind and mental processes. The leaves of this plant have been traditionally used for spiritual and medicinal purposes by the Mazatec Indians. Traditional use involves chewing the leaves or using them to make a tea for medicinal purposes or to induce a "mystical" or hallucinogenic experience for spiritual purposes.

Products that claim to contain *S. divinorum* – or its main active ingredient, salvinorin A – are widely available on the Internet and are sold in various "head shops" and natural food stores. The products are sold in a number of forms, including fresh or dried leaves, liquids or seeds and plant cuttings for growing purposes. However, consumers have no way to know what these illegal products actually contain.

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### Risks of Using *Salvia divinorum*

*S. divinorum*'s effects, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations;
- dysphoria (feeling unwell, uneasy or unhappy);
- out-of-body experiences;
- uncontrollable laughter;
- loss of consciousness;
- short-term memory loss;
- lack of physical coordination;
- slurred speech and awkward sentence patterns.

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product;
- how much is used;



- the purity of the product (it may be mixed with other substances);
- how it is taken (e.g., chewed, swallowed or smoked);
- the user's mood and expectations.

Scientists know which brain receptors are targeted by the active ingredient, salvinorin A, but very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or permanent damage;
- how it interacts with other substances, including other drugs, natural health products and alcohol.

The potential of *S. divinorum* to produce physical dependence and/or addiction is also not known.

Health Canada recommends that you avoid using *S. divinorum*. Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs and other substances that distort reality. (See the "Need More Info?" section below for links to resources that can help you with this.)

### Legal Status of *Salvia divinorum*

#### In Canada

When *S. divinorum* is manufactured, sold or represented for use in modifying organic functions in humans, and hallucinogens work by modifying organic functions in the brain, it meets the definition of a Natural Health Product (NHP) in accordance with the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*. It is illegal to sell NHPs in Canada unless they have been reviewed and approved by Health Canada and labelled with one of the following:

- a Natural Product Number (NPN); or
- a Drug Identification Number - Homeopathic Medicine (DIN-HM).

As of January 2010 no products containing *S. divinorum* have been approved by Health Canada. All unauthorized drugs and NHPs are subject to compliance and enforcement actions by the Health Products and Food Branch Inspectorate.

Neither *S. divinorum* nor salvinorin A are currently regulated under the *Controlled Drugs and Substances Act* (CDSA). This is because there is not enough information available to determine whether regulation as a controlled substance is warranted. In an effort to collect more information about the use of *S. divinorum*, questions on it were included in the 2008-2009 Youth Smoking Survey, the 2009 Canadian Alcohol and Drug Use Monitoring Survey and the 2009 Ontario Student Drug Use and Health Survey (OSDUHS). The results from the 2009 OSDUHS were published on November 18, 2009 and indicate that among responding students in Ontario, 4.4% reported using *Salvia divinorum* at least once in the past year. Data from the other two surveys

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<#>international requirements and trends in controlling the substance;¶  
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will be available later in 2010 and it is anticipated that such data will contribute to future decisions that Health Canada may make about this plant and its active ingredient. See the Need More Info? section below for more information on the surveys that are collecting information about *Salvia divinorum* use in Canada and for more detailed findings from the 2009 OSDUHS.

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**Deleted:** help address some of the information gaps about this substance and

### In Other Countries

Several countries have placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on their sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution (e.g., no sales to anyone under the age of 18).

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¶  
*S. divinorum* is a species of sage that belongs to the mint family. It is known to have psychotropic effects, which means it affects the mind and mental processes. The leaves of this plant have been traditionally used for spiritual and medicinal purposes by the Mazatec Indians in. Traditional use involves chewing the leaves or using them to make a tea for medicinal purposes or to induce a "mystical" or hallucinogenic experience for spiritual purposes.¶  
¶  
Products that claim to contain *S. divinorum* – or its main active ingredient, salvinorin A – are widely available on the Internet and are sold in various "head shops" and natural food stores. The products are sold in a number of forms, including fresh or dried leaves, liquids or seeds and plant cuttings for growing purposes. However, consumers have no way to know what these illegal products actually contain. ¶

### Health Canada's Role

Health Canada continues to collect and consider information regarding *S. divinorum* and will continue to consult with key stakeholders including health officials in other countries and law enforcement officials here at home. This will assist in determining Health Canada's future approach to decision-making regarding *S. divinorum*.

Complaints about illegal sale of drugs containing *S. divinorum* can be made to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

### Reporting Adverse Reactions

You can report any adverse reactions to the Canada Vigilance Program by one of the following three ways:

- Report online at the MedEffect™ Canada Web site
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and either:
  - Fax toll-free to 1-866-678-6789
  - Mail to: Canada Vigilance Program  
Health Canada  
AL 0701C  
Ottawa, ON K1A 0K9

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**Comment [D1]:** We are doing nothing to mitigate risk other than asking people not to use it.  
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To have postage pre-paid, download the postage paid label from the MedEffect™ Canada Web site. The Canada Vigilance Reporting Form and the adverse reaction reporting guidelines may also be obtained via this Web site.

### Need More Info?

- For information about the Government of Canada's **Anti-Drug Strategy**, go to: [www.nationalantidrugstrategy.gc.ca/](http://www.nationalantidrugstrategy.gc.ca/)  
The Prevention section on this site has a number of helpful resources for parents, including:

**Comment [D2]:** This sentence appears to be out of place as there is no reference anywhere in the article to Adverse Drug Reactions. For the purpose of context, perhaps there should be an opening line saying that HC is always interested in obtaining information about incidents of adverse effects?

- **Tips on Talking to Your Teenager**, at: [www.hc-sc.gc.ca/hc-ps/pubs/adp-apd/talk-aborder/index-eng.php](http://www.hc-sc.gc.ca/hc-ps/pubs/adp-apd/talk-aborder/index-eng.php)
- **What to Do if Your Teen is Using Drugs**, at: [www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html](http://www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html)
- Information on natural health products and the *Natural Health Products Regulations* can be found at: [www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php)

For more on the surveys that are collecting information about *Salvia divinorum* use in Canada, see:

- **The 2008-2009 Youth Smoking Survey**, at: [www.yss.uwaterloo.ca/yssssite\\_app/controller/index.cfm](http://www.yss.uwaterloo.ca/yssssite_app/controller/index.cfm) and
- **The 2009 Canadian Alcohol and Drug Use Monitoring Survey**, at: [www.hc-sc.gc.ca/hl-vs/drug-drogués/cadums-escad-eng.php](http://www.hc-sc.gc.ca/hl-vs/drug-drogués/cadums-escad-eng.php)
- **The 2009 Ontario Student Drug Use and Health Survey**, at: [www.camh.net/Research/osdus.html](http://www.camh.net/Research/osdus.html)

**Additional Resources:**

- U.S. Drug Enforcement Administration: Drugs and Chemicals of Concern: *Salvia divinorum* and Salvinorin A at: [www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)
- U.S. Department of Health & Human Services, **National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006** at: [www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf](http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf)
- For additional articles on health and safety issues go to the *It's Your Health* Web section at: [www.healthcanada.gc.ca/iyh](http://www.healthcanada.gc.ca/iyh)

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

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Shahid Perwaiz  
HPFBI : Collin Pinto  
HPFB comms: Elizabeth Keeping, Blossom Leung

. When assessing whether to add a substance to one of the Schedules to the CDSA, Health Canada considers the following factors:

- international requirements and trends in controlling the substance;
- similarity to other substances already regulated under the CDSA;
- whether there may be legitimate uses of the substance (e.g., potential health benefits, use in manufacturing, etc.);
- the potential for abuse and the risk of addiction associated with the substance;
- the extent of actual abuse of the substance in Canada and elsewhere;
- overall risk to public health and safety posed by the substance.

In the case of *S. divinorum*, there is simply

May 10/10 version from Denis

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May 10, 2010

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### Media Lines Regulatory Control of Salvia Divinorum

**Issue**

Since 2006, Health Canada has noted ongoing media interest in the availability of *Salvia divinorum* in Canada. Health Canada has received numerous enquiries from various municipalities and members of the public. Health Canada has not taken steps to control the sale of *Salvia divinorum* based on reports from scientific studies suggesting that it is used by

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**Key**

- *Salvia* is used because of its effects on the brain

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- *Salvia divinorum* is a naturally occurring psychoactive substance in the mint family (Lamiaceae). It is used primarily for its hallucinogenic properties. *Salvia divinorum* products would meet the definition of a drug under the *Food and Drugs Act*. To date, no *Salvia divinorum* products have been licensed for sale in Canada. The illegal sale of these products would be subject to compliance and enforcement actions by Health Canada.

Deleted: Since it is used primarily for its hallucinogenic properties, *S. divinorum* products would meet the definition of a drug under the *Food and Drugs Act*. To date, no *S. divinorum* products have been licensed for sale in Canada. The illegal sale of these products would be subject to compliance and enforcement actions by Health Canada.

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- It is not approved as a Natural Product (NPN)

JK.

- Health Canada is not aware of any international agreements regarding the use of *Salvia divinorum*. *Salvia divinorum* is a controlled substance in some countries.

**Supplementary Material**

**On the classification**

- When *Salvia divinorum* is used for its psychoactive properties, it is considered a drug under the *Food and Drug Regulations*. The definition of a drug in the *Food and Drug Regulations* includes substances that modify or interfere with the normal functions of the body.

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### Media Lines Regulatory Control of Salvia Divinorum

#### Issue

Since 2006, Health Canada has noted ongoing media interest regarding the availability of *Salvia divinorum* in Canada. Health Canada has also received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum*, particularly given reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties.

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#### Key Messages:

- Health Canada advises Canadians not to use *S. divinorum* products because very little is known about the substance and its potential effects on the brain and/or body.
- When *S. divinorum* is manufactured, sold or represented as a hallucinogen to modify organic functions in the brain, it meets the definition of a Natural Health Product (NHP) in accordance with the Natural Health Products Regulations and the definition of a drug under the *Food and Drugs Act*.
- It is illegal to sell NHPs in Canada unless they have been reviewed and approved by Health Canada and labelled with a Natural Product Number (NPN) or a Drug Identification Number – Homeopathic Medicine (DIN-HM).
- Health Canada continues to collect and study information as it becomes available, and to consult with law and health officials domestically and internationally to determine the best way to manage the risks associated with the use of *Salvia divinorum* and whether it needs to be controlled under the *Controlled Drugs and Substances Act*.

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Deleted: Since it is used primarily for its hallucinogenic properties, *S. divinorum* products would meet the definition of a drug under the *Food and Drugs Act*. To date, no *S. divinorum* products have been licensed for sale in Canada. The illegal sale of these products would be subject to compliance and enforcement actions by Health Canada.

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#### Supplementary Messages:

##### On the classification of *Salvia divinorum*:

- When *S. divinorum* is manufactured, sold or represented for use in modifying organic functions in humans, and hallucinogens such as *S. divinorum*, it meets the definition of a Natural Health Product (NHP) in accordance with the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*.

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- It is illegal to sell NHPs in Canada unless they have been approved by Health Canada and assigned a Natural Product Number (NPN) or Drug Identification Number - Homeopathic Medicine. As of January 2010, no *S. divinorum* products have been approved for sale by Health Canada. The sale and distribution of unauthorized drugs and NHPs are subject to compliance and enforcement actions by the Health Products and Food Branch Inspectorate.
- In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA).
- *Salvia divinorum* is not listed under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these conventions.
- Several countries (Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) have placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Although some individual U.S. states have implemented laws restricting its use, sale and/or distribution, *Salvia divinorum* and salvinorin A are not federally regulated under the *Controlled Substances Act* in the United States.

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***If pressed on the lack of statistics on *Salvia divinorum* use in Canada:***

- Health Canada is taking steps to address this lack of data. Questions about the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey, the 2009 Canadian Alcohol and Drug Use Monitoring Survey. The results from these surveys are scheduled to be released in the Spring/Summer of 2010.
- It is anticipated that the data from these surveys will contribute to future decisions that Health Canada may make about this plant and its active ingredient.

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***If pressed regarding the results of the 2009 Ontario Student Drug Use and Health Survey:***

- The results from the 2009 Ontario Student Drug Use and Health Survey were published on November 18, 2009 and indicate that among responding students in Ontario, 4.4% reported using *Salvia divinorum* at least once in the past year. Health Canada will consider this data in its ongoing examination of *Salvia divinorum* and salvinorin A.

**Questions and Answers**

**Q1 – If Health Canada is aware of *Salvia divinorum*'s ill-effects, why isn't it illegal?**



A1 – When *S. divinorum* is manufactured, sold or represented for use as a hallucinogen it meets the definition of a drug under the *Food and Drugs Act*. No drug can be sold legally without being approved by Health Canada prior to sale in Canada; as of January 2010, no *S. divinorum* NHPs have been approved for sale. The illegal sale of NHPs containing *S. divinorum* is subject to compliance and enforcement actions by the Health Products and Food Branch Inspectorate.

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With respect to the ill effects, not enough controlled scientific studies looking into the physical and psychotropic effects of *Salvia divinorum* on humans and animals have been carried out. As such, it is difficult to predict the potential for addiction and abuse of *Salvia divinorum*. More controlled systematic research in this area is needed.

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## Q2 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?

A2 – The *Natural Health Products Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *Salvia divinorum*.

## Q3 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?

A3 – *Salvia divinorum* products that are not in compliance with the *Natural Health Products Regulations* and/or are found to pose a risk to the health of Canadians may be subject to compliance and enforcement action by Health Canada. Complaints about the illegal sale of drugs containing *S. divinorum* can be referred to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

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Comment [D1]: I think the term "import target" could be viewed as vague for the general public. See proposed alternate wording.

## Q4 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum* as a controlled substance. What does that involve and what stage is it at?

Deleted: An import target for products containing *Salvia divinorum* has already been placed with Canada Border Services Agency.

A4 - Health Canada considers several factors in determining whether scheduling a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in controlling the substance;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada has only limited information on some of the above-mentioned factors, and thus there is simply not enough information available to determine whether regulation of *Salvia divinorum* under the CDSA is warranted.

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It is anticipated that the data from the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey in addition to the results from the 2009 Ontario Student Drug Use and Health Survey will help address some of the information gaps about this substance. Data from the two national surveys will be available in 2010.

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**Q5 – Didn't an internal report from Health Canada's Marketed Health Products Directorate recommend that *Salvia divinorum* be scheduled under the CDSA? Why has that recommendation not been acted upon?**

A5 – See A4

**Deleted:** Health Canada will continue to collect and consider information regarding *Salvia divinorum* as it becomes available.¶

**Q6 – What is the significance of the adverse reaction reports that Health Canada has received with respect to the use of *Salvia divinorum*?**

A6 – Health Canada has received four domestic adverse reaction reports related to the use of *Salvia divinorum* as a hallucinogen through the Canada Vigilance database. The number of reports and the nature of reactions reported are, however, not adequate to characterize the risk to the general population. These data also cannot be used to determine the incidence of use in the general population, as Health Canada does not have any information about the number of individuals using or who have used *Salvia divinorum*.

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**If pressed: Q. Has Health Canada issued any kind of warning to Canadians about the use of *Salvia divinorum*?**

A. Health Canada is developing an It's Your Health (IYH) article on *Salvia divinorum* to help inform the general public about the risks associated with the use of this substance.

### **Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

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The leaves of this plant have been used traditionally for spiritual and medicinal purposes by the Mazatec Indians in Mexico.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

While some users have reported that the psychotropic effects of *Salvia divinorum* resemble those induced by other hallucinogens, such as LSD and phencyclidine, the overall experience appears to be quite unique and generally is reported to be unpleasant.

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Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) estimated that:

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year.
- 5.4% of students (grades 7-12) ever used *S. divinorum*.
- Use of *S. divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

Data from the 2007 report on Alcohol and Other Drugs published by the Addictions Foundation of Manitoba estimated that:

- 3.7% of males vs. 2.2% of females (grades 7-12) used *S. divinorum* during that year.

Data from a 2006 National Survey on Drug Use and Health Report, published by the U.S. Substance Abuse and Mental Health Services Administration estimated that:

- 0.3% of persons aged 12 or older used *S. divinorum* in 2006.
- 0.6% of persons between the ages of 12 and 17 used *S. divinorum* in 2006.
- 1.7% of persons between the ages of 18 to 25 used *S. divinorum* in 2006.
- Young adults (18-25) were nearly three times more likely than youths aged 12-17 to have used *S. divinorum* in 2006.
- Males between the ages of 12-25 were three to four times more likely than females in the same age range to have used *S. divinorum* in 2006.

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¶ While some users have reported that the psychotropic effects of *Salvia divinorum* resemble those induced by other hallucinogens, such as LSD and phencyclidine, the overall experience appears to be quite unique and generally is reported to be unpleasant.

**Prepared by:** Cheryl Tremblay, OCS, CSTD

**Input by:** Lisa Mackay IYH/PACCB, Hanan Abramovici HECSB/ODARS, Jocelyn Kula, HECSB/OCS, Robin Marles HPFB/NHPD, Robert Leitch HPFB/MHPD, Collin Pinto, HPFB/HPFBI

**Approved by:**

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Anne Lamar, ADM, PACCB (pending)  
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May 10, 2010  
Version from Denis

## *Salvia divinorum*

### Issue

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Recently there have been reports suggesting that Canadian teens and young adults are using a substance called *Salvia divinorum* (*S. divinorum*) for its ability to produce hallucinations. *S. divinorum* is a plant, some street names for which include: Sally D, Lady Sally, Maria pastora, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff, incense special, and salvia.

Health Canada recommends that you avoid using this plant because very little is known about the effects it may have on your body and/or brain. There is also no way to predict how it will affect you with each use.

### Background

*S. divinorum* is a species of sage that belongs to the mint family. It is known to have psychotropic effects, which means it affects the mind and mental processes. The leaves of this plant have been traditionally used for spiritual and medicinal purposes by the Mazatec Indians. Traditional use involves chewing the leaves or using them to make a tea for medicinal purposes or to induce a "mystical" or hallucinogenic experience for spiritual purposes.

Products that claim to contain *S. divinorum* – or its main active ingredient, salvinorin A – are widely available on the Internet and are sold in various "head shops" and natural food stores. The products are sold in a number of forms, including fresh or dried leaves, liquids or seeds and plant cuttings for growing purposes. However, consumers have no way to know what these illegal products actually contain.

Deleted: Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs. However, when *S. divinorum* is manufactured, sold or represented for use as a hallucinogen it meets the definition of a drug under the *Food and Drugs Act*. No drug can be sold legally without a licence authorizing it to be marketed in Canada. As of January 2010, no *S. divinorum* product has been licensed. ¶

Deleted: *S. divinorum* is a plant. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff, incense special, and salvia. ¶

### Risks of Using *Salvia divinorum*

*S. divinorum*'s effects, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations;
- dysphoria (feeling unwell, uneasy or unhappy);
- out-of-body experiences;
- uncontrollable laughter;
- loss of consciousness;
- short-term memory loss;
- lack of physical coordination;
- slurred speech and awkward sentence patterns.

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product;
- how much is used;

- the purity of the product (it may be mixed with other substances);
- how it is taken (e.g., chewed, swallowed or smoked);
- the user's mood and expectations.

Scientists know which brain receptors are targeted by the active ingredient, salvinorin A, but very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or permanent damage;
- how it interacts with other substances, including other drugs, natural health products and alcohol.

The potential of *S. divinorum* to produce physical dependence and/or addiction is also not known.

Health Canada recommends that you avoid using *S. divinorum*. Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs and other substances that distort reality. (See the "Need More Info?" section below for links to resources that can help you with this.)

### Legal Status of *Salvia divinorum*

#### In Canada

When *S. divinorum* is manufactured, sold or represented for use in modifying organic functions in humans, and hallucinogens work by modifying organic functions in the brain, it meets the definition of a Natural Health Product (NHP) in accordance with the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*. It is illegal to sell NHPs in Canada unless they have been reviewed and approved by Health Canada and labelled with one of the following:

- a Natural Product Number (NPN); or
- a Drug Identification Number - Homeopathic Medicine (DIN-HM).

As of January 2010 no products containing *S. divinorum* have been approved by Health Canada. All unauthorized drugs and NHPs are subject to compliance and enforcement actions by the Health Products and Food Branch Inspectorate.

Neither *S. divinorum* nor salvinorin A are currently regulated under the *Controlled Drugs and Substances Act* (CDSA). This is because there is not enough information available to determine whether regulation as a controlled substance is warranted. In an effort to collect more information about the use of *S. divinorum*, questions on it were included in the 2008-2009 Youth Smoking Survey, the 2009 Canadian Alcohol and Drug Use Monitoring Survey and the 2009 Ontario Student Drug Use and Health Survey (OSDUHS). The results from the 2009 OSDUHS were published on November 18, 2009 and indicate that among responding students in Ontario, 4.4% reported using *Salvia divinorum* at least once in the past year. Data from the other two surveys

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**Deleted:** Also, remember that just because a drug is plant-based or "natural," does not mean it is safe. Under certain conditions of use, *S. divinorum* meets the definition of a "natural health product" (NHP) under Health Canada's *Natural Health Products Regulations*. However, no NHPs containing this plant or Salvinorin A have been approved for sale in Canada. This means that products claiming to contain *S. divinorum* have not been reviewed by Health Canada for safety, efficacy or quality. As such, they may be counterfeit or contain other ingredients that pose risks to health. ¶

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<#>a Natural Product Number (NPN); or ¶  
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will be available later in 2010 and it is anticipated that such data will contribute to future decisions that Health Canada may make about this plant and its active ingredient. See the Need More Info? section below for more information on the surveys that are collecting information about *Salvia divinorum* use in Canada and for more detailed findings from the 2009 OSDUHS.

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### In Other Countries

Several countries have placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on their sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution (e.g., no sales to anyone under the age of 18).

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¶  
¶ *S. divinorum* is a species of sage that belongs to the mint family. It is known to have psychotropic effects, which means it affects the mind and mental processes. The leaves of this plant have been traditionally used for spiritual and medicinal purposes by the Mazatec Indians in. Traditional use involves chewing the leaves or using them to make a tea for medicinal purposes or to induce a "mystical" or hallucinogenic experience for spiritual purposes. ¶

¶  
¶ Products that claim to contain *S. divinorum* – or its main active ingredient, salvinorin A – are widely available on the Internet and are sold in various "head shops" and natural food stores. The products are sold in a number of forms, including fresh or dried leaves, liquids or seeds and plant cuttings for growing purposes. However, consumers have no way to know what these illegal products actually contain. ¶

### Health Canada's Role

Health Canada continues to collect and consider information regarding *S. divinorum* and will continue to consult with key stakeholders including health officials in other countries and law enforcement officials here at home. This will assist in determining Health Canada's future approach to decision-making regarding *S. divinorum*.

Complaints about illegal sale of drugs containing *S. divinorum* can be made to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

### Reporting Adverse Reactions

You can report any adverse reactions to the Canada Vigilance Program by one of the following three ways:

Report online at the [MedEffect™ Canada Web site](#)

Call toll-free at 1-866-234-2345

Complete a [Canada Vigilance Reporting Form](#) and either:

Fax toll-free to 1-866-678-6789

Mail to: Canada Vigilance Program  
Health Canada  
AL 0701C  
Ottawa, ON K1A 0K9

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Comment [D1]: We are doing nothing to mitigate risk other than asking people not to use it.

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Comment [D2]: This sentence appears to be out of place as there is no reference anywhere in the article to Adverse Drug Reactions. For the purpose of context, perhaps there should be an opening line saying that HC is always interested in obtaining information about incidents of adverse effects?

To have postage pre-paid, download the postage paid label from the [MedEffect™ Canada Web site](#). The [Canada Vigilance Reporting Form](#) and the adverse reaction reporting guidelines may also be obtained via this Web site.

### Need More Info?

• For information about the Government of Canada's **Anti-Drug Strategy**, go to:

[www.nationalantidrugstrategy.gc.ca/](http://www.nationalantidrugstrategy.gc.ca/)

The Prevention section on this site has a number of helpful resources for parents, including:

- **Tips on Talking to Your Teenager**, at: [www.hc-sc.gc.ca/hc-ps/pubs/adp-apd/talk-aborder/index-eng.php](http://www.hc-sc.gc.ca/hc-ps/pubs/adp-apd/talk-aborder/index-eng.php)
- **What to Do if Your Teen is Using Drugs**, at: [www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html](http://www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html)
- Information on natural health products and the *Natural Health Products Regulations* can be found at: [www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php)

For more on the surveys that are collecting information about *Salvia divinorum* use in Canada, see:

- **The 2008-2009 Youth Smoking Survey**, at: [www.yss.uwaterloo.ca/ysssite\\_app/controller/index.cfm](http://www.yss.uwaterloo.ca/ysssite_app/controller/index.cfm) and
- **The 2009 Canadian Alcohol and Drug Use Monitoring Survey**, at: [www.hc-sc.gc.ca/hl-vs/drug-drogues/cadums-escad-eng.php](http://www.hc-sc.gc.ca/hl-vs/drug-drogues/cadums-escad-eng.php)
- **The 2009 Ontario Student Drug Use and Health Survey**, at: [www.camh.net/Research/osdus.html](http://www.camh.net/Research/osdus.html)

Additional Resources:

- U.S. Drug Enforcement Administration: Drugs and Chemicals of Concern: *Salvia divinorum* and Salvinorin A at: [www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)
- U.S. Department of Health & Human Services, **National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006** at: [www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf](http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf)
- For additional articles on health and safety issues go to the *It's Your Health* Web section at: [www.healthcanada.gc.ca/iyh](http://www.healthcanada.gc.ca/iyh)

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

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Lisa Mackay: 613-954-0105 – [Lisa.Mackay@hc-sc.gc.ca](mailto:Lisa.Mackay@hc-sc.gc.ca)

Comments from: HECSB - CSTD (OCS&ODARS) & HPFB – NHPD & HPFBI

Contacts: HECSB: Jocelyn Kula, Cheryl Tremblay, Suzanne Desjardin, Denis Arseneault,  
Hanan Abaramovici  
HECSB comms: Christine Roush, Bronwyn Cline



HPFB-NHPD: Valerie Hurry, Robin Marles

HPFB-MHPD: Scott Jordan (Draft Two only), Robert Leitch, Mano Murty,  
Shahid Perwaiz

HPFBI : Collin Pinto

HPFB comms: Elizabeth Keeping, Blossom Leung

. When assessing whether to add a substance to one of the Schedules to the CDSA, Health Canada considers the following factors:

- international requirements and trends in controlling the substance;
- similarity to other substances already regulated under the CDSA;
- whether there may be legitimate uses of the substance (e.g., potential health benefits, use in manufacturing, etc.);
- the potential for abuse and the risk of addiction associated with the substance;
- the extent of actual abuse of the substance in Canada and elsewhere;
- overall risk to public health and safety posed by the substance.

In the case of *S. divinorum*, there is simply

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May 10, 2010

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### Media Lines Regulatory Control of Salvia Divinorum

#### Issue

Since 2006, Health Canada has noted ongoing media interest regarding the availability of *Salvia divinorum* in Canada. Health Canada has also received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum*, particularly given reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties.

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#### Key Messages:

- Health Canada advises Canadians not to use *S. divinorum* products because very little is known about the substance and its potential effects on the brain and/or body.
- When *S. divinorum* is manufactured, sold or represented as a hallucinogen to modify organic functions in the brain, it meets the definition of a Natural Health Product (NHP) in accordance with the Natural Health Products Regulations and the definition of a drug under the Food and Drugs Act.
- It is illegal to sell NHPs in Canada unless they have been reviewed and approved by Health Canada and labelled with a Natural Product Number (NPN) or a Drug Identification Number – Homeopathic Medicine (DIN-HM).
- Health Canada continues to collect and study information as it becomes available, and to consult with law and health officials domestically and internationally to determine the best way to manage the risks associated with the use of *Salvia divinorum* and whether it needs to be controlled under the Controlled Drugs and Substances Act.

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Deleted: Since it is used primarily for its hallucinogenic properties, *S. divinorum* products would meet the definition of a drug under the Food and Drugs Act. To date, no *S. divinorum* products have been licensed for sale in Canada. The illegal sale of these products would be subject to compliance and enforcement actions by Health Canada.

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#### Supplementary Messages:

##### On the classification of *Salvia divinorum*:

- When *S. divinorum* is manufactured, sold or represented for use in modifying organic functions in humans, and hallucinogens such as *S. divinorum*, it meets the definition of a Natural Health Product (NHP) in accordance with the Natural Health Products Regulations and the definition of a drug under the Food and Drugs Act.

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- It is illegal to sell NHPs in Canada unless they have been approved by Health Canada and assigned a Natural Product Number (NPN) or Drug Identification Number - Homeopathic Medicine. As of January 2010, no *S. divinorum* products have been approved for sale by Health Canada. The sale and distribution of unauthorized drugs and NHPs are subject to compliance and enforcement actions by the Health Products and Food Branch Inspectorate.

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- In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA).
- *Salvia divinorum* is not listed under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these conventions.
- Several countries (Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) have placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Although some individual U.S. states have implemented laws restricting its use, sale and/or distribution, *Salvia divinorum* and salvinorin A are not federally regulated under the *Controlled Substances Act* in the United States.

***If pressed on the lack of statistics on *Salvia divinorum* use in Canada:***

- Health Canada is taking steps to address this lack of data. Questions about the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey, the 2009 Canadian Alcohol and Drug Use Monitoring Survey. The results from these surveys are scheduled to be released in the Spring/Summer of 2010.
- It is anticipated that the data from these surveys will contribute to future decisions that Health Canada may make about this plant and its active ingredient.

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***If pressed regarding the results of the 2009 Ontario Student Drug Use and Health Survey:***

- The results from the 2009 Ontario Student Drug Use and Health Survey were published on November 18, 2009 and indicate that among responding students in Ontario, 4.4% reported using *Salvia divinorum* at least once in the past year. Health Canada will consider this data in its ongoing examination of *Salvia divinorum* and salvinorin A.

**Questions and Answers**

**Q1 - If Health Canada is aware of *Salvia divinorum*'s ill-effects, why isn't it illegal?**

A1 – When *S. divinorum* is manufactured, sold or represented for use as a hallucinogen it meets the definition of a drug under the *Food and Drugs Act*. No drug can be sold legally without being approved by Health Canada prior to sale in Canada; as of January 2010, no *S. divinorum* NHPs have been approved for sale. The illegal sale of NHPs containing *S. divinorum* is subject to compliance and enforcement actions by the Health Products and Food Branch Inspectorate.

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With respect to the ill effects, not enough controlled scientific studies looking into the physical and psychotropic effects of *Salvia divinorum* on humans and animals have been carried out. As such, it is difficult to predict the potential for addiction and abuse of *Salvia divinorum*. More controlled systematic research in this area is needed.

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**Q2 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?**

A2 – The *Natural Health Products Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *Salvia divinorum*.

**Q3 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A3 – *Salvia divinorum* products that are not in compliance with the *Natural Health Products Regulations* and/or are found to pose a risk to the health of Canadians may be subject to compliance and enforcement action by Health Canada. Complaints about the illegal sale of drugs containing *S. divinorum* can be referred to the Health Products and Food Branch Inspectorate at 1-800-267-9675. . ↓

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Comment [D1]: I think the term "import target" could be viewed as vague for the general public. See proposed alternate wording.

Deleted: An import target for products containing *Salvia divinorum* has already been placed with Canada Border Services Agency.

**Q4 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum* as a controlled substance. What does that involve and what stage is it at?**

A4 - Health Canada considers several factors in determining whether scheduling a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in controlling the substance;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada has only limited information on some of the above-mentioned factors, and thus there is simply not enough information available to determine whether regulation of *Salvia divinorum* under the CDSA is warranted.

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It is anticipated that the data from the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey in addition to the results from the 2009 Ontario Student Drug Use and Health Survey will help address some of the information gaps about this substance. Data from the two national surveys will be available in 2010.

**Deleted:** and contribute to future decisions that Health Canada may make about this plant and its active ingredient. The

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**Deleted:** Health Canada will continue to collect and consider information regarding *Salvia divinorum* as it becomes available.

**Q5 – Didn't an internal report from Health Canada's Marketed Health Products Directorate recommend that *Salvia divinorum* be scheduled under the CDSA? Why has that recommendation not been acted upon?**

A5 – See A4

**Q6 – What is the significance of the adverse reaction reports that Health Canada has received with respect to the use of *Salvia divinorum*?**

A6 – Health Canada has received four domestic adverse reaction reports related to the use of *Salvia divinorum* as a hallucinogen through the Canada Vigilance database. The number of reports and the nature of reactions reported are, however, not adequate to characterize the risk to the general population. These data also cannot be used to determine the incidence of use in the general population, as Health Canada does not have any information about the number of individuals using or who have used *Salvia divinorum*.

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**If pressed: Q. Has Health Canada issued any kind of warning to Canadians about the use of *Salvia divinorum*?**

A. Health Canada is developing an It's Your Health (IYH) article on *Salvia divinorum* to help inform the general public about the risks associated with the use of this substance.

### **Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

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The leaves of this plant have been used traditionally for spiritual and medicinal purposes by the Mazatec Indians in Mexico.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

While some users have reported that the psychotropic effects of *Salvia divinorum* resemble those induced by other hallucinogens, such as LSD and phencyclidine, the overall experience appears to be quite unique and generally is reported to be unpleasant.

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Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) estimated that:

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year.
- 5.4% of students (grades 7-12) ever used *S. divinorum*.
- Use of *S. divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

Data from the 2007 report on Alcohol and Other Drugs published by the Addictions Foundation of Manitoba estimated that:

- 3.7% of males vs. 2.2% of females (grades 7-12) used *S. divinorum* during that year.

Data from a 2006 National Survey on Drug Use and Health Report, published by the U.S. Substance Abuse and Mental Health Services Administration estimated that:

- 0.3% of persons aged 12 or older used *S. divinorum* in 2006.
- 0.6% of persons between the ages of 12 and 17 used *S. divinorum* in 2006.
- 1.7% of persons between the ages of 18 to 25 used *S. divinorum* in 2006.
- Young adults (18-25) were nearly three times more likely than youths aged 12-17 to have used *S. divinorum* in 2006.
- Males between the ages of 12-25 were three to four times more likely than females in the same age range to have used *S. divinorum* in 2006.

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**Deleted:** *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs. ¶

¶ While some users have reported that the psychotropic effects of *Salvia divinorum* resemble those induced by other hallucinogens, the overall experience appears to be quite unique and generally is reported to be unpleasant.

Prepared by: Cheryl Tremblay, OCS, CSTD

Input by: Lisa Mackay IYH/PACCB, Hanan Abramovici HECSB/ODARS, Jocelyn Kula, HECSB/OCS, Robin Marles HPFB/NHPD, Robert Leitch HPFB/MHPD, Collin Pinto, HPFB/HPFBI

Approved by:

[NAME] Director, Bureau of Policy and Regulatory Affairs, NHPD (pending)  
[NAME] Director, Marketed Biologics, Biotechnology and Natural Health Products Bureau, MHPD (pending)  
[NAME] Director, HPFBI (pending)  
Diane Allan, Director, OCS, CSTD, HECS (pending)  
Cathy Sabiston, DG, CSTD, HECS (pending)  
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HECS Legal (pending)  
HPFB Legal (pending)

Paul Glover, ADM, HECSB (pending)  
Meena Ballantyne, ADM, HPFB (pending)  
Anne Lamar, ADM, PACCB (pending)  
DMO (pending)  
MO (pending)

PCO (pending)



## Salvia divinorum

### Issue

Salvia divinorum (S. divinorum) is a species of sage belonging to the mint family. Some street names for S. divinorum include: Sally D, Lady Sally, Maria pastora, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff, incense special, and salvia.

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Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs.

Health Canada recommends that you avoid using this plant because very little is known about the effects it may have on your body and/or brain. There is also no way to predict how it will affect you with each use.

Comment [JK1]: We are suggesting deletion of this para as it seems to introduce a whole lot of complex ideas that are then not fully explained until later in the article.....

### Background

*S. divinorum* is known to have psychotropic effects, which means it can affect the mind and mental processes. The leaves of this plant have been used traditionally by the Mazatec Indians for medicinal purposes (chewing the leaves or using them to make a tea) and spiritual purposes (smoking the leaves to induce a "mystical" or hallucinogenic experience).

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Products that claim to contain *S. divinorum* – or its main active ingredient, salvinorin A – are widely available on the Internet and are sold in various "head shops" and natural food stores. The products are sold in a number of forms, including fresh or dried leaves, liquids or seeds and plant cuttings for growing purposes.

### Risks Associated with the Use of *Salvia divinorum*

The effects of *S. divinorum*, which vary from person to person, are often described as unpleasant and may include the following:

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- hallucinations;
- dysphoria (feeling unwell, uneasy or unhappy);
- out-of-body experiences;
- uncontrollable laughter;
- loss of consciousness;
- short-term memory loss;
- lack of physical coordination; and
- slurred speech and awkward sentence patterns.

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product;

- how much is used;
- the purity of the product (it may be mixed with other substances);
- how it is taken (e.g., chewed, swallowed or smoked);
- the user's mood and expectations.

While scientists know which brain receptors are targeted by the active ingredient, salvinorin A, very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or permanent damage;
- how it interacts with other substances, including other drugs, natural health products and alcohol.

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The potential of *S. divinorum* to produce physical dependence and/or addiction is also not known.

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### Minimizing Your Risk

Health Canada recommends that you avoid using *S. divinorum*. Just because a drug is plant-based or "natural", does not mean that it is safe.

Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs and other substances that distort reality. (See the "Need More Info?" section below for links to resources that can help you with this.)

### Legal Status of *Salvia divinorum*

#### In Canada

When *S. divinorum* is manufactured, sold or represented for use in modifying organic functions in humans, and hallucinogens work by modifying organic functions in the brain, it meets the definition of a Natural Health Product (NHP) in accordance with the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*. It is illegal to sell NHPs in Canada unless they have been reviewed and approved by Health Canada and labelled with one of the following:

- a Natural Product Number (NPN); or
- a Drug Identification Number - Homeopathic Medicine (DIN-HM).

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As of January 2010 no products containing *S. divinorum* have been approved by Health Canada. All unauthorized drugs and NHPs are subject to compliance and enforcement actions by the Department.

Neither *S. divinorum* nor salvinorin A are currently regulated under the *Controlled Drugs and Substances Act* (CDSA). This is because there is not enough information available to determine whether regulation as a controlled substance is warranted. In an effort to collect more information about the use of *S. divinorum*, questions on it were included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey (OSDUHS). The results from the 2009 OSDUHS were published in November 2009. See the Need More Info? section below for more information on the surveys that are collecting information about *Salvia divinorum* use in Canada and for more detailed findings from the 2009 OSDUHS indicate that 4.9% of responding students in Grades 7-12 have used *Salvia divinorum* at least once in the past year.

**In Other Countries**

Several countries including but not limited to Australia, Belgium, Germany, Italy, Japan, etc., have placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A.

In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on their sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution, e.g., no sales to anyone under the age of 18, etc.

**Background**

*S. divinorum* is known to have psychotropic effects, which means it affects the mind and mental processes. The leaves of this plant have been used traditionally by the Mazatec Indians for both medicinal purposes (chewing the leaves or using them to make a tea) and spiritual purposes (smoking the leaves to induce a "mystical" or hallucinogenic experience).

Products that claim to contain *S. divinorum* – or its main active ingredient, salvinorin A – are widely available on the Internet and are sold in various "head shops" and natural food stores. The products are sold in a number of forms, including fresh or dried leaves, liquids or seeds and plant cuttings for growing purposes.

**Health Canada's Role**

Health Canada continues to collect and consider information regarding *S. divinorum* and will continue to consult with key stakeholders including health officials in other countries and law enforcement officials here at home. This will assist in determining Health Canada's future approach to decision-making regarding *S. divinorum*.

Complaints about illegal sale of drugs containing *S. divinorum* can be made to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

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Comment [JK4]: This should be updated to reflect the fact that the YSS results are now released.....

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## Reporting Adverse Reactions

You can report any adverse reactions to the Canada Vigilance Program by one of the following three ways:

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Call toll-free at 1-866-234-2345

Complete a [Canada Vigilance Reporting Form](#) and either:

Fax toll-free to 1-866-678-6789

Mail to: Canada Vigilance Program  
Health Canada  
AL 0701C  
Ottawa, ON K1A 0K9

To have postage pre-paid, download the [postage paid label](#) from the [MedEffect™ Canada Web site](#). The [Canada Vigilance Reporting Form](#) and the adverse reaction reporting guidelines may also be obtained via this Web site.

## Need More Info?

- For information about the Government of Canada's **Anti-Drug Strategy**, go to:

[www.nationalantidrugstrategy.gc.ca/](http://www.nationalantidrugstrategy.gc.ca/)

The Prevention section on this site has a number of helpful resources for parents, including:

- **Tips on Talking to Your Teenager**, at: [www.hc-sc.gc.ca/hc-ps/pubs/adp-apd/talk-aborder/index-eng.php](http://www.hc-sc.gc.ca/hc-ps/pubs/adp-apd/talk-aborder/index-eng.php)

- **What to Do if Your Teen is Using Drugs**, at:

[www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html](http://www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html)

- Information on natural health products and the **Natural Health Products Regulations** can be found at: [www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php)

For more on the surveys that are collecting information about *Salvia divinorum* use in Canada, see:

- **The 2008-2009 Youth Smoking Survey**, at:

[www.yss.uwaterloo.ca/ysssite\\_app/controller/index.cfm](http://www.yss.uwaterloo.ca/ysssite_app/controller/index.cfm) and

- **The 2009 Canadian Alcohol and Drug Use Monitoring Survey**, at: [www.hc-sc.gc.ca/hl-vs/drug-droques/cadums-escad-eng.php](http://www.hc-sc.gc.ca/hl-vs/drug-droques/cadums-escad-eng.php)

- **The 2009 Ontario Student Drug Use and Health Survey**, at:

[www.camh.net/Research/osdus.html](http://www.camh.net/Research/osdus.html)

Additional Resources:

- U.S. Drug Enforcement Administration: Drugs and Chemicals of Concern: *Salvia divinorum* and Salvinorin A at: [www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)

• U.S. Department of Health & Human Services, **National Survey on Drug Use and Health:  
Use of Specific Hallucinogens: 2006** at:  
[www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf](http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf)

• For additional articles on health and safety issues go to the *It's Your Health* Web section at:  
[www.healthcanada.gc.ca/iyh](http://www.healthcanada.gc.ca/iyh)

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

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Lisa Mackay: 613-954-0105 – [Lisa.Mackay@hc-sc.gc.ca](mailto:Lisa.Mackay@hc-sc.gc.ca)

Comments from: HECSB - CSTD (OCS&ODARS) & HPFB – NHPD & HPFBI

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HPFBI : Collin Pinto  
HPFB comms: Elizabeth Keeping, Blossom Leung

**Page 3: [1] Comment [D7]**

**DARSENAU**

**2010-05-10 1:36:00 PM**

This sentence appears to be out of place as there is no reference anywhere in the article to Adverse Drug Reactions. For the purpose of context, perhaps there should be an opening line saying that HC is always interested in obtaining information about incidents of adverse effects?

DRAFT

May 26, 2010

## Media Lines Regulatory Control of *Salvia Divinorum*

### Issue

Since 2006, Health Canada has noted ongoing media interest regarding the availability of *Salvia divinorum* in Canada. Health Canada has also received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum*, particularly given reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties.

### Key Messages:

- Health Canada advises Canadians not to use products containing *S. divinorum* because very little is known about the substance and its potential effects on the brain and/or body.
- Because of its hallucinogenic properties, products containing *S. divinorum* meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*.
- It is illegal to sell NHPs in Canada unless they have been reviewed and approved by Health Canada and labelled with a Natural Product Number (NPN) or a Drug Identification Number – Homeopathic Medicine (DIN-HM). The illegal sale of products containing *S. divinorum* may be subject to compliance and enforcement action under the *Food and Drug Act*.
- Health Canada will continue to collect and study information about *S. divinorum* as it becomes available, and to consult with law enforcement and health officials domestically and internationally in order to determine the best way to manage the risks associated with its availability in Canada.

### Supplementary Messages:

*On the classification of *Salvia divinorum*:*

- When products containing *S. divinorum* are manufactured, sold or represented for use in modifying organic functions in humans (where this would include having a hallucinogenic effect), they meet the definition of a Natural Health Product (NHP) in accordance with the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*.

It is illegal to sell NHPs in Canada unless they have been approved by Health Canada and assigned a Natural Product Number (NPN) or Drug Identification Number - Homeopathic Medicine. As of January 2010, no products containing *S. divinorum* s have however been approved for sale by Health Canada.

- In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA).
- *Salvia divinorum* is not listed under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these Conventions.
- Several countries (Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) have placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Although some individual U.S. states have implemented laws restricting its use, sale and/or distribution, *Salvia divinorum* and salvinorin A are not federally regulated under the *Controlled Substances Act* in the United States.

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**Comment [JK1]:** We have edited this text but at the end of the day, the content is exceedingly repetitive with the key messages on Page 1. Accordingly, I suggest that we delete all the highlighted text and change the supp heading to read "Salvia as a Controlled Substance"

**Deleted:** has been licensed

**Deleted:** All unauthorized drugs and NHPs are subject to compliance and enforcement actions by the Health Products and Food Branch Inspectorate. ¶

***If pressed on the lack of statistics on *Salvia divinorum* use in Canada:***

- Health Canada is taking steps to address this lack of data. Questions about the use of *Salvia divinorum* were included in the 2008-2009 Youth Smoking Survey, and the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS). The results from the Youth Smoking Survey were released on May 31, 2010 and the 2009 CADUMS results are scheduled to be released in late June 2010
- It is anticipated that the data from these surveys will contribute to future decisions that Health Canada may make about how this plant and its active ingredient should be regulated.

**Deleted:** <#>As of January 2010, Health Canada had not issued any Natural Product Numbers (NPN) or Drug Identification Numbers - Homeopathic Medicine (DIN-HM) for *Salvia divinorum* products.¶

***If pressed regarding the results of the 2009 Ontario Student Drug Use and Health Survey:***



- The results from the 2009 Ontario Student Drug Use and Health Survey were published on November 18, 2009 and indicate that among responding students in Ontario, 4.4% reported using *Salvia divinorum* at least once in the past year. Health Canada will consider this data in its ongoing examination of *Salvia divinorum* and salvinorin A.

## Questions and Answers

**Q1 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why isn't it illegal?**

A1 – Because *S. divinorum* meets the definition of an NHP under the *Natural Health Product Regulations*, it is illegal to manufacture, sell or provide products containing *S. divinorum* without their being approved by Health Canada prior to sale.

With respect to adverse effects, not enough controlled scientific studies looking into the physical and psychotropic effects of *Salvia divinorum* on humans and animals have been carried out. As such, it is difficult to predict the potential for addiction and abuse associated with *Salvia divinorum*, and it is for this reason, that Health Canada is not proceeding to regulate it as a controlled substance at this point in time.

**Q2 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?**

A2 – The *Natural Health Products Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *Salvia divinorum*.

**Q3 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A3 – *Salvia divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. Complaints about the illegal sale of drugs containing *S. divinorum* can be referred to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

**Q4 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum* as a controlled substance. What does that involve and what stage is it at?**

**Comment [JK2]:** Lisa- I think NHPD should be consulted again on this one as now I understand there is something called the Raw Material Policy that may apply??

**Comment [JK3]:** Point is that if they don't meet the regs, they don't meet the regs, it is moot, whether they also pose a risk to health.....

**Deleted:** and/or are found to pose a risk to the health of Canadians

**Comment [JK4]:** I am removing the reference to import target for two reasons: 1) unless we want to get into a detailed explanation of what an import target is, it is probably best to leave the term out as most people will not understand and 2) I have actually confirmed with the Inspectorate and apparently, the import targets that were in place for *Salvia* have now expired.

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**Deleted:** An import target for products containing *Salvia divinorum* has already been placed with Canada Border Services Agency.

A4 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada has only limited information on some of the above-mentioned factors, and thus there is simply not enough information available to determine whether regulation of *Salvia divinorum* under the CDSA is warranted.

It is anticipated that the data from the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey in addition to the results from the 2009 Ontario Student Drug Use and Health Survey will help address some of the information gaps about this substance. Data from the Youth Smoking Survey has just been released and data from the 2009 edition of CADUMS will be available in late June 2010.

**Q5 – Didn't an internal report from Health Canada's Marketed Health Products Directorate recommend that *Salvia divinorum* be scheduled under the CDSA? Why has that recommendation not been acted upon?**

A5 – See A4

**Q6 – What is the significance of the adverse reaction reports that Health Canada has received with respect to the use of *Salvia divinorum*?**

A6 – Health Canada has received four domestic adverse reaction reports related to the use of *Salvia divinorum* as a hallucinogen through the Canada Vigilance database. The number of reports and the nature of reactions reported are, however, not adequate to characterize any risk of similar reactions to the general population. In particular, Health Canada does not have any information about the number of individuals in Canada using or who have used *Salvia divinorum*.

*If pressed on whether Health Canada has issued any kind of warning to Canadians about *Salvia divinorum**

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A. Health Canada is developing an It's Your Health (IYH) article on *Salvia divinorum* to help inform the general public about the risks associated with the use of this substance.

### **Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for spiritual and medicinal purposes by the Mazatec Indians in Mexico.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

While some users have reported that the psychotropic effects of *Salvia divinorum* resemble those induced by other hallucinogens, such as LSD and phencyclidine, the overall experience appears to be quite unique.

Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that:

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year.
- 5.4% of students (grades 7-12) ever used *S. divinorum*.
- Use of *S. divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

Data from the 2007 report on Alcohol and Other Drugs published by the Addictions Foundation of Manitoba indicate that:

- 3.7% of males vs. 2.2% of females (grades 7-12) used *S. divinorum* during that year.

Data from a 2006 National Survey on Drug Use and Health Report, published by the U.S. Substance Abuse and Mental Health Services Administration estimated that:

- 0.3% of persons aged 12 or older used *S. divinorum* in 2006.
- 0.6% of persons between the ages of 12 and 17 used *S. divinorum* in 2006.
- 1.7% of persons between the ages of 18 to 25 used *S. divinorum* in 2006.
- Young adults (18-25) were nearly three times more likely than youths aged 12-17 to have used *S. divinorum* in 2006.
- Males between the ages of 12-25 were three to four times more likely than females in the same age range to have used *S. divinorum* in 2006.

**Deleted:** *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs. ¶

¶ While some users have reported that the psychotropic effects of *Salvia divinorum* resemble those induced by other hallucinogens, such as LSD and phencyclidine, the overall experience appears to be quite unique and generally is reported to be unpleasant.

**Prepared by:** \_\_Cheryl Tremblay, OCS, CSTD

**Input by:** Lisa Mackay IYH/PACCB, Hanan Abramovici HECSB/ODARS, Jocelyn Kula,  
HECSB/OCS, Robin Marles HPFB/NHPD, Robert Leitch HPFB/MHPD, Collin Pinto,  
HPFB/HPFBI

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**Approved by:**

[NAME] Director, Bureau of Policy and Regulatory Affairs, NHPD (pending)  
[NAME] Director, Marketed Biologics, Biotechnology and Natural Health Products Bureau,  
MHPD (pending)  
[NAME] Director, HPFBI (pending)  
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Anne Lamar, ADM, PACCB (pending)  
DMO (pending)  
MO (pending)

PCO (pending)

DRAFT  
May 26, 2010

## Media Lines Regulatory Control of *Salvia Divinorum*

### Issue

Since 2006, Health Canada has noted ongoing media interest regarding the availability of *Salvia divinorum* in Canada. Health Canada has also received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum*, particularly given reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties.

### Key Messages:

- Health Canada advises Canadians not to use products containing *S. divinorum* and/or salvinorin A because very little is known about the substance and its potential effects on the brain and/or body, and its impact on physical and mental functions.
- Because of its hallucinogenic properties, products containing *S. divinorum* and/or salvinorin A meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*.
- It is illegal to sell NHPs in Canada unless they have been reviewed and approved by Health Canada and labelled with a Natural Product Number (NPN) or Exemption Number or a Drug Identification Number – Homeopathic Medicine (DIN-HM). The illegal sale of products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drug Act*.
- Health Canada will continue to collect and study information about *S. divinorum* as it becomes available, and to consult with law enforcement and health officials domestically and internationally in order to determine the best way to manage the risks associated with its availability in Canada.

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### Supplementary Messages:

#### *On the classification of *Salvia divinorum*:*

- When products containing *S. divinorum* and/or salvinorin A are manufactured, sold or represented for use in modifying organic functions in humans (where this would include having a hallucinogenic effect), they meet the definition of a

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Natural Health Product (NHP) in accordance with the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*.

It is illegal to sell NHPs in Canada unless they have been authorized by Health Canada and assigned a Natural Product Number (NPN) or Exemption Number or Drug Identification Number - Homeopathic Medicine. As of September 2010, no products containing *S. divinorum* and/or salvinorin A have been approved for sale by Health Canada.

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- In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA).
- *Salvia divinorum* is not listed under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these Conventions.
- Several countries (Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) have placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Although some individual U.S. states have implemented laws restricting its use, sale and/or distribution, *Salvia divinorum* and salvinorin A are not federally regulated under the *Controlled Substances Act* in the United States.

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#### ***If pressed on the lack of statistics on *Salvia divinorum* use in Canada:***

- Health Canada is taking steps to address the paucity of data. Questions about the use of *Salvia divinorum* were included in the 2008-2009 Youth Smoking Survey, and the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS). The results from the Youth Smoking Survey were released on May 31, 2010 and the 2009 CADUMS results were released on June 24, 2010.
- It is anticipated that the data from these surveys will contribute to future decisions that Health Canada may make about how this plant and its active ingredient should be regulated.

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#### ***If pressed regarding the results of the 2009 Ontario Student Drug Use and Health Survey:***

- The results from the 2009 Ontario Student Drug Use and Health Survey were published on November 18, 2009 and indicate that among responding students in Ontario, 4.4% reported using *Salvia divinorum* at least once in the past year. Health Canada will consider this data in its ongoing examination of *Salvia divinorum* and salvinorin A.

#### **Questions and Answers**

**Q1 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why isn't it illegal?**

A1 – Because *S. divinorum* meets the definition of an NHP under the *Natural Health Product Regulations*, it is illegal to manufacture, sell or provide products containing *S. divinorum* and/or salvinorin A without their being authorized by Health Canada prior to sale. With respect to adverse effects, there are insufficient controlled scientific studies looking into the physical and psychotropic effects of *Salvia divinorum* on humans. As such, it is difficult to predict the potential for addiction and abuse associated with *Salvia divinorum*. Health Canada will continue to analyze the available evidence in order to determine the most appropriate method of control of *S. divinorum*.

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**Q2 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?**

A2 – The *Natural Health Products Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *Salvia divinorum*.

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**Q4 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum* as a controlled substance. What does that involve and what stage is it at?**

A4 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

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Health Canada is continuing to analyze information related to the above-mentioned factors as it becomes available in order to determine the most appropriate mechanism of control of *S. divinorum*.

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**Q5 – Didn't an internal report from Health Canada's Marketed Health Products Directorate recommend that *Salvia divinorum* be scheduled under the CDSA? Why has that recommendation not been acted upon?**

A5 – See A4

**Q6 – What is the significance of the adverse reaction reports that Health Canada has received with respect to the use of *Salvia divinorum*?**

A6 – Health Canada has received four domestic adverse reaction reports related to the use of *Salvia divinorum* as a hallucinogen through the Canada Vigilance database. The number of reports and the nature of reactions reported are, however, not adequate to characterize any risk of similar reactions to the general population. In particular, Health Canada has limited information about the number of individuals in Canada using or who have used *Salvia divinorum*.

***If pressed on whether Health Canada has issued any kind of warning to Canadians about *Salvia divinorum*:***

A. Health Canada is developing an It's Your Health (IYH) article on *Salvia divinorum* to help inform the general public about the risks associated with the use of this substance.

### **Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

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The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

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- Use of *S. divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

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It is anticipated that the data from the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey in addition to the results from the 2009 Ontario Student Drug Use and Health Survey will help address some of the information gaps about this substance.

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**Deleted:** [what about extrapolation from the surveys cited above?] ¶

**Deleted:** While some users have reported that the psychotropic effects of *Salvia divinorum* resemble those induced by other hallucinogens, such as LSD and phencyclidine, the overall experience appears to be quite unique. [this is subjective and does not give information] ¶



Data from the 2007 report on Alcohol and Other Drugs published by the Addictions Foundation of Manitoba indicate that:

- 3.7% of males vs. 2.2% of females (grades 7-12) used *S. divinorum* during that year.

Data from a 2006 National Survey on Drug Use and Health Report, published by the U.S. Substance Abuse and Mental Health Services Administration estimated that:

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- 0.6% of persons between the ages of 12 and 17 used *S. divinorum* in 2006.
- 1.7% of persons between the ages of 18 to 25 used *S. divinorum* in 2006.
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- Males between the ages of 12-25 were three to four times more likely than females in the same age range to have used *S. divinorum* in 2006.

**Prepared by:** Cheryl Tremblay, OCS, CSTD

**Input by:** Lisa Mackay IYH/PACCB, Hanan Abramovici HECSB/ODARS, Jocelyn Kula, HECSB/OCS, Robin Marles HPFB/NHPD, Mano Murty HPFB/MHPD (31/08/10), Robert Leitch HPFB/MHPD, Collin Pinto, HPFB/HPFBI

**Approved by:**

[NAME] Director, Bureau of Policy and Regulatory Affairs, NHPD (pending)  
[NAME] Director, Marketed Biologics, Biotechnology and Natural Health Products Bureau, MHPD (pending)  
[NAME] Director, HPFBI (pending)  
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HECS Legal (pending)  
HPFB Legal (pending)  
Paul Glover, ADM, HECSB (pending)  
Meena Ballantyne, ADM, HPFB (pending)  
Anne Lamar, ADM, PACCB (pending)  
DMO (pending)  
MO (pending)

PCO (pending)

Stephanie  
Chandler/HC-SC/GC/CA  
2010-05-31 11:09 AM

To Daniel Galarneau/HC-SC/GC/CA@HWC  
cc  
bcc  
Subject Fw: Proposed changes to Salvia IAS

Hi Daniel,

Here is the latest draft of the IAS for Salvia.



Draft Salvia Divinorum IAS Jan 13 2010.doc

The email attached below includes a summary of the proposed changes, which Denis and I had discussed and he was going to look over before we presented them to Jocelyn. I've been waiting to meet with Jocelyn before actually starting on the next IAS draft.

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Policy and Regulatory Affairs Division/ Division des politiques et affaires réglementaires  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca  
----- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2010-05-31 11:04 AM -----

Stephanie  
Chandler/HC-SC/GC/CA  
2010-05-28 01:17 PM

To Denis Arsenault/HC-SC/GC/CA  
cc  
Subject Proposed changes to Salvia IAS

Hi Denis,

I've made a list of some of the main proposed changes to the IAS for Salvia that we already discussed. Let me know your thoughts.



Proposed changes to IAS for Salvia divinorum.doc

I've also prepared some initial Pros and Cons for the options we discussed. I realize Jocelyn hasn't approved the options themselves yet, but thought it might be helpful for discussion anyway...



Identification and Analysis of Options\_2.doc

Steph

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# Issue Analysis Summary

DRAFT

## Scheduling *Salvia Divinorum* and/or *Salvinorin A* under the CDSA

Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Controlled Substances and Tobacco and Directorate

January 13, 2010

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### 1. APPROVALS

This Issue Analysis Summary is approved.

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Diane Allan, Director  
Office of Controlled Substances  
Tobacco and Drugs Directorate

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[DD/MM/2009]

### 2. ISSUE

In Canada, neither the herb *Salvia divinorum* (*S. divinorum*) nor its main active ingredient, salvinorin A, are controlled under the *Controlled Drugs and Substances Act* (CDSA). Health Canada has received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *S. divinorum*, particularly given reports from scientific and media sources suggesting that *S. divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health

Canada has also noted an ongoing media interest regarding the availability of *S. divinorum* in Canada.

### 3. PURPOSE

To assess *Salvia divinorum* and/or salvinorin A against the criteria for the addition of a substance to one of the Schedules to the CDSA, in order to determine whether or not *S. divinorum*, and/or salvinorin A, should be regulated as controlled substances in Canada.

### 4. CONTEXT

*Salvia divinorum* is a species of sage which belongs to the mint family, and which is found in the form of dried leaves, extract and plant cuttings. Also known as "diviner's sage", the plant is known to induce illusions and hallucinations when chewed or smoked. Salvinorin A, the psychoactive ingredient in *S. divinorum*, which is also referred to chemically as a neoclerodane diterpene, is found primarily in the leaves, and to a lesser extent in the stems.<sup>1</sup>

*S. divinorum* is widely touted as a "legal" alternative to street drugs on the Internet, and has also been reported to be one of the most prevalently marketed herbal dietary supplements available for use as an alternative to illicit drugs of abuse among adolescents and young adults.<sup>2</sup> While very little is known about how and where *S. divinorum* is sold in Canada, it is suspected that it is mainly purchased over the Internet and/or bought at head shops, and alternative life style stores, etc.

A 2006 National Survey on Drug Use and Health Report, published in February 2008 by the Substance Abuse and Mental Health Administration in the United States, also estimated that:

- 1.8 million persons aged 12 or older used *Salvia divinorum* in their lifetime, with approximately 750,000 having done so in the past year;
- Use was more common among young adults (18 to 25 years old) as opposed to older adults (> 26 years of age);
- Young adults were nearly three times more likely than youths, aged 12 to 17, to have used *Salvia divinorum* in the past year; and
- Use was more common in males than in females.

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1 U.S. Department of Justice Drug Enforcement Administration. 2002. Drugs and Chemicals of Concern: Salvia Divinorum (salvinorin A, divinorin A) URL:

[http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm) Nov 2008

2 Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.

The use of *S. divinorum* as a psychotropic agent first came to Health Canada's attention in 2002. In 2004, Health Canada received four adverse drug reaction (ADR) reports associated with the use of *S. divinorum* as a hallucinogen, with three being considered non-serious (requiring no medical attention) and the fourth being considered serious (medical intervention was required) and involving the concomitant use of alcohol in a person diagnosed with Attention Deficit Disorder.

Further to the receipt of the aforementioned ADRs, the Marketed Health Products Directorate (MHPD) and the Natural Health Products Directorate (NHPD), of the Health Products and Food Branch (HPFB), prepared an issue analysis summary (IAS), which recommended that *S. divinorum* and its active ingredient salvinorin A be regulated as a controlled substance (a recommendation that was maintained when the IAS was updated in November 2006).

Later, in December 2005, MHPD and NHPD prepared a Signal Assessment (SA) (updated in June, 2007) that eventually led to the preparation of a Health Risk Assessment (HRA), which concluded that *S. divinorum* or salvinorin A-containing health products should be restricted from over-the-counter use. Should any such (unauthorized) health products be found on the Canadian market, they should be removed from sale. Such products would constitute a Type II Health Risk, defined as "A situation in which there is a reasonable probability that the use of, or exposure to, a product, will cause moderate or mild adverse health consequences.

Further to an ADM discussion in April 2007, DSCSD organized a meeting with MHPD, NHPD and the Inspectorate of HPFB (HPFBI) on May 16, 2007 to discuss *S. divinorum*. At that time, it was decided that *S. divinorum* would be classified by HPFB as a Type II substance. MHPD was to send the HRA and SA to DCSCD, look into preparing an adverse reaction case presentation in the ADR Newsletter, and explore the possibility of developing a product advisory. HPFBI was to determine compliance activities based on the HRA Type II classification and check with Canada Border Services Agency (CBSA) to determine if any further information regarding *S. divinorum* shipments was available. The Office of Research and Surveillance, DSCSD was to continue to work on the *S. divinorum* Fact Sheet and explore the feasibility of a health food/natural food store survey on *S. divinorum*. OCS was to gather information from Australia regarding its scheduling decision and to find out whether the DEA had any plans to schedule *S. divinorum* in the near future.

On September 13, 2007, a meeting was organized between DSCSD, MHDP, NHPD and HPFBI to discuss what is known about *S. divinorum* from a regulatory perspective and to reach consensus on next steps.

The following action items came out of this meeting:

- (1) DSCSD to submit a response to the MHPD/NHPD analytical documents and MHPD/NHPD to make changes accordingly;
- (2) DSCSD to finalize the latest version of the media lines on *S. divinorum* and put them forward, via Communications, for approval in HPFB;
- (3) DSCSD to find out the status of draft fact sheet that was being developed by its Office

of Research and Surveillance;

(4) HPFBI to discuss the potential allocation of additional resources, e.g., additional inspectors, etc. to the *S. divinatorum* file; and

(5) DSCSD to explore the notion of scheduling, i.e., carry out a preliminary scheduling assessment, as part of a mid to long-term action plan.

The Director Generals of DSCSD, MHPD, TPD and the HPFBI also met on September 26, 2008 to discuss an update on issues relating to *S. divinatorum* and to determine an agreed upon approach for subsequent steps.

The following action items came out of that meeting:

(1) Review and provide comments on *S. divinatorum* IAS and SA and revise and re-issue IAS and SA, as needed;

(2) circulate draft Fact Sheet for comment and explore the possibility of developing a public-friendly communication;

(3) prepare draft media lines for *S. divinatorum* and circulate for comment;

(4) contact DAS labs for any information on *S. divinatorum*;

(5) prepare project charter for *S. divinatorum* working group;

(6) contact Public Health Agency Canada (PHAC) for representation;

(7) continue work on scheduling assessment for *S. divinatorum*; and

(8) continue sharing information relating to *S. divinatorum* as it arises.

#### **4.1 Legislative Frameworks for Drug Control in Canada**

##### **4.1.1 Food and Drug Regulations**

The *Food and Drug Regulations* (F&DR) serve to ensure the safety, efficacy, and quality of health products offered for sale in Canada, including drugs and medical devices. Prior to being given market authorization, a manufacturer must present substantive scientific evidence of a product's safety, efficacy and quality and Health Canada reviews this information carefully. If the review is satisfactory, a Notice of Compliance (NOC) is issued and appropriate Drug Identification Numbers (DINs) are assigned.

A "drug" is defined under the F&DR as any substance or mixture of substances manufactured, sold or represented for use in

(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,

(b) restoring, correcting or modifying organic functions in human beings or animals, or

(c) disinfection in premises in which food is manufactured, prepared or kept;

##### **4.1.2 Natural Health Product Regulations**

The *Natural Health Products Regulations* (NHPR) came into force in January, 2004 to provide Canadians with ready access to natural health products (NHPs) that are safe, effective, and of high quality, while respecting freedom of choice and philosophical and cultural diversity. The NHPR contain a product licensing system that requires that all licensed products display a product identification number preceded by the prefix NPN, or, in the case of a homeopathic medicine, by the letters DIN-HM on their labels. The number is issued once a product is authorized for sale in Canada by the Natural Health Products Directorate. Product authorization requires either reference to a *natural health product monograph* or submission of other evidence of safety and health claim. A system of site licensing is also included in the NHPR which requires that all manufacturers, packagers, labellers, and importers be licensed; sites have procedures in place respecting distribution records and product recalls; where applicable, sites have procedures in place for the handling, storage and delivery of their products, and sites meet good manufacturing practice requirements.

The definition of an NHP under the NHPR has both a function and substance component. The function component refers to those substances that are manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
- (b) restoring or correcting organic functions in humans; or
- (c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

The substance component refers to whether the product or medicinal ingredient therein, is safe for consideration as an over-the-counter product, can be available for self-care and self-selection, and does not require a prescription to be sold.

#### **4.1.3 Controlled Drugs and Substances Act and its Regulations**

The CDSA provides a legislative framework for the control of substances that can alter mental processes and that may produce harm to the health of an individual or to society when diverted or misused. Except as authorized under its regulations, activities such as possession, possession for the purposes of trafficking, trafficking, importation, exportation, possession for the purposes of exportation and production of controlled substances are prohibited under the CDSA.

The substances regulated under the CDSA are grouped into eight Schedules, and each Schedule is associated with particular penalties as described in Part I of the CDSA.

In determining whether a substance should be regulated as a controlled substance, and into which Schedule to the CDSA is should be placed, Health Canada considers the following factors:



- International requirements and trends in control/scheduling;
- Chemical and pharmacological similarity to other substances already scheduled under the CDSA;
- Legitimate uses of the substance (i.e. therapeutic, industrial or commercial);
- Potential for abuse and/or addiction liability of the substance;
- Extent of actual abuse in Canada and internationally; and
- Overall risk to public health and safety of Canadians.

## 4.2 Assessment of *Salvia Divinorum* for Scheduling Purposes

### 4.2.1 International Requirements and Trends in Control/Scheduling

At the present time, neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and therefore do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these conventions.

#### ***Australia***

In June, 2002, Australia became the first country to prohibit *S. divinorum* and salvinorin A. Although both *S. divinorum* and salvinorin A are listed on Schedule 9 of Australia's Standard for the Uniform Scheduling of Drugs and Poisons on the basis of "high potential for abuse and risk to public health and safety", no substantiation of this risk was provided at the time of this scheduling decision. Schedule 9 is Australia's most restrictive drug schedule, and includes "substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities."<sup>3</sup>

#### ***Belgium***

A decree was passed in Belgium on October 22, 2006 which added *S. divinorum* to the list of controlled substances.

#### ***Denmark***

Shortly after, in 2003, Denmark prohibited *S. divinorum* and salvinorin A by adding them to their list of "category B" controlled substances, a category which also includes psilocybin mushrooms, cocaine, amphetamine, and several others substances that are only legal for medicinal and scientific purposes. Illegal possession carries a penalty of up to two years in prison.

#### ***Germany***

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<sup>3</sup> [http://www.cognitiveliberty.org/news/salvia\\_australia.htm](http://www.cognitiveliberty.org/news/salvia_australia.htm)

*S. divinorum* (plant and plant parts) was added to Appendix I of the *Narcotics Act* in Germany on March 1, 2008, making it illegal to produce, traffic, or possess. The law does not specifically mention salvinorin A.

### ***Italy***

On June 25, 2004, the Italian Ministry of Health issued an ordinance prohibiting the sale of *S. divinorum*, and its active constituent salvinorin A. On January 11, 2005, the Ministry of Health made possession of *S. divinorum* and salvinorin A illegal by placing them in "Tabella 1" of the *Tabella Sostanze Stupefacenti o Psicotrope*.

### ***Japan***

On November 9, 2006, the Japanese government added a group of thirty-three drugs to its list of controlled substances, including salvinorin A. The drugs will be banned under a revised pharmaceutical law, under which persons involved in their illegal import, production, and sale i.e., that beyond medical treatment or research purposes, will be subject to up to five years imprisonment or to a fine of up to five million yen.

### ***Spain***

On January 28, 2004 the Spanish Ministry of Health and Consumption issued an order prohibiting the sale of *S. divinorum*, along with a long list of other alleged "toxic" herbs. The regulation went into effect on May 6, 2004 and only prohibits activities related to commerce. Possession and/or use are not considered to be criminal offences.

In Estonia, Finland, Iceland and Norway *S. divinorum* is treated as a medicinal herb and it is illegal to import it without a relevant prescription from a doctor.

### ***United States of America***

*S. divinorum* and salvinorin A are not included in the Schedules to the United States *Controlled Substances Act*, although some individual states have implemented laws restricting its use, sale and/or distribution. As of October 2009, fourteen states have enacted legislation placing regulatory controls on *S. divinorum* and/or salvinorin A. Delaware, Florida, Illinois, Kansas, Nebraska, North Dakota, Ohio, Oklahoma, and Virginia have placed *S. divinorum* and/or salvinorin A into Schedule I of state law.

California, Louisiana, Maine, North Carolina and Tennessee have enacted other forms of legislation restricting the distribution of the plant. Legislative bills proposing regulatory controls died in Alabama, Alaska, Georgia, Indiana, Maryland, South Carolina, Texas and West Virginia.

### ***California***

For example, effective January 1, 2009, the sale or distribution of *S. divinorum* or salvinorin A, or any substance or material containing *S. divinorum* or salvinorin A, to any person under 18 years of age became a misdemeanor in the state of California that is now punishable by imprisonment in a county jail for not more than six months, by a fine of no more than \$1,000, or both.

### ***Louisiana***

In 2005, Louisiana passed a bill which prohibits the possession, production, manufacture and distribution of a material, compound, mixture, or preparation intended for human consumption which contains a hallucinogenic plant. A "hallucinogenic plant" is defined as "any part or portion" of the forty plants listed, which includes *S. divinorum*.

### ***Maine***

In Maine, *S. divinorum* and salvinorin A are regulated similar to how tobacco products are controlled. Adults eighteen years of age or over can legally purchase and use the material, but selling or providing *S. divinorum* or salvinorin A to anyone under the age of eighteen is a criminal offence. Possession by a minor is a civil violation, punishable by a fine, community service, or both.

### ***North Carolina***

On February 11, 2009, Senate Bill 138 was introduced to the North Carolina State Legislature which sought to make *Salvia divinorum* and salvinorin A Schedule I controlled substances in that state. This bill was later amended to make possession of *S. divinorum* an infraction, a minor crime punishable by a maximum \$25 fine. A third possession offence would be charged as a misdemeanor. There are no separate penalties for manufacturing or sales. This bill includes two exemptions. One permits growing the plant for aesthetic, landscaping, or decorative purposes; the other allows for university-affiliated medical or pharmacological research. The amended version passed the Senate unanimously on May 14, 2009, the House approved it on August 5, 2009 and it was signed into law on August 28, 2009. The new law came into effect on December 1, 2009.

### ***Tennessee***

On July 1, 2006, Tennessee classified the deliberate production, manufacture, distribution, or possession of the active chemical ingredient in the hallucinogenic plant *S. divinorum* as a Class A misdemeanor. It is not however a criminal offence to possess, plant, cultivate, grow, or harvest *S. divinorum* for aesthetic, landscaping, or decorative purposes. The law also does not apply to any dosage that is legally obtainable from a

retail establishment without a prescription when it is recognized by the FDA as a homeopathic drug.

In addition, the U.S. Department of Justice Drug Enforcement Agency (DEA) has also placed *S. divinorum* and salvinorin A on a list of drugs and chemicals “of concern,” without legal implication.

#### 4.2.2 Chemical and Pharmacological Similarity to Other Substances Listed in the CDSA

The psychoactive ingredient in *Salvia divinorum* is salvinorin A. Other plants which contain psychotropic terpenoids are *Artemisia absinthium* (wormwood) and *Cannabis sativa*. Salvinorin A is considered by some as the most potent natural hallucinogen ever isolated.<sup>4</sup>

Unlike all other hallucinogens, salvinorin A is structurally distinct and does not interact with the serotonin-2A receptor or any other molecular target of classical hallucinogens. It thus affects the brain in a way that is quite unique.<sup>5</sup> Recent pharmacological screenings of receptors have found it to be a highly potent and selective  $\kappa$ -opioid receptor (KOR) agonist.<sup>6</sup>

The psychomimetic effects of *S. divinorum* closely resemble schizophrenia symptoms induced by LSD or PCP.<sup>7</sup> Yet, it is said to have only weak influence on the prevailing mood of the user which differentiates it from other hallucinogens such as LSD and psilocybin.<sup>8</sup> Its strong dissociative effects are often compared to those of ketamine. Users have reported that the psychedelic effects of *S. divinorum* were most similar to those caused by psilocybin mushrooms.<sup>9</sup> However, users familiar with the effects of other hallucinogens agree that despite certain similarities to classical hallucinogens, the visions and overall experience is quite unique.<sup>10</sup> In addition, while the psychedelic effects of *S. divinorum* are similar to those of classical psychedelics regarding changes in perception and somatic sensations. *S. divinorum* causes an

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<sup>4</sup> Ott J. Ethnopharmacognosy and human pharmacology of *Salvia divinorum* and salvinorin A. *Curare*. 1995 18: 103-129. Unofficial transcription available online. URL <http://www.sagewisdom.org/ott2.html>

<sup>5</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>6</sup> Roth BL, Baner K, Westkaemper R, Siebert D, Rice KC, Steinberg S, Ernsberger P, Rothman RB. Salvinorin A: a potent naturally occurring nonnitrogenous kappa opioid selective agonist. *Proc Natl Acad Sci U S A*. 2002 Sep 3;99(18):11934-9.

<sup>7</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>8</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>9</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>10</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6 and González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

unusually high degree of sedation, weakness and fatigue, while the increased de-realization is not commonly reported for classical psychedelics.<sup>11</sup> The combination of these effects seems to correlate with that of other KOR agonists such as pentazocine.<sup>12</sup>

#### 4.2.3 Legitimate Uses of Salvia *Divinorum*

There are no legitimate medical or industrial uses for *S. divinorum* in Canada.

Although selective kappa receptor agonists have been shown to produce analgesic effects, adverse effects such as psychotomimesis, dysphoria and diuresis have been observed in studies investigating their therapeutic use.<sup>13</sup>

*Salvia divinorum* has traditionally been used for spiritual and medicinal purposes by the Mazatec Indians in Oaxaca, Mexico,<sup>14</sup> where an infusion of the leaves or ingestion of the leaves is used to treat gastrointestinal problems, headaches, rheumatism, anemia and swelling of the stomach.<sup>15</sup> Its main use is however for its psychoactive properties in the aid of producing “mystical” or hallucinogenic experiences as part of spiritual rituals.<sup>16</sup>

#### 4.2.4 Potential for Abuse Liability and/or Addiction Liability of the Substance

Most clinically used opioid analgesics (e.g. codeine, oxycodone, morphine) are selective for the  $\mu$ -opioid receptor (MOR) and can be habit-forming<sup>17</sup> because activation of the MORs causes euphoria, which makes the user want to take them. As previously mentioned, salvinorin A is a potent, selective agonist of the  $\kappa$ -opioid receptor (KOR), and in contrast to the euphoria produced by MOR agonists, the KOR agonists are negatively reinforcing and aversive.<sup>18</sup> In addition, KOR

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<sup>11</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>12</sup> Arasteh K, Poudevida S, Farre M, Roset PN, Cami J. Response patterns of the Spanish version of the 49-item short form of the Addiction Research Center Inventory after the use of sedatives, stimulants, and opioids. Drug Alcohol Depend. 1999 Jun 1;55(1-2):117-25.

<sup>13</sup> Barker RL, Fawcett J, Barkin SJ. 2002. Chronic pain management with a focus on the role of newer antidepressants and centrally acting agents. In: Pain Management: A Practical Guide for Clinicians, 6th edition, Weiner RS ed. CRC Press, Boca Raton, FL. pp. 415-34 and **Error! Main Document Only.** Tidgewell et al., 2004. A facile method for the preparation of deuterium labelled salvinorin A: Biorganic & Medicinal Chemistry Letters, 14: 5099-5102.

<sup>14</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>15</sup> Munro, T. The Chemistry of Salvia divinorum. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

<sup>16</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage Salvia divinorum. Life Sci. 2005 Dec 22;78(5):527-31.

<sup>17</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.

<sup>18</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590, Cooper S. Interactions between endogenous opioids and dopamine: Implications for reward and aversion. In:

agonists have analgesic properties but are not associated with respiratory depression like MOR agonists. Initially, these effects provided hope for the development of an analgesic absent of addiction liability and respiratory depression, however, it was soon discovered that KOR agonists produced dysphoria and psychomimetic effects such as confusion, hallucinations and depersonalization.<sup>19</sup> Finally, while MOR increases the release of dopamine, the activation of KOR decreases dopamine release in the nucleus accumbens.<sup>20</sup>

The onset and intensity of the effects of *Salvia divinorum* appear to be related to the route of administration by which it is taken. Traditional uses generally produce mild effects because the leaves are rolled and chewed or crushed and prepared as a foamy infusion whereby the salvinorin A is degraded in the gastrointestinal system before being absorbed into the bloodstream. These methods rely on contact with the oral mucosa for absorption and the level of effect relates quite closely to the length of time the material spends in the mouth. Onset of effect generally takes 5-10 minutes which build over the next hour and last for another hour before the effects begin to subside.<sup>21</sup>

Routes that avoid the hepatic first-pass effect are the quickest and most intense.<sup>22</sup> Salvinorin A can be isolated from the plant to make a powder which can be vaporized and inhaled. This method of administration is the most powerful and only requires 200-500µg of salvinorin A powder to produce the same effects as those of fresh leaves. The onset of effect felt from vaporizing salvinorin A powder is about 30 seconds and effects last for about 5-10 minutes and subside over the next 30 minutes.<sup>23</sup>

Smoking is by far the most popular method of administration<sup>24</sup> and this is accomplished by smoking the dried leaves or a concentrated extract using a pipe or bong. Dried leaves may also be fortified with a concentrated extract of salvinorin A and/or a concentrated extract can also be

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*The Mesolimbic Dopamine System: From Motivation to Action.* Willner P and Scheel-Kruger J (editors) Wiley, Chester, England, 1991, pp. 331-366, and Shippenberg TS, Herz A, Spanagel R, Bals-Kubik R, Stein C. Conditioning of opioid reinforcement: neuroanatomical and neurochemical substrates. *Ann N Y Acad Sci.* 1992 Jun 28;654:347-56.

<sup>19</sup> Pfeiffer A, Brantl V, Herz A, Emrich HM. Psychotomimesis mediated by kappa opiate receptors. *Science.* 1986 Aug 15;233(4765):774-6, Rimoy GH, Wright DM, Bhaskar NK, Rubin PC. The cardiovascular and central nervous system effects in the human of U-62066E. A selective opioid receptor agonist. *Eur J Clin Pharmacol.* 1994;46(3):203-7, and Walsh SL, Strain EC, Abreu ME, Bigelow GE. Enadoline, a selective kappa opioid agonist: comparison with butorphanol and hydromorphone in humans. *Psychopharmacology (Berl).* 2001 Sep;157(2):151-62.

<sup>20</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.

<sup>21</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>22</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.

<sup>23</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>24</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62 and Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

used sublingually. *S. divinorum* nor salvinorin A are not injected because the powder is insoluble in water.<sup>25</sup>

Although the various modes of administration lead to variable onset and duration of the effects, the effects of *S. divinorum* are generally accepted to be: becoming objects, visions of various two-dimensional surfaces, films and membranes, revisiting places of the past (particularly childhood), loss of the body and/or identity, various sensations of motion (being pulled or twisted by a force of some kind), uncontrollable hysterical laughter, and overlapping realities (perceptions of being in more than one place).<sup>26</sup> Laughter, happiness, sense of well-being and dissociative effects were deemed the best aspects of *S. divinorum* by users, second only to the "trip" that the drug elicits.<sup>27</sup> Depersonalization, speaking gibberish, widening of consciousness, subjective illusions of rapid movement, flying or hovering however have also been reported.<sup>28</sup>

The aversive effects of previously studied KOR agonists would predict that the risk of addiction to *S. divinorum* is negligible, however, very few controlled scientific studies of the physical and psychotropic effects of *Salvia divinorum* on humans have been carried out and, therefore, using these studies to predict its potential for addiction and abuse is difficult. In addition, in the studies that have been conducted, there is conflicting information around the addiction liability of *S. divinorum* in both animals and humans. More controlled systematic research in this area is needed. Further studies on the mediated decrease of dopamine as well as the impact of dose on the reward and aversive effects are also warranted.

Another aspect of *S. divinorum*'s abuse potential stems from its availability. As previously mentioned it is widely available for purchase on the Internet through drug promotional sites and is also sold in various "head shops" and corner stores. In addition, the potential for high yields and ease of extraction may make buying and selling the drug quite affordable and attractive. Originally the concerns for the abuse potential were minimal since it was concluded that 1 kg of dried leaves yielded only 3 to 6 human doses of salvinorin A. However, it was discovered that vaporizing and inhaling 200-500 µg had profound hallucinogenic effects.<sup>29</sup> The extraction of salvinorin A from the plant is very easy and with care, approximately 1.5 grams of pure salvinorin A per kilogram of dried leaves (8kg of fresh leaves) can be isolated. Therefore, even poor yields of a gram per kilograms of dried leaves would provide a dose for 2000 human

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<sup>25</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs*. 1994 Jul-Sep;26(3):277-83.

<sup>26</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>27</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>28</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5 and Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>29</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

doses.<sup>30</sup> This easy isolation makes buying the drug quite affordable. *S. divinorum* leaves sell for \$0.50-7 per gram, plants for \$20-45 and the liquid extract for \$4-10 per millilitre.<sup>31</sup>

#### 4.2.5 Extent of Actual Abuse in Canada and Internationally

Very limited data exists regarding the actual population use of *Salvia divinorum* across the Canadian population. To address this lack of data, questions about the use of *S. divinorum* were included in the 2008-2009 Youth Smoking Survey, the 2009 Canadian Alcohol and Drug Use Monitoring Survey and the 2009 Ontario Student Drug Use and Health Survey.

The results from the 2009 Ontario Student Drug Use and Health Survey were published on November 18, 2009 and indicate that:

- Among all responding students in Ontario, 4.4% report using *Salvia divinorum* at least once in the past year;
- Males (6.2%) are significantly more likely than females (2.3%) to use *Salvia divinorum*;
- There is significant grade variation, with *Salvia divinorum* use most likely among 11<sup>th</sup> graders (8.6%) and 12<sup>th</sup> graders (8.4%); and
- There are significant regional variations, with students in the North (9.2%) most likely to use *Salvia divinorum*.

Further data from the two national surveys, i.e., the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey, will be available in 2010.

As far as law enforcement is concerned, the Department has only received a limited number of communications indicating concern with respect to *S. divinorum* and none of these have advised that the use of *S. divinorum* poses any threat to public safety.

Health Canada's Drug Analysis Services (DAS) has collected some raw data regarding the number of samples identified as containing salvinorin A in the DAS labs, however, as the plant and/or substance is not in the CDSO druglist, it is not possible to have records of any seizures of it in the database.

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<sup>30</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs*. 1994 Jul-Sep;26(3):277-83.

<sup>31</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.



**NUMBER OF SAMPLES FOUND TO CONTAIN SALVINORIN A**

Year Return Completed	Count
2006	6
2007	8
2008	6
2009	To be updated

In addition, the National Forensic Laboratory Information System (NFLIS) and the System to Retrieve Information from Drug Evidence (STRIDE) in the United States is a Drug Enforcement Agency (DEA) database that collects scientifically verified data on analyzed samples in state and local forensic labs. It also includes data from STRIDE, which are analyzed samples from DEA labs. The following table shows *Salvia divinorum* items seized from 2000 through 2008.

**ANALYZED SALVIA DIVINORUM or SALVINORIN A SEIZURES**

(Number of items/Exhibits)

Source	2000	2001	2002	2003	2004	2005	2006	2007	2008*
NFLIS-State/Local <sup>1</sup>	0	0	0	0	1	8	12	12	32
STRIDE <sup>2</sup>	0	0	1	1	1	0	0	0	0
<b>TOTAL</b>	0	0	1	1	2	8	12	12	32

Data Source: NFLIS & STRIDE, 2008 data queried 11/24/2008

<sup>1</sup> NFLIS reported items of salvinorin A

<sup>2</sup> STRIDE reported items of *Salvia divinorum*.

\* Includes only January – September data in 2008.

Two reports regarding the abuse of *S. divinorum* have been published in the academic literature. The first was an international case report in which a young man (19 years of age) described his perceptions after inhaling the smoke from *S. divinorum*. The peak psychotropic effects, including prickling of the skin, fever-like hot flashes, muscular tremor, and depersonalization, were reached in less than five minutes after inhalation of an unknown amount of dried leaves.<sup>32</sup> The second case involved a 15-year-old male who presented to psychiatric emergency services with acute onset of paranoia, déjà vu, blunted affect, thought blocking and slowed speech, after smoking *Salvia divinorum* over an unknown period of time. During his hospitalization all symptoms improved significantly except the feeling of déjà vu. Based on this case presentation, the author suggested that the feelings of déjà vu may be considered long-term effects of *Salvia* use.<sup>33</sup> However, given that this is the only case report in which déjà vu was associated with the use of *S. divinorum*, more reports are needed to substantiate this finding.

In addition to the above-mentioned case reports, in 2006, a case was reported in the U.S. in which a 17-year-old boy committed suicide after smoking *S. divinorum* for unknown period

<sup>32</sup> **Error! Main Document Only.** Bucheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>33</sup> **Error! Main Document Only.** Singh S. (2007) Adolescent salvia substance abuse. *Addiction*. 102, 823-824.

of time.<sup>34</sup> It should be noted that alcohol and general depression were the main confounders in this case. This case did, however, result in the state of Delaware passing a law outlawing *S. divinorum*, and classifying it as a Schedule I controlled substance with other hallucinogenic substances.

It is difficult to determine the extent of actual abuse of *S. divinorum* as there appear to be inconsistencies in the literature regarding risk aversion. For example, one author states: "Many who have used salvinorin A find the experience extremely unnerving, frightening and overly intense and most have no desire to repeat the experience."<sup>35</sup>, however, this aversion to the drug is not an effect being echoed in other studies and reports.<sup>36</sup> Moreover, over eighty percent of users surveyed on a web-based questionnaire about their *S. divinorum* use said they would probably or definitely use *S. divinorum* again.<sup>37</sup> Therefore, despite the fact that users have reported the negative effects of *S. divinorum* as: the short duration of action, lack of control over the experience, persisting negative effects (most often anxiety)<sup>38</sup> sweating, chills, increased diuresis, impaired vigilance,<sup>39</sup> and negative after-effects including tiredness, feeling head heavy, dizziness, physical exhaustion, and some degree of malaise or 'hangover' as they 'comedown' from the drug,<sup>40</sup> it is difficult to determine the influence these effects have on the use of *S. divinorum*.

#### 4.2.6 Overall Risk to Public Health and Safety of Canadians

The increase in the number of enquiries from various municipalities and members of the public and in the amount of media interest regarding the availability of *Salvia divinorum* in Canada may be an indication that the recreational use of *S. divinorum* as a hallucinogen may be on the rise in Canada. It is, however, premature to make this assumption as Health Canada presently does not have any viable statistics on the actual population use of *S. divinorum* across the Canadian population.

The potential for harm to the user and/or other individuals may be increased as users may get up and walk around without apparent awareness of their movements, behaviour or surroundings, distinction between self and surroundings is lost, and at doses greater than 1mg of salvinorin A,

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<sup>34</sup> <http://www.kvbc.com/Global/story.asp?S=4893692>

<sup>35</sup> Turner DM. Salvinorin - The Psychedelic Essence of Salvia Divinorum. Panther Press, San Francisco, CA 1996.

<sup>36</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62, Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5, and Valdès LJ 3rd. Salvia divinorum and the unique diterpene hallucinogen, Salvinorin (divinorin) A. J Psychoactive Drugs. 1994 Jul-Sep;26(3):277-83.

<sup>37</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>38</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>39</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5.

<sup>40</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

out of body experiences are frequent and loss of consciousness has been reported.<sup>41</sup>

As stated earlier, there are no approved medical uses for *S. divinorum* in Canada. Health Canada has also not received nor approved any submissions for natural health products for sale in Canada. Therefore, products that claim to contain this substance have not been extensively reviewed by Health Canada and as such, may be counterfeit or may contain other ingredients that may pose risks to health. For example, like all drugs of abuse, the users are often unaware of the potency and adulterants in the products they are purchasing. A study by Wolowich *et al.* (2006)<sup>42</sup>, showed that the salvinorin A content in five out of five *S. divinorum* products were falsely indicated on the label and 4 out of 5 products contained unidentified adulterants (i.e. vitamin E, caffeine).

Health Canada has only anecdotal information about the use of *S. divinorum* in Canada and the risk of abuse and/or risk that *S. divinorum* poses to the health and safety of Canadians. Although reports of domestic adverse reactions related to the use of *S. divinorum* as a hallucinogen have been received through the Canada Vigilance database, it is important to note that the number of reports and the nature of reactions reported are not adequate to characterize the risk to the general population. These data cannot be used to determine incidence of use in the general population, as Health Canada does not have any information about the number of individuals using or who have used *S. divinorum*.

**s.21(1)(a)**

**5. ASSESSMENT OF RISKS AND BENEFITS (OPTIONAL)**

**s.21(1)(b)**

<sup>41</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>42</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five Salvia divinorum herbal products. Pharmacotherapy. 2006 Sep;26(9):1268-72.

**Page(s) 000774 to\à 000777**

**Is(Are) exempted pursuant to section(s)  
est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**

## 7. CONSIDERATIONS

*S. divinorum*'s KOR-mediated aversive and dysphoric effects do not appear to be hampering its use. Young adults have begun smoking the leaves and leaf extract recreationally.<sup>46</sup> It can be purchased through online botanical companies and other drug promotional sites and is often touted as a legal alternative to substances such as cannabis and mescaline.<sup>47</sup> Interestingly though, after being widely available for over a decade, the drug has not had any extreme social impact as did LSD or MDMA.<sup>48</sup>

The following points should be considered:

- Over the past few years, there has been an increase in the number of enquiries that Health Canada is receiving from various municipalities and members of the public regarding the availability of *Salvia divinorum* as a hallucinogen.

<sup>46</sup> Hazelden Foundation, 2004. Drug Abuse Trends. June 2004. URL: [www.research.hazelden.org](http://www.research.hazelden.org).

<sup>47</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

<sup>48</sup> Munro, T. The Chemistry of *Salvia divinorum*. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

- Health Canada has also observed a steady increase in the amount of media interest regarding the availability of *S. divinorum* in Canada.

*Salvia divinorum* meets the definition of a natural health product (NHP) under the *Natural Health Product Regulations* (NHPR). This means that products containing *S. divinorum* must be approved by Health Canada prior to sale in Canada and that product's that are not in compliance with the NHPR may be subject to compliance and enforcement actions. As Health Canada has yet to receive and/or approve any applications for natural health products containing *S. divinorum* for sale on the Canadian market, it is difficult to ascertain how much *S. divinorum* is currently sold or consumed in Canada at the present time. Several challenges also arise with respect to the importation and domestic movement of such products as they are often declared as incense and therefore cannot be considered non-market natural health products. In addition, compliance and enforcement actions, such as voluntary stop-sales, forfeiture, destruction, and administrative seizure, cannot be implemented unless the labeling clearly indicates that the product is to be used for consumption and/or pharmacological effects (ie. statements regarding contraindications or restrictions on use) upon which the product will no longer meet the definition of a consumer product (i.e. incense) and will meet the definition of a NHP. The NHPR are therefore limited in their capacity to control the availability of *S. divinorum* beyond the scope of scenarios listed above.

- It is also hard to know because we have no way of tracking or counting

## 8. RECOMMENDATION

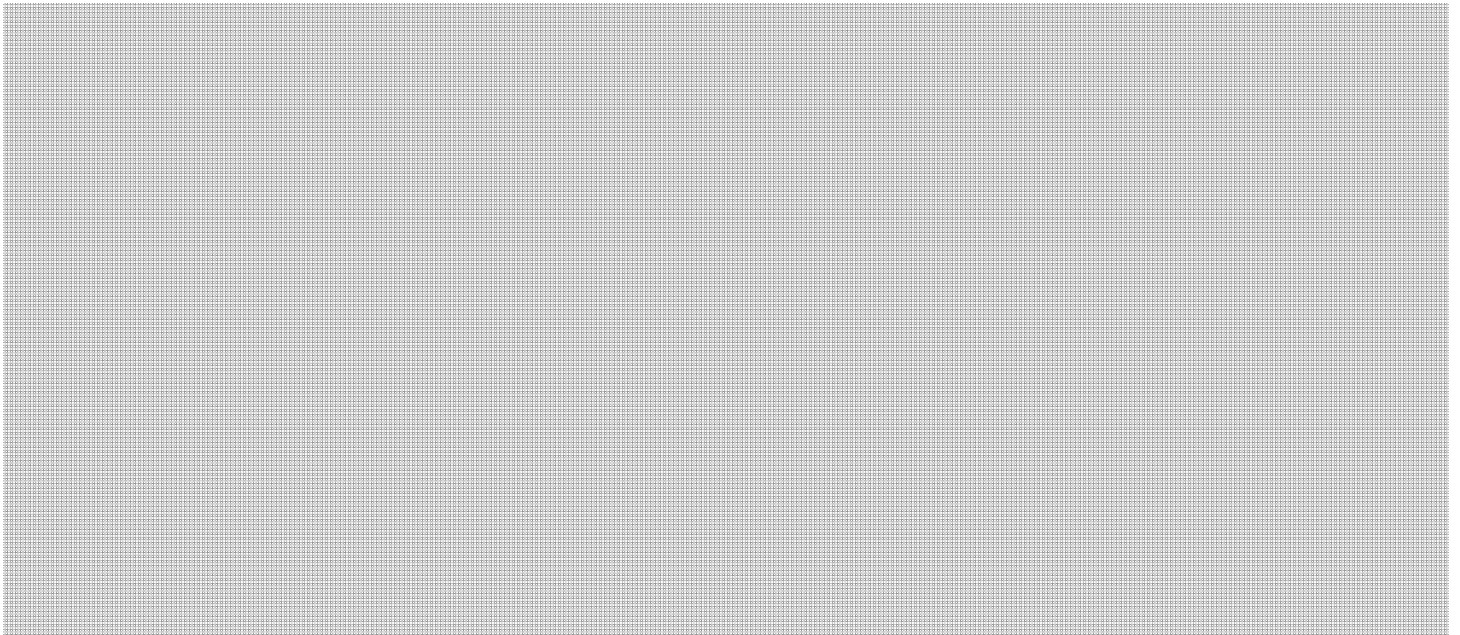
**9. CONSULTATIONS**

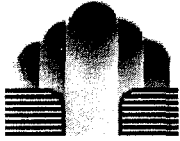
- Drug Analysis Services (DAS)
- Royal Canadian Mounted Police (RCMP)
- Canada Border Services Agency (CBSA)

**s.21(1)(a)**

**s.21(1)(b)**

**10. IMPLEMENTATION AND EVALUATION**





Jocelyn Kula/HC-SC/GC/CA  
2010-06-01 01:14 PM

To Lisa MacKay/HC-SC/GC/CA@HWC  
cc Stephanie Chandler/HC-SC/GC/CA@HWC, Denis Arsenault  
bcc  
Subject Fw: Input on Revised IYH and MLs for Salvia

Hi Lisa,

Apologies, I attached the wrong version of the media lines.....



Salvia MLs + OCS Input May 26 2010.doc

---

Jocelyn Kula  
Manager/ Gestionnaire  
Policy and Regulatory Affairs Division/ Division des politiques et affaires réglementaires  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0125 Fax: (613) 946-4224  
----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2010-06-01 01:13 PM -----



Jocelyn Kula/HC-SC/GC/CA  
2010-06-01 01:07 PM

To Lisa MacKay/HC-SC/GC/CA  
cc Denis Arsenault, Stephanie Chandler/HC-SC/GC/CA@HWC  
Subject Input on Revised IYH and MLs for Salvia

Hi Lisa

Please accept my apologies for taking so very long to get input back to you on these documents. Denis did his part very quickly after you sent the docs to us; it is just that all the prep work for my court case and even the week I was away for the case were so chaotic that I really had no time for anything else.

In any case, here is our input. As you will see, we are still suggesting some changes to the documents, all with the view of a) trying to improve consistency between wording in the IYH and the MLs, and b) making sure that we truly accurate vis a vis the legal status sections/ info. I realize that this likely means another round of circulation to other parties, but you can feel free to put it all on us if you like!



Salvia MLs + OCS Input May 26 2010.doc



IYH + OCS Input May 31 2010.doc

Regarding our comments on the Youth Smoking Survey, here is the link to the 2008-09 results, which were released on May 31, 2010.

<http://www.yss.uwaterloo.ca/index.cfm?section=5&page=288>

Please don't hesitate to contact Denis or I if you have any questions on our input. That said, I am trying to "divorce" Denis from this file, as we have a new person who just started picking up work on the file in my



office- Stephanie Chandler (copied above).

Regards,

Jocelyn

---

Jocelyn Kula  
Manager/ Gestionnaire  
Policy and Regulatory Affairs Division/ Division des politiques et affaires réglementaires  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0125 Fax: (613) 946-4224



2010-06-01 10:03 AM

To :stephanie.chandler@hc-sc.gc.ca

cc

bcc

Subject [Fwd: Re: Salvia]

----- Original Message -----

Subject: Re: Salvia  
From: "Sherrey Collier" <sherrey.collier@hc-sc.gc.ca>  
Date: Mon, 31 May, 2010 7:04 pm  
To: "Jocelyn Kula" <jocelyn.kula@hc-sc.gc.ca>  
Cc: "Daniel Galarneau" <Daniel.Galarneau@hc-sc.gc.ca>

Very helpful, thx Jocelyn.

Jocelyn  
Kula/HC-SC/GC/CA

2010-05-31 11:36  
AM

Sherrey Collier/HC-SC/GC/CA@HWC

To  
cc

Daniel  
Galarneau/HC-SC/GC/CA@HWC

Subject

Re: Salvia(Document link: Sherrey Collier)

Hi Sherrey,

The inter-branch discussions in 2007-08 did not conclude that Salvia should be scheduled under the CDSA, but rather that the HPFB conclusion of that nature was not based on a fullsome scheduling assessment (in fact, OCS had not been consulted on the issue analysis MHPD and NHPD had prepared) and that such an assessment was required before any decisions as to how the substance should be regulated could be made. We are now in the final stages of preparing that scheduling assessment, and while we have not yet come to a firm conclusion (the document has not yet gone to the CSS-WG for discussion), it does not seem at this point, that scheduling under the CDSA is warranted at this time. This is the approach that has been taken in the IYH article and related media lines that are currently in the final stages of development.

Hope this helps.

Jocelyn

---

Jocelyn Kula  
Manager/ Gestionnaire  
Policy and Regulatory Affairs Division/ Division des politiques et affaires  
réglementaires  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la  
santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0125 Fax: (613) 946-4224

Sherrey  
Collier/HC-SC/GC/  
CA

2010-05-31 10:46  
AM

"Jocelyn Kula"  
<jocelyn.kula@hc-sc.gc.ca>

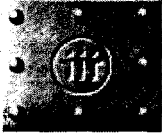
To

cc


Subject

Salvia

Hi Jocelyn,  
Could you pls give me an update on salvia from your perspective? Are you  
working towards possibly scheduling it as per Branch discussions in 2007  
and 2008 or is that on hold?  
Thx,  
Sherrey



Mark  
Kozlowski/HC-SC/GC/CA  
2010-06-01 08:44 AM

To Jocelyn Kula/HC-SC/GC/CA@HWC  
cc "Mr. Daniel Galarneau" <Daniel.Galarneau@hc-sc.gc.ca>,  
"Stephanie Chandler" <stephanie.chandler@hc-sc.gc.ca>  
bcc  
Subject Re: Salvia 

Perfect! Over to your group...

MK

Jocelyn  
Kula/HC-SC/GC/CA

06/01/2010 08:35 AM

To Mark Kozlowski/HC-SC/GC/CA@HWC  
cc "Stephanie Chandler" <stephanie.chandler@hc-sc.gc.ca>, "Mr. Daniel Galarneau"  
<Daniel.Galarneau@hc-sc.gc.ca>  
Subject Re: Salvia Link

It would appear that CBSA internal communications are not as strong as they should be...

I think it's best that we take this on, so that we can put them in touch with the right people in NHPD and the HPFBI.

FYI, there is supposed to be a general customs target in place for salvia.

Thx  
JK  
Sent by blackberry

Jocelyn Kula  
Manager/ Gestionnaire  
Policy and Regulatory Affairs Division/ Division des politiques et affaires reglementaires

----- Original Message -----

**From:** Mark Kozlowski  
**Sent:** 2010-06-01 08:27 AM EDT  
**To:** Jocelyn Kula  
**Subject:** Salvia

Jocelyn,

Would PRAD respond to something like this, or do you consider this more of a status request. To me, it appears that they know Salvia is not controlled, but are looking for additional info.

MK

----- Forwarded by Mark Kozlowski/HC-SC/GC/CA on 06/01/2010 08:25 AM -----

"Alfaro, Nina"

<Nina.Alfaro@cbsa-asfc.gc.ca>

To 'Mark Kozlowski' <Mark.Kozlowski@hc-sc.gc.ca>

cc "Steele, Debra" <Debra.Steele@cbsa-asfc.gc.ca>, "Badour, Dan"

<Dan.Badour@cbsa-asfc.gc.ca>

06/01/2010 08:14 AM

Subje  
ct

Hello Mark,

Could you tell me if HC has made any decisions/determinations regarding this plant? Do we plan on following other nations in banning or controlling this substance? Because of its highly hallucinogenic properties (especially relating to human health and safety), would HC advise the CBSA to detain the substance pending a HC determination of its admissibility? Would HC be concerned if this substance was being sold in retail outlets?

Any information you could provide, (or if you could point me in the right direction) would be appreciated,

Thanks Mark.

***Salvia divinorum*** (also known as **Diviner's Sage**,<sup>[2]</sup> **ska María Pastora**,<sup>[3]</sup> **Seer's sage**,<sup>[4]</sup> and by its genus name **Salvia**) is a psychoactive plant which can induce dissociative effects. Its native habitat is within cloud forest in the isolated Sierra Mazateca of Oaxaca, Mexico, growing in shady and moist locations.<sup>[5][6]</sup> The plant grows to over a meter high,<sup>[1]</sup> has hollow square stems, large leaves, and occasional white flowers with violet calyx. Botanists have not determined whether *Salvia divinorum* is a cultigen or a hybrid; native plants reproduce vegetatively, rarely producing viable seed.<sup>[7][8]</sup>

Nina Alfaro

Senior Intelligence Officer/Agente principale du renseignement

613-948-8595 télécopieur / fax 613-957-8555

[nina.alfaro@cbsa-asfc.gc.ca](mailto:nina.alfaro@cbsa-asfc.gc.ca)

Intelligence Directorate/ Direction du renseignement

Canada Border Services Agency / Agence des services frontaliers du Canada

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24/7 613-957-8397

24/7 E-mail: CBSA-ASFC-Dist\_Intell-HQ-FPL@cbsa-asfc.gc.ca



Health  
Canada Santé  
Canada

**Our Mandate:**

To promote good nutrition and informed use of drugs, food, medical devices and natural health products, and to maximize the safety and efficacy of drugs, food, natural health products, medical devices, biologics and related biotechnology products in the Canadian marketplace and health system.

# **Health Products and Food Branch Inspectorate**

## **Border Integrity Approach**

### **POL-0059**

Supersedes:  
New Document

Date Issued:  
June 1, 2010

Date of Implementation:  
June 1, 2010

***Disclaimer***

*This document does not constitute part of the Food and Drugs Act (Act) or its associated Regulations and in the event of any inconsistency or conflict between that Act or Regulations and this document, the Act or the Regulations take precedence. This document is an administrative document that is intended to facilitate compliance by the regulated party with the Act, the Regulations and the applicable administrative policies. This document is not intended to provide legal advice regarding the interpretation of the Act or Regulations. If a regulated party has questions about their legal obligations or responsibilities under the Act or Regulations, they should seek the advice of legal counsel.*

**Canada**

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### **1.0 Purpose**

This document outlines to the public, staff and stakeholders of the Health Products and Food Branch Inspectorate (Inspectorate) the main elements of the Inspectorate National Border Integrity Program. Through a risk based approach this program aims to effectively and consistently administer the requirements of the *Food and Drugs Act (FDA)* and its associated *Regulations* as they apply to the importation and exportation of health products under the mandate of the Inspectorate.

### **2.0 Background**

The mandate of the Health Products and Food Branch (HPFB) is to take an integrated approach to the management of the risks and benefits of health products and food by minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food; promoting conditions that enable Canadians to make healthy choices; and, providing the public with information so that they can make informed decisions about their health.

The Inspectorate is responsible for the delivery of compliance and enforcement activities aimed to protect the integrity of the supply chain through the use of appropriate measures to manage health and safety risks posed to Canadians due to the use of health products. It is estimated that eighty percent of health products available to Canadians are imported<sup>1</sup>. Consumers rely on Health Canada to verify that only health products approved for sale are available to them in the Canadian market.

In order to achieve a comprehensive regulatory system, it is necessary for the Inspectorate to not only work in collaboration with other government departments, but also establish strategic partnerships with healthcare professionals, industry, consumers, and stakeholders, both domestic and international, in order to maintain a safe supply of health products within the Canadian marketplace.

The National Border Integrity Program delivered by the Inspectorate addresses the challenges created by an increase in the importation of new health products; the rapid expansion of global trade; and the complexity of the supply chain including consumer direct access to less expensive or socially stigmatized products available through internet marketing. The Inspectorate takes a risk management approach to the delivery of the program and collaborates closely with various partners.

In order to achieve a comprehensive regulatory system, it is necessary for the Inspectorate to work in collaboration with other government departments, and to establish strategic partnerships with health care professionals, industry, consumers, and stakeholders, both domestic and international, in order to maintain a safe supply of health products within the Canadian market. The partnership with the Canada Border Services Agency (CBSA) facilitates the enforcement of the requirements under the *FDA* with respect to importation and exportation of health products to mitigate the health and safety risks posed to Canadians.

### **3.0 Scope**

This document outlines the Inspectorate's plan for the delivery of the Border Integrity Program which applies to all health products under the Inspectorate's mandate including: medical devices; human drugs, natural

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<sup>1</sup> Canada's Proposed Food and Consumer Safety Action Plan 2007.

Health Canada / Health Products and Food Branch Inspectorate

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health products; blood and blood components for transfusion; semen for assisted conception; human cells, tissues, organs for transplantation; and veterinary drugs moving across the Canadian border.

#### 4.0 Definitions

The following terms are defined for the purposes of this document:

**Food and Drugs Act:** A federal statute regulating the health and safety of food, drugs, cosmetics, and medical devices. The Minister of Health is responsible for the administration of the *Act*.

**Health Products:** A health product includes any product under the mandate of the Health Products and Food Branch (HPFB), with the exception of food products. The HPFB has regulatory responsibilities in the following health product areas: drugs for human use; blood and blood products; medical devices; transplanted tissues and organs; biologics and genetic therapies; natural health products; and veterinary drugs.

#### 5.0 Policy Statement

The Inspectorate, through the National Border Integrity Program and in partnership with CBSA, ensures the consistent administration of the *FDA* at the border and provides information to Canadians so that they can make informed choices related to the importation and exportation of health products. The program applies a risk-based approach to achieve the greatest impact and efficiency of resources by expediting border processing of compliant health products while systematically assessing the compliance of health products that are suspected to be in violation of the *FDA* and its associated *Regulations*.

#### 6.0 Responsibilities

The maintenance and enhancement of health and safety is a responsibility that is shared among government and industry, consumers, healthcare professionals and their respective associations.

It is the Inspectorate's responsibility to conduct border integrity activities in accordance with the pillars of the Border Integrity Program articulated in this document.

Importers must comply with all Canadian legislative and regulatory requirements and have a responsibility for ensuring the safety of all products that they bring into the Canadian market. Healthcare professionals are encouraged to inform the HPFBI of any problems they encounter (adverse reactions, malfunctions, and non-compliance) that may be related to these health products, including those that have been imported. They should ensure that the health products they provide to their clients and patients are authorized by Health Canada.

Consumers have a responsibility for the maintenance of their health and the safe use of marketed health products. In addition, consumers are asked to inform the HPFBI of any problems that they encounter (adverse reactions, malfunctions, and non-compliance) through the use of health products. Consumers are advised to only import products which are authorized for sale in Canada.

#### 7.0 Border Integrity Activities

The National Border Integrity Program supported by four pillars to ascertain that only health products that are in compliance with the *Food and Drugs Act* and associated *Regulations* will enter Canada through importation:

Health Canada / Health Products and Food Branch Inspectorate

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1. Effective legislative and regulatory framework;
2. Strategic domestic and international partnerships;
3. Increased awareness and public education and;
4. Efficient use of information technology.

### **7.1 Effective legislative and regulatory framework**

Under the *Food and Drugs Act* and its *Regulations*, the Inspectorate has the authority to inspect and take samples of health products intended for importation into Canada upon their arrival. The Inspectorate also requests CBSA to target and detain specific shipments or products for an admissibility determination by the Inspectorate. If at the border, the Inspectorate concludes that a shipment contains health products intended for distribution in Canada that are not in compliance with the *FDA*, the Inspectorate will take the appropriate compliance and enforcement actions based on risk that may include the refusal of entry, use of targets and lookouts to prevent future importation of such products, seizure and/or voluntary disposal.

The CBSA assists Health Canada by detaining shipments of health products for their inspection and decision regarding admissibility. Authority for CBSA to detain such shipments is contained in Section 101 of the *Customs Act*.

### **7.2 Partnership Development (Domestic and International)**

The creation of a National Border Integrity Program is the result of the Inspectorate's goal to seek innovative solutions and ways to improve our business by learning from "best practices" of other regulatory agencies. Many countries have also placed a high priority on border security and the Inspectorate aims to develop and participate in domestic and international partnerships, to share intelligence data and to establish effective mechanisms that support joint actions.

The Inspectorate continues to collaborate with various federal departments and other regulatory agencies such as CBSA, the US Food and Drug Administration, Royal Canadian Mounted Police and other organizations within the health portfolio to prevent, detect, and deter non-compliant health products from entering the country. This is achieved by developing intelligence capacity related to specific incidents, detection methods, lessons learned, and laboratory techniques both domestically and globally to supply program areas with information to enable strategic monitoring, investigations, and laboratory analysis.

The CBSA and the Inspectorate are committed to establishing service standards that guide the criteria for detecting non-compliant health products at the border, and the timeframes for making admissibility determinations.

### **7.3 Public awareness and education**

Effective border integrity is enhanced with the help of an informed public who can both recognize and understand the risks associated with the importation of non-compliant health products. In the context of the National Border Integrity Program, the Inspectorate delivers health promotion activities to inform the CBSA, the general public and trade-chain partners, including importers, brokers, and freight-forwarders, about the requirements to legally import health products into Canada.

### **7.4 Information Technology**

The Inspectorate recognizes the importance of using emerging technological methods to track, trace and verify compliance of health products at the border and within the supply chain. The Inspectorate is one of approximately forty organizations within eleven government departments, participating in the Single Window

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initiative led by CBSA. The initiative is aimed at improving the administration of regulatory requirements at the border as they apply to commercial shipments in an electronic commerce world.

The Single Window Initiative supports the delivery of the Inspectorates Border Integrity Program by using automated risk assessment solution capable of identifying high-risk goods using the Inspectorate criteria that require increased scrutiny while expediting the flow of low-risk goods. For more information on this initiative, refer to the following website.:

<http://cbsa-asfc.gc.ca/eservices/ogd-amg/menu-eng.html#c01>

## **8.0 Associated Documents**

### *Customs Act*

<http://laws.justice.gc.ca/en/showdoc/cs/C-52.6>

### *Canadian Border Services Agency Act*

<http://laws.justice.gc.ca/en/showtdm/cs/C-1.4>

### *Food and Drugs Act*

<http://laws.justice.gc.ca/en/showdoc/cs/F-27>

### *Food and Drugs Regulations*

<http://laws.justice.gc.ca/en/showdoc/cr/C.R.C.-c.870>

### *Medical Devices Regulations*

<http://laws.justice.gc.ca/en/showdoc/cr/SOR-98-282>

### *Natural Health Products Regulations*

<http://laws.justice.gc.ca/en/showdoc/cr/SOR-2003-196>

### *Safety of Human Cells, Tissues and Organs for Transplantation Regulations*

<http://laws.justice.gc.ca/en/showtdm/cr/SOR-2007-118>

### *Processing and Distribution of Semen for Assisted Conception Regulations*

<http://laws.justice.gc.ca/en/F-27/SOR-96-254/index.html>

### **POL-0001 Compliance and Enforcement**

[http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/pol/pol\\_1\\_tc-tm\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/pol/pol_1_tc-tm_e.html)

**Guidance Document on the Import Requirements for Health Products under the *Food and Drugs Act* and its *Regulations* (GUI-0084)**

**7.0 Natural Health Products (NHP)**

Natural Health Products are regulated by Health Canada under the authority of the Food and Drugs Act and the Natural Health Product Regulations.

**Commercial Importations**

**Figure 3. Commercial Importation Requirements for Natural Health Products**

<b>Commercial Importations</b>	<b>Health Canada Requirements</b>
NHP	A product licence (NPN or DIN-HM) for each product. The importer must hold a Site Licence (SL) The foreign manufacturing site must be listed on the Importer's SL.
NHP imported for use in a clinical trial	A Notice of Authorization (NOA) authorizing the use of the product in a clinical trial is issued by the Natural Health Products Directorate (NHPD) of Health Canada. A copy of this authorization must be provided at the port of entry.

**Personal Use Importations**

**Figure 4. Personal Use Importation Requirements for Natural Health Products**

<b>Personal Use Importations</b>	<b>Health Canada Requirements</b>
NHP	<p>Individuals are permitted to import a single course of treatment or a 90-day supply based on the directions for use, whichever is less, of an NHP.</p> <p>The NHP must be for the individual's own personal use or for the use of a person for whom they are responsible and with whom they are travelling.</p> <p>The NHP must be shipped/carried in one of the following:</p> <ul style="list-style-type: none"> <li>Hospital or pharmacy dispensed packaging;</li> <li>Original retail packaging; or</li> <li>have the original label affixed to it which clearly indicates what the health product is and what it contains.</li> </ul>

## PRAD Telephone Enquiry

**Date of Call:** June 2, 2010

**Subject:** Potential of scheduling *Salvia divinorum* under the CDSA

**Language of Correspondence:** English

**Caller Name:** Deb Steele

**Caller Organization:** Canada Border Services Agency

**Caller Telephone Number:** (613) 954-5188

### CALL SUMMARY:

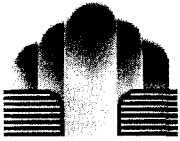
Deb Steele from the Canada Border Services Agency (CBSA) inquired as to whether there are any plans to schedule *Salvia divinorum* under the *Controlled Drugs and Substances Act*.

I indicated that while there are no plans at this time to schedule *Salvia divinorum* under the *Controlled Drugs and Substances Act*, products containing *Salvia divinorum* are considered to meet the definition of a Natural Health Product (NHP) (in accordance with the *Natural Health Products Regulations*) when manufactured, sold or represented for use in modifying organic functions, i.e., hallucinogenic effects.

It is illegal to sell NHPs in Canada unless they have been approved by Health Canada and assigned a Natural Product Number (NPN) or Drug Identification Number - Homeopathic Medicine. No products containing *S. divinorum* s have, however, been approved for sale by Health Canada.

Notwithstanding these regulatory provisions, Deb Steele asked whether there are any plans for import controls of any kind, and whether further measures will be taken in the future.

Denis Arsenault  
Section Head - Policy  
Policy and Regulatory Affairs Division  
Office of Controlled Substances



Jocelyn Kula/HC-SC/GC/CA

2010-06-02 05:58 PM

To Diane Marcheterre/HC-SC/GC/CA@HWC

cc Collin Pinto/HC-SC/GC/CA@HWC, Daniel  
Galarneau/HC-SC/GC/CA@HWC, Ian  
Grimwood/HC-SC/GC/CA@HWC, Lawrence

bcc

Subject Re: Fw: Salvia

Thanks Diane,

My assistant Isabel will send out an invitation to suit Ian's and my availabilities.

Isabel- pls make a note that we may need to arrange a teleconference as Ian may not be able to attend in person. The rest of us here will need a meeting room though.

Jocelyn

---

Jocelyn Kula  
Manager/ Gestionnaire  
Policy and Regulatory Affairs Division/ Division des politiques et affaires réglementaires  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0125 Fax: (613) 946-4224  
Diane Marcheterre/HC-SC/GC/CA

Diane  
Marcheterre/HC-SC/GC/CA

2010-06-02 01:17 PM

To Jocelyn Kula/HC-SC/GC/CA@HWC

cc Collin Pinto/HC-SC/GC/CA@HWC, Daniel  
Galarneau/HC-SC/GC/CA@HWC, Jocelyn  
Kula/HC-SC/GC/CA@HWC, Lawrence  
Cheung/HC-SC/GC/CA@HWC, Stephanie  
Chandler/HC-SC/GC/CA@HWC, Ian  
Grimwood/HC-SC/GC/CA@HWC

Subject Re: Fw: Salvia


Hello,  
Please find Ian's availability for next week

Tuesday the 8th - AM  
Thursday the 10th - AM and PM

Thank you

Diane Marcheterre  
Administrative Assistant  
Border Integrity / Intégrité frontalière  
HPFB-Inspectorate  
Tel: (613) 960-0617  
Fax: (613) 960-2156  
Ian Grimwood/HC-SC/GC/CA

Ian Grimwood/HC-SC/GC/CA  
2010-06-01 05:33 PM

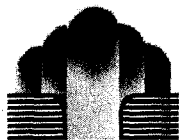
To Jocelyn Kula/HC-SC/GC/CA@HWC  
cc Collin Pinto/HC-SC/GC/CA@HWC, Daniel Galarneau/HC-SC/GC/CA@HWC, Lawrence Cheung/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC, Diane Marcheterre/HC-SC/GC/CA@HWC  
Subject Re: Fw: Salvia 

Diane can you provide Jocelyn with some times next week....


I will bring one member from my team...

Depending on timing it may be better if I can call in.. less personal I know but 123 is SO far away! ;)

Ian Grimwood  
a/Manager / i/Gestionnaire  
Border Integrity Unit / Unité d'Intégrité Frontalière  
Inspectorate / Inspectorat  
Health Products and Food Branch / Direction générale des produits de santé et des aliments  
Tel: (613) 957-9994  
Fax: (613) 960-2156  
Jocelyn Kula/HC-SC/GC/CA



Jocelyn Kula/HC-SC/GC/CA  
2010-06-01 05:27 PM

To Ian Grimwood/HC-SC/GC/CA@HWC  
cc Collin Pinto/HC-SC/GC/CA@HWC, Daniel Galarneau/HC-SC/GC/CA@HWC, Lawrence Cheung/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC  
Subject Re: Fw: Salvia 

Hi Ian,

I think it would be great if you could spend a bit of time connecting the dots on border integrity for me, but would like to include a few others from my division that might benefit from the discussion as well. And unfortunately, Friday does not work for me as I am on leave that day.

Can you let me know when you might be available for a short meeting to discuss this further next week? We can host you here at 123 Slater or patch you in by phone if you really can't leave Graham Spry. And feel free to involve others who might need to be there.

In the interim, we will draft a short response to the enquiry that kick-started my email to you, and run it by you before we send.

Jocelyn




Jocelyn Kula  
Manager/ Gestionnaire  
Policy and Regulatory Affairs Division/ Division des politiques et affaires réglementaires  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0125 Fax: (613) 946-4224  
Ian Grimwood/HC-SC/GC/CA

Ian  
Grimwood/HC-SC/GC/CA

2010-06-01 05:02 PM

To Jocelyn Kula/HC-SC/GC/CA@HWC

cc Collin Pinto/HC-SC/GC/CA@HWC, Daniel  
Galarneau/HC-SC/GC/CA@HWC, Lawrence  
Cheung/HC-SC/GC/CA@HWC, Stephanie  
Chandler/HC-SC/GC/CA@HWC

Subject Re: Fw: Salvia 

Well luckily I'm pretty versed in the border stuff, at least for health products! ;) ;P

Probably fast/easier if we chat. I have meetings most of the rest of the week.. but is Friday for a few  
minutes between 2-3:30 good for you?

Ian Grimwood  
a/Manager / i/Gestionnaire  
Border Integrity Unit / Unité d'Intégrité Frontalière  
Inspectorate / Inspectorat  
Health Products and Food Branch / Direction générale des produits de santé et des aliments  
Tel: (613) 957-9994  
Fax: (613) 960-2156  
Jocelyn Kula/HC-SC/GC/CA




Jocelyn Kula/HC-SC/GC/CA

2010-06-01 10:07 AM

To Ian Grimwood/HC-SC/GC/CA@HWC

cc Collin Pinto/HC-SC/GC/CA@HWC, Daniel  
Galarneau/HC-SC/GC/CA@HWC, Lawrence  
Cheung/HC-SC/GC/CA@HWC, Stephanie  
Chandler/HC-SC/GC/CA@HWC

Subject Re: Fw: Salvia 

Thanks Ian

I did not know that the import alerts had been allowed to expire. Guess I don't really understand all of this  
border integrity stuff as well as I should as I didn't think that the decision to consider salvia as an NHP was  
mutually exclusive of any attempt to have border officers look for imports of the substance. You are right,  
that technically, salvia does meet the definition of an NHP. I guess the issue is whether there isn't more  
we can do to prevent loads of the stuff coming into Canada given that our scheduling assessment does  
not support regulation as a controlled substance (next to no evidence of abuse potential, addiction liability  
and only mild anecdotal information about risk to public health and safety).


Perhaps you can explain how the raw material policy works?

Jocelyn

---

Jocelyn Kula  
Manager/ Gestionnaire  
Policy and Regulatory Affairs Division/ Division des politiques et affaires réglementaires  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0125 Fax: (613) 946-4224  
Ian Grimwood/HC-SC/GC/CA

Ian  
Grimwood/HC-SC/GC/CA  
2010-06-01 09:58 AM

To Jocelyn Kula/HC-SC/GC/CA@HWC  
cc Collin Pinto/HC-SC/GC/CA@HWC, Daniel Galarneau/HC-SC/GC/CA@HWC, Lawrence Cheung/HC-SC/GC/CA@HWC  
Subject Re: Fw: Salvia 

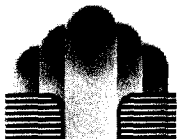
Hello Jocelyn.

The Inspectorate does not have any import alerts active for Salvia at the moment.


We used to have a few alerts active however they were allowed to expire in 2008 and 2009 ( one or two on specific importers and one on Salvia Extracts in general). They were allowed to expire after consultation with the "lead" inspector on the file/

If warranted we can re-establish an import alert however as I understand it Salvia can be considered an NHP and could fall under the NHPD Raw Material Policy.

Ian Grimwood  
a/Manager / i/Gestionnaire  
Border Integrity Unit / Unité d'Intégrité Frontalière  
Inspectorate / Inspectorat  
Health Products and Food Branch / Direction générale des produits de santé et des aliments  
Tel: (613) 957-9994  
Fax: (613) 960-2156  
Jocelyn Kula/HC-SC/GC/CA



Jocelyn Kula/HC-SC/GC/CA  
2010-06-01 09:36 AM

To Ian Grimwood/HC-SC/GC/CA@HWC, Collin Pinto/HC-SC/GC/CA@HWC  
cc  Daniel Galarneau/HC-SC/GC/CA@HWC  
Subject Fw: Salvia

s.19(1)

Hi Ian and Collin,

Can one of you please confirm whether there is still an active customs target in place for salvia/ salvia divinorum? Just that we have received the enquiry below from the Intelligence Directorate at CBSA, and I want to be sure that I provide the correct response.

If the target is still in place, can you pls advise as to what exactly it covers?

For your information, we are presently finalizing our scheduling assessment of salvia, and while we don't have an approved recommendation at this point, our assessment essentially supports the approach being taken by the IYH that is currently in development, i.e., scheduling under the CDSA is not warranted at this time.

Thanks in advance,

Jocelyn

---

Jocelyn Kula  
Manager/ Gestionnaire  
Policy and Regulatory Affairs Division/ Division des politiques et affaires réglementaires  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0125 Fax: (613) 946-4224  
----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2010-06-01 09:31 AM -----

Jocelyn Kula/HC-SC/GC/CA

Mark Kozlowski

----- Forwarded by Mark Kozlowski/HC-SC/GC/CA on 06/01/2010 08:25 AM -----



"Alfaro, Nina"  
<Nina.Alfaro@cbsa-asfc.gc.ca>

06/01/2010 08:14 AM

To 'Mark Kozlowski' <Mark.Kozlowski@hc-sc.gc.ca>

cc "Steele, Debra" <Debra.Steele@cbsa-asfc.gc.ca>, "Badour, Dan" <Dan.Badour@cbsa-asfc.gc.ca>

Subject

Hello Mark,

Could you tell me if HC has made any decisions/determinations regarding this plant? Do we plan on following other nations in banning or controlling this substance? Because of its highly hallucinogenic properties (especially relating to human health and safety), would HC advise the CBSA to detain the substance pending a HC determination of its admissibility? Would HC be concerned if this substance was being sold in retail outlets?

Any information you could provide, (or if you could point me in the right direction) would be appreciated,

Thanks Mark.

***Salvia divinorum*** (also known as **Diviner's Sage**,<sup>[2]</sup> **ska María Pastora**,<sup>[3]</sup> **Seer's sage**,<sup>[4]</sup> and by its genus name **Salvia**) is a psychoactive plant which can induce dissociative effects. Its native habitat is within cloud forest in the isolated Sierra Mazateca of Oaxaca, Mexico, growing in shady and moist locations.<sup>[5][6]</sup> The plant grows to over a meter high,<sup>[1]</sup> has hollow square stems, large leaves, and occasional white flowers with violet calyx. Botanists have not determined whether *Salvia divinorum* is a cultigen or a hybrid; native plants reproduce vegetatively, rarely producing viable seed.<sup>[7][8]</sup>

Nina Alfaro

Senior Intelligence Officer/Agente principale du renseignement

613-948-8595 télécopieur / fax 613-957-8555

[nina.alfaro@cbsa-asfc.gc.ca](mailto:nina.alfaro@cbsa-asfc.gc.ca)

Intelligence Directorate/ Direction du renseignement

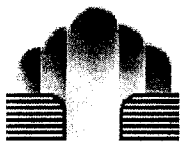
Canada Border Services Agency / Agence des services frontaliers du Canada

300 rue Slater Ottawa ON K1A 0L8

Gouvernement of Canada / Gouvernement du Canada

24/7 613-957-8397

24/7 E-mail: [CBSA-ASFC-Dist\\_Intell-HQ-FPL@cbsa-asfc.gc.ca](mailto:CBSA-ASFC-Dist_Intell-HQ-FPL@cbsa-asfc.gc.ca)



Jocelyn Kula/HC-SC/GC/CA  
2010-06-03 09:37 AM

To "Denis Arsenault" <denis.arsenault@hc-sc.gc.ca>,  
"Stephanie Chandler" <stephanie.chandler@hc-sc.gc.ca>  
cc  
bcc  
Subject Fw: Salvia Divinorum

Some rare feedback!  
Sent by blackberry

Jocelyn Kula  
Manager/ Gestionnaire  
Policy and Regulatory Affairs Division/ Division des politiques et affaires reglementaires  
Arafo Talane

----- Original Message -----  
From: Arafo Talane  
Sent: 2010-06-03 09:33 AM EDT  
To: Jocelyn Kula  
Cc: Isabel Shanahan  
Subject: Fw: Salvia Divinorum

Hello,  
Fyi.  
Merci!

s.19(1)

----- Forwarded by Arafo Talane/HC-SC/GC/CA on 2010-06-03 09:31 AM -----



2010-06-03 07:57 AM

To OCS-BSC <ocs-bsc@hc-sc.gc.ca>  
cc  
Subject Re: Salvia Divinorum

This answered everything I needed to know! Thank you very much!



On Tue, Jun 1, 2010 at 4:53 PM, OCS-BSC <ocs-bsc@hc-sc.gc.ca> wrote:

Dear [redacted]

Thank you for your e-mail inquiry of April 7, 2010, regarding the legal status of Salvia divinorum.

Salvia divinorum is a species of sage which belongs to the mint family. It is found in a number of formats, including seeds, extract and plant cuttings for growing purposes.

While several countries have placed controls on the import and/or sale of Salvia divinorum and/or salvinorin A, neither are presently regulated in

Canada under the Controlled Drugs and Substances Act (CDSA). Nevertheless, *Salvia divinorum* can, in some instances, be regulated as a natural health product under the Natural Health Product Regulations (NHPR) if it is sold for a specific therapeutic purpose. However, Health Canada has not to date issued any Natural Product Numbers or Homeopathic Medicine Numbers for *Salvia divinorum* products. This means that *Salvia* products that are being sold as natural health products that are not in compliance with the NHPR may be subject to compliance and enforcement action under the Food and Drugs Act.

With respect to the age restrictions on “legal access” to *Salvia divinorum* which you mention in your e-mail, this likely refers to measures adopted in other jurisdictions (e.g., the state of California in the United States). There are no such measures in place in Canada as *Salvia divinorum* is not regulated in this country.

Health Canada recommends that the use of this substance be avoided as very little is known about the damage it may cause to the body, including the brain. There is also no way to predict how it will affect an individual with each use.

Sincerely,

Diane Allan  
Director  
Office of Controlled Substances  
Controlled Substances and Tobacco Directorate  
Healthy Environments and Consumer Protection Branch  
Health Canada

June 3<sup>rd</sup>, 2010

**Issue:** Increased Traffic of *Salvia divinorum* hallucinogenic psychoactive plant across Canadian Borders.

**Inquiry:** Mrs. Deb Steele of Canada's Border Services Agency(CBSA) had communicated to Mrs. Brenda Paine, Director of the Office of Policy and Strategic Planning, Controlled Substances and Tobacco Directorate regarding potential scheduling of a hallucinogenic drug, and had requested that a staff member in OCS communicate with her. Mrs. Paine's inquiry was re-routed through the Director's office of the Office of Controlled Substances.

**Program History:**

Numerous discussions between HPFB's Natural Health Products Directorate and HECS Office of Controlled Substances have been conducted in the past. HPFB considers *Salvia divinorum* and its active ingredient Natural Health Products despite no NPN's having been assigned.

**Global History:**

In Canada, there has been some media coverage as to the availability of *Salvia divinorum* in the country, where it is still legal to possess, cultivate and sell.

In the United States, *Salvia divinorum*, is not regulated under the *Controlled Substances Act*, however some states have either promulgated (e.g. Delaware, Louisiana, Missouri) or have proposed their own legislation (e.g. Alabama, Alaska, California, Florida, Georgia, Iowa, Illinois, New Jersey, New York, Ohio, Oregon, Pennsylvania, and Texas).

As of May 2007, the U.S. DEA has been conducting an analysis to possibly Schedule *Salvia divinorum*. The considerations for scheduling are as follows;

- Actual and potential for abuse
- Pharmacology
- Other current scientific knowledge
- History and current pattern of abuse
- Scope, duration, and significance of abuse
- Public health risk
- Psychic or physiological dependence liability
- If it is an immediate precursor of a controlled substance

*Salvia divinorum* legislation might be difficult to police as the plant has a nondescript appearance nor, does it have a distinctive odour. It resembles a normal house plant and can be grown by hydroponics or high-powered lights.

Countries having some form of legal control include; Finland, Australia, Denmark, Spain, Italy, Sweden, Belgium, Croatia, Lithuania, Germany, Russia, Poland, and Romania.

- August 2002, *Finland* prohibited importation of *Salvia divinorum* without a prescription from a doctor.
- June 2002, *Australia* became the first country to ban *Salvia divinorum* and *salvinorin A*.
- August 2003, *Denmark* classed *Salvia divinorum* and *salvinorin A* as category B drugs in Danish law (same category as psilocybin mushrooms, cocaine, amphetamine, and other substances only legal for medicinal and scientific purposes).
- February 2004, *Spain* made the commerce of *Salvia divinorum* illegal. The use and possession thereof is not.
- March 2005 *Italy* placed both *Salvia divinorum* and *salvinorin A* on their Table I of outlawed psychotropic substances.
- April 2006, *Sweden* added *Salvia divinorum* and *salvinorin A* to their list of controlled substances.
- May 2006, *Salvia divinorum* was added to the *Belgian* list of illegal products.
- August 2007, *Chile* decreed the trafficking of *Salvia divinorum* and *salvinorin A* illegal.
- April 2008, *Salvia divinorum* was banned in *Croatia* by its addition to the official list of illegal substances and plants.
- May 2008, *Lithuania* banned the plant
- February 2008, banned in *Germany* by its addition to the official list of illegal substances.
- April 2009, sales and import of *Salvia divinorum* were banned in *Russia*.
- May 2009, *Poland* has made the sale, possession and consumption of *Salvia divinorum* illegal.
- February 2010, *Salvia divinorum* and *salvinorin A-F* were made illegal under Law 143/2000 in *Romania*.

No legal action has been taken in the *United Kingdom* regarding *Salvia divinorum*.

**Follow-up action:** Mr. Nathan Isotalo of the Office of Controlled Substances had returned Mrs. Steele's inquiry. There appears to be disagreement in the literature as to the potency of the drug, the intensity of its effects. Some claim that the plant can produce a more rapid and intense psychoactive high when compared with LSD whereas other researchers claim the opposite. Increased traffic at points of entry into Canada has prompted CBSA inspectorate to seize these plants at numerous border crossings.

Although unspecified by CBSA, in the international literature there appears to be an association of *Salvia divinorum* with *Salvinorin* or *Salvinorin A*.

**Recommendation:** Continue monitoring to determine whether Scheduling or regulatory action is required.



## Latest IYA on *Salvia divinorum*

### Issue

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff, incense special, and salvia.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs.

Health Canada recommends that you avoid using this plant because very little is known about the effects it may have on your body and/or brain. There is also no way to predict how it will affect you with each use.

**Comment [JK1]:** We are suggesting deletion of this para as it seems to introduce a whole lot of complex ideas that are then not fully explained until later in the article.....

### Background

*S. divinorum* is known to have psychotropic effects, which means it can affect the mind and mental processes. The leaves of this plant have been used traditionally by the Mazatec Indians for medicinal purposes (chewing the leaves or using them to make a tea) and spiritual purposes (smoking the leaves to induce a "mystical" or hallucinogenic experience).

Products that claim to contain *S. divinorum* – or its main active ingredient, salvinorin A – are widely available on the Internet and are sold in various "head shops" and natural food stores. The products are sold in a number of forms, including fresh or dried leaves, liquids or seeds and plant cuttings for growing purposes.

### Risks Associated with the Use of *Salvia divinorum*

The effects of *S. divinorum*, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations;
- dysphoria (feeling unwell, uneasy or unhappy);
- out-of-body experiences;
- uncontrollable laughter;
- loss of consciousness;
- short-term memory loss;
- lack of physical coordination; and
- slurred speech and awkward sentence patterns.

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product;
- how much is used;

- the purity of the product (it may be mixed with other substances);
- how it is taken (e.g., chewed, swallowed or smoked);
- the user's mood and expectations.

While scientists know which brain receptors are targeted by the active ingredient, salvinorin A, very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or permanent damage;
- how it interacts with other substances, including other drugs, natural health products and alcohol.

The potential of *S. divinorum* to produce physical dependence and/or addiction is also not known.

### Minimizing Your Risk

Health Canada recommends that you avoid using *S. divinorum*. Just because a drug is plant-based or "natural", does not mean that it is safe.

Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs and other substances that distort reality. (See the "Need More Info?" section below for links to resources that can help you with this.)

### Legal Status of *Salvia divinorum*

#### In Canada

When *S. divinorum* is manufactured, sold or represented for use in modifying organic functions in humans, and hallucinogens work by modifying organic functions in the brain, it meets the definition of a Natural Health Product (NHP) in accordance with the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*. It is illegal to sell NHPs in Canada unless they have been reviewed and approved by Health Canada and labelled with one of the following:

- a Natural Product Number (NPN); or
- a Drug Identification Number - Homeopathic Medicine (DIN-HM).

As of January 2010 no products containing *S. divinorum* have been approved by Health Canada. All unauthorized drugs and NHPs are subject to compliance and enforcement actions by the Department.

Neither *S. divinorum* nor salvinorin A are currently regulated under the *Controlled Drugs and Substances Act* (CDSA). This is because there is not enough information available to determine whether regulation as a controlled substance is warranted. In an effort to collect more information about the use of *S. divinorum*, questions on it were included in the 2008-2009 Youth Smoking Survey, the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) and the 2009

**Comment [JK2]:** Suggesting deletion of this info as it should come under Legal Status

**Comment [JK3]:** Just think we should keep this at the departmental level as people outside won't know what the HPFBI is necessarily.....

Ontario Student Drug Use and Health Survey (OSDUHS). The results from the 2009 OSDUHS were published on November 18, 2009 and indicate that among responding students in Ontario, 4.4% reported using *Salvia divinorum* at least once in the past year. Data from the Youth Smoking Survey was published on May 31, 2010 and indicate that 4.9% of responding students in Grades 7-12 have used *Salvia divinorum* at least once in the past year.

Data Data from these surveys and the 2009 edition of CADUMS (to be released in June 2010) will contribute to future decisions that Health Canada may make regarding the regulation of *S. divinorum* and/or its active ingredient. See the Need More Info? section below for more information on the surveys that are collecting information about *Salvia divinorum* use in Canada and for more detailed findings from the 2009 OSDUHS.

**Comment [JK4]:** This should be updated to reflect the fact that the YSS results are now released.....

#### In Other Countries

Several countries including but not limited to Australia, Belgium, Germany, Italy, Japan, etc., have placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A.

In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on their sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution, e.g., no sales to anyone under the age of 18, etc.

#### **Background**

*S. divinorum* is known to have psychotropic effects, which means it affects the mind and mental processes. The leaves of this plant have been used traditionally by the Mazatec Indians for both medicinal purposes (chewing the leaves or using them to make a tea) and spiritual purposes (smoking the leaves to induce a "mystical" or hallucinogenic experience). Products that claim to contain *S. divinorum* – or its main active ingredient, salvinorin A – are widely available on the Internet and are sold in various "head shops" and natural food stores. The products are sold in a number of forms, including fresh or dried leaves, liquids or seeds and plant cuttings for growing purposes.

**Comment [JK5]:** We realize this may be a template issue but to us, these paras would make much more sense if they appeared earlier in the document as they provide some context for the article as a whole and where HC's interest in providing info to people about it

#### **Health Canada's Role**

Health Canada continues to collect and consider information regarding *S. divinorum* and will continue to consult with key stakeholders including health officials in other countries and law enforcement officials here at home. This will assist in determining Health Canada's future approach to decision-making regarding *S. divinorum*.

**Comment [D6]:** We are doing nothing to mitigate risk other than asking people not to use it.

Complaints about illegal sale of drugs containing *S. divinorum* can be made to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

**Comment [D7]:** This sentence appears to be out of place as there is no reference anywhere in the article to Adverse Drug Reactions. For the purpose of context, perhaps there should be an opening line saying that HC is always interested in obtaining information about incidents of adverse effects?

#### **Reporting Adverse Reactions**

You can report any adverse reactions to the Canada Vigilance Program by one of the following three ways:

Report online at the MedEffect™ Canada Web site

Call toll-free at 1-866-234-2345

Complete a Canada Vigilance Reporting Form and either:

Fax toll-free to 1-866-678-6789

Mail to: Canada Vigilance Program

Health Canada

AL 0701C

Ottawa, ON K1A 0K9

To have postage pre-paid, download the postage paid label from the MedEffect™ Canada Web site. The Canada Vigilance Reporting Form and the adverse reaction reporting guidelines may also be obtained via this Web site.

### Need More Info?

- For information about the Government of Canada's **Anti-Drug Strategy**, go to:  
[www.nationalantidrugstrategy.gc.ca/](http://www.nationalantidrugstrategy.gc.ca/)

The Prevention section on this site has a number of helpful resources for parents, including:

- **Tips on Talking to Your Teenager**, at: [www.hc-sc.gc.ca/hc-ps/pubs/adp-apd/talk-aborder/index-eng.php](http://www.hc-sc.gc.ca/hc-ps/pubs/adp-apd/talk-aborder/index-eng.php)
- **What to Do if Your Teen is Using Drugs**, at:  
[www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html](http://www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html)

• Information on natural health products and the **Natural Health Products Regulations** can be found at: [www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php)

For more on the surveys that are collecting information about *Salvia divinorum* use in Canada, see:

- **The 2008-2009 Youth Smoking Survey**, at:  
[www.yss.uwaterloo.ca/ysssite\\_app/controller/index.cfm](http://www.yss.uwaterloo.ca/ysssite_app/controller/index.cfm) and
- **The 2009 Canadian Alcohol and Drug Use Monitoring Survey**, at: [www.hc-sc.gc.ca/hl-vs/drug-drogués/cadums-escad-eng.php](http://www.hc-sc.gc.ca/hl-vs/drug-drogués/cadums-escad-eng.php)
- **The 2009 Ontario Student Drug Use and Health Survey**, at:  
[www.camh.net/Research/osdus.html](http://www.camh.net/Research/osdus.html)

### Additional Resources:

- U.S. Drug Enforcement Administration: Drugs and Chemicals of Concern: *Salvia divinorum* and Salvinorin A at:  
[www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)
- U.S. Department of Health & Human Services, **National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006** at:  
[www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf](http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf)
- For additional articles on health and safety issues go to the **It's Your Health** Web section at: [www.healthcanada.gc.ca/iyh](http://www.healthcanada.gc.ca/iyh)

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

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Lisa Mackay: 613-954-0105 – [Lisa.Mackay@hc-sc.gc.ca](mailto:Lisa.Mackay@hc-sc.gc.ca)

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DRAFT



Isabel  
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2010-06-10 12:02 PM

To Collin Pinto/HC-SC/GC/CA@HWC, Daniel  
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cc Diane Marcheterre/HC-SC/GC/CA@HWC, Jocelyn  
Kula/HC-SC/GC/CA@HWC

bcc

Subject Teleconference set up for 1:00 today

I will set up the starphone

Isabel Shanahan  
Assistant to the Manager  
Policy & Regulatory Affairs Division  
Office of Controlled Substances  
Healthy Environments and Consumer Safety Branch  
Tel: (613) 946-0123 Fax: (613) 946-4224

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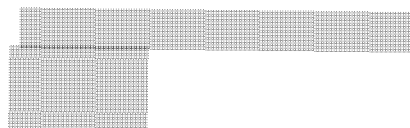
Subject Automated Confirmation 4063244

## Confirmation : Service automatisé 4063244

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Heure de la conférence :	13:00	Fuseau horaire :	Est
Durée (en minutes) :	60	Nombre de lignes :	2

Numéro(s) d'accès :  
Code d'accès des participants :  
Code d'accès du président :



### Coordonnées des personnes à contacter

Nom du département : Santé Canada

Nom du président :	Ms. Jocelyn Kula	Numéro de téléphone :	613-946-0125
Numéro de dossier du président :	1398576		
Nom de la personne-ressource :	Ms. Isabel Shanahan	Numéro de téléphone :	613-946-0123
Code de facturation :	9990268		

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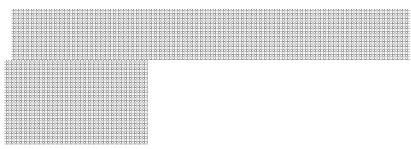
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Department name: Health Canada

Moderator name: Ms. Jocelyn Kula      Telephone number: 613-946-0125  
Moderator file number: 1398576  
Contact name: Ms. Isabel Shanahan      Telephone number: 613-946-0123  
Billing code: 9990268

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# Issue Analysis Summary

DRAFT  
(NOT CIRCULATED)

## Scheduling *Salvia Divinorum* and/or *Salvinorin A* under the CDSA

Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Controlled Substances and Tobacco and Directorate

June 10, 2010

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10. OUTCOME EVALUATION

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#### 1. ISSUE

In Canada, neither the herb *Salvia divinorum* (*S. divinorum*) nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA). Health Canada has received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *S. divinorum*, particularly given reports from scientific and media sources suggesting that *S. divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has also noted an ongoing media interest regarding the availability of *S. divinorum* in Canada.

#### 2. PURPOSE

To assess *Salvia divinorum* and/or salvinorin A against the criteria for the addition of a substance to one of the Schedules of the CDSA, <sup>and</sup> in order to determine whether or not ~~*S. divinorum*, and/or salvinorin A~~, <sup>they</sup> should be regulated as controlled substances in Canada.

#### 3. CONTEXT

*Salvia divinorum* is a species of sage which belongs to the mint family, and which is found in the form of dried leaves, extract and plant cuttings. Also known as "diviner's sage", the plant is known to induce illusions and hallucinations when chewed or smoked. Salvinorin A, the

psychoactive ingredient in *S. divinorum*, which is also referred to chemically as a neoclerodane diterpene, is found primarily in the leaves, and to a lesser extent in the stems.<sup>1</sup>

*S. divinorum* is widely touted as a "legal" alternative to street drugs on the Internet, and has also been reported to be one of the most prevalently marketed herbal dietary supplements available for use as an alternative to illicit drugs of abuse among adolescents and young adults.<sup>2</sup> While very little is known about how and where *S. divinorum* is sold in Canada, it is suspected that it is mainly purchased over the Internet and/or bought at head shops, and alternative life style stores, etc.

The use of *S. divinorum* as a psychotropic agent first came to Health Canada's attention in 2002. In 2004, Health Canada received four adverse drug reaction (ADR) reports associated with the use of *S. divinorum* as a hallucinogen, with three being considered non-serious (requiring no medical attention) and the fourth being considered serious (medical intervention was required) and involving the concomitant use of alcohol in a person diagnosed with Attention Deficit Disorder.

Further to the receipt of the aforementioned ADRs, the Marketed Health Products Directorate (MHPD) and the Natural Health Products Directorate (NHPD), of the Health Products and Food Branch (HPFB), prepared an issue analysis summary (IAS), which recommended that *S. divinorum* and its active ingredient salvinatorin A be regulated as a controlled substance (a recommendation that was maintained when the IAS was updated in November 2006).

Later, in December 2005, MHPD and NHPD prepared a Signal Assessment (SA) (updated in June 2007) that eventually led to the preparation of a Health Risk Assessment (HRA), which concluded that *S. divinorum* or salvinatorin A-containing health products should be restricted from over-the-counter use. Should any such (unauthorized) health products be found on the Canadian market, they should be removed from sale. Such products would constitute a Type II Health Risk according to the Recall Policy of the Health Products and Food Branch Inspectorate (HPFBI), such a risk is defined as "a situation in which the use of, or exposure to, a product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote".

Further to an ADM discussion in April 2007, the Drug Strategy and Controlled Substances Directorate (DSCSD) organized a meeting with MHPD, NHPD and the Inspectorate of HPFB (HPFBI) to discuss *S. divinorum*. At that time, it was decided that *S. divinorum* would be classified by HPFBI as a Type II substance. HPFBI was to determine compliance activities based on the HRA Type II classification and check with Canada Border Services Agency (CBSA) to determine if any further information regarding *S. divinorum* shipments was available.

<sup>1</sup> U.S. Department of Justice Drug Enforcement Administration. 2002. Drugs and Chemicals of Concern: Salvia Divinorum (salvinatorin A, divinorin A) URL:

[http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm) Nov 2008

<sup>2</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.

On September 13, 2007, a meeting was organized between DSCSD, MHDP, NHPD and HPFBI to discuss what is known about *S. divinorum* from a regulatory perspective and to reach consensus on next steps. It was determined that DSCSD would conduct a scheduling assessment of *S. divinorum* to explore the possibility of scheduling this substance under the CDSA.

The Director Generals of DSCSD, MHPD, TPD and the HPFBI also met on September 26, 2008 to discuss an update on issues relating to *S. divinorum* and to determine an agreed upon approach for subsequent steps. It was decided that media lines and a proposal for an "It's Your Health" article on *S. divinorum* would be prepared, and circulated for comment.

### 3.1 Legislative Frameworks for Drug Control in Canada

#### 3.1.1 Food and Drug Regulations (under the Food and Drug Act)

The *Food and Drug Regulations* (F&DR) serve to ensure the safety, efficacy, and quality of health products offered for sale in Canada, including drugs and medical devices. Prior to being given market authorization, a manufacturer must present substantive scientific evidence of a product's safety, efficacy and quality, and Health Canada reviews this information carefully. If the review is satisfactory, a Notice of Compliance (NOC) is issued and appropriate Drug Identification Numbers (DINs) are assigned.

A "drug" is defined under the F&DR as any substance or mixture of substances manufactured, sold or represented for use in

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
- (b) restoring, correcting or modifying organic functions in human beings or animals, or
- (c) disinfection in premises in which food is manufactured, prepared or kept;

As no products containing *S. divinorum* or its extracts have been reviewed and approved by Health Canada as of January 2010, it is illegal to ~~sell or represent~~ *S. divinorum* as a drug.

#### 3.1.2 Natural Health Product Regulations (under the Food and Drug Act)

The *Natural Health Products Regulations* (NHPR) came into force in January, 2004 to provide Canadians with ready access to natural health products (NHPs) that are safe, effective, and of high quality, while respecting freedom of choice and philosophical and cultural diversity. The NHPR contain a product licensing system that requires that all licensed products display a Natural Product Number (NPN), or, in the case of a homeopathic medicine, Drug Identification Number - Homeopathic Medicine (DIN-HM), on their labels. The number is issued once a product is authorized for sale in Canada by the Natural Health Products Directorate. Product authorization requires either reference to a *natural health product monograph* or submission of other evidence of safety and health claim. A system of site licensing is also included in the

NHPR which requires that all manufacturers, packagers, labellers, and importers be licensed; sites have procedures in place respecting distribution records and product recalls; where applicable, sites have procedures in place for the handling, storage and delivery of their products, and sites meet good manufacturing practice requirements.

The definition of an NHP under the NHPR has both a function and substance component. The function component refers to those substances that are manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
- (b) restoring or correcting organic functions in humans; or
- (c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

The substance component refers to whether the product or medicinal ingredient therein is safe for consideration as an over-the-counter product, can be available for self-care and self-selection, and does not require a prescription to be sold. To be considered a NHP, no direct health claims need to be made regarding the substance. In the case of *S. divinorum*, it is generally marketed for its hallucinogenic properties which are considered a modification of an organic function. Therefore such products would be considered NHPs.

As of January 2010, no products containing *S. divinorum* have been reviewed and approved by Health Canada. Therefore sale of such a product is illegal under the NHPR.

and no NHPs or DIN-NMs have been issued

an unlicensed hallucinogen such as Salvia divinorum

### 3.1.3 Controlled Drugs and Substances Act and its Regulations

The CDSA provides a legislative framework for the control of substances that can alter mental processes and that may produce harm to the health of an individual or to society when diverted or misused. Except as authorized under its regulations, activities such as possession, possession for the purposes of trafficking, trafficking, importation, exportation, possession for the purposes of exportation and production of controlled substances are prohibited under the CDSA.

The substances regulated under the CDSA are grouped into eight Schedules, and each Schedule is associated with particular penalties as described in Part I of the CDSA.

In determining whether a substance should be regulated as a controlled substance, and into which Schedule of the CDSA it should be placed, Health Canada considers the following factors:

- International requirements and trends in control/scheduling;
- Chemical and pharmacological similarity to other substances already scheduled under the CDSA;
- Legitimate uses of the substance (i.e. therapeutic, industrial or commercial);

- Potential for abuse a
- Extent of actual abu
- Overall risk to publi

- updated template? Done.  
 - update DAS table? - See Elizabeth  
 - citation of international legislation? No.

### 3.2 Assessment of Sal

#### 3.2.1 International Reqr

At the present time, neith  
Nations Drug Control C  
substances in any of the

#### **Australia**

In June, 2002, Australia became the first country to prohibit *S. divinorum* and salvinorin A. Although both *S. divinorum* and salvinorin A are listed on Schedule 9 of Australia's Standard for the Uniform Scheduling of Drugs and Poisons on the basis of "high potential for abuse and risk to public health and safety", no substantiation of this risk was provided at the time of this scheduling decision. Schedule 9 is Australia's most restrictive drug schedule, and includes "substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities."<sup>3</sup>

Cite



#### **Belgium**

A decree was passed in Belgium on October 22, 2006 which added *S. divinorum* to the list of controlled substances which includes substances such as psilocybin mushrooms, khat and peyote cactus.<sup>4</sup>

#### **Denmark**

In 2003, Denmark prohibited *S. divinorum* and salvinorin A by adding them to their list of "category B" controlled substances, a category which also includes psilocybin mushrooms, cocaine, amphetamine, and several others substances that are only legal for medicinal and scientific purposes. Illegal possession carries a penalty of up to two years in prison.

#### **Germany**

*S. divinorum* (plant and plant parts) was added to Appendix I of the *Narcotics Act* in Germany on March 1, 2008, making it illegal to produce, traffic, or possess. The law does not specifically

<sup>3</sup> [http://www.cognitiveliberty.org/news/salvia\\_australia.htm](http://www.cognitiveliberty.org/news/salvia_australia.htm)

<sup>4</sup> <http://eldd.emcdda.europa.eu/html.cfm/index5176EN.html?pluginMethod=eldd.shownewsdetails&id=20/12/2006BELGIUM:%20New%20substances%20controlled%20include%20mCPP%20and%20khat>

mention salvinorin A.

### **Italy**

On June 25, 2004, the Italian Ministry of Health issued an ordinance prohibiting the sale of *S. divinorum* and its active constituent salvinorin A. On January 11, 2005, the Ministry of Health made possession of *S. divinorum* and salvinorin A illegal by placing them in "Tabella 1" of the *Tabella Sostanze Stupefacenti o Psicotrope*.

### **Japan**

On November 9, 2006, the Japanese government added a group of thirty-three drugs to its list of controlled substances, including salvinorin A. The drugs will be banned under a revised pharmaceutical law, under which persons involved in their illegal import, production, and sale i.e. (that beyond medical treatment or research purposes,) will be subject to up to five years imprisonment or to a fine of up to five million yen.

### **Spain**

On January 28, 2004 the Spanish Ministry of Health and Consumption issued an order prohibiting the sale of *S. divinorum*, along with a long list of other allegedly "toxic" herbs. The regulation went into effect on May 6, 2004 and only prohibits activities related to commerce. Possession and/or use are not considered to be criminal offences.

→ other ~~European~~ countries.

In Estonia, Finland, Iceland and Norway *S. divinorum* is treated as a medicinal herb and it is illegal to import it without a relevant prescription from a doctor.

### **United States of America**

*S. divinorum* and salvinorin A are not included in the Schedules of the United States *Controlled Substances Act*, although some individual states have implemented laws restricting its use, sale and/or distribution. As of May 2010, nineteen states have enacted legislation placing regulatory controls on *S. divinorum* and/or salvinorin A. Delaware, Florida, Hawaii, Illinois, Kansas, Kentucky, Mississippi, Missouri, Nebraska, North Dakota, Ohio, Oklahoma, South Dakota and Virginia have placed *S. divinorum* and/or salvinorin A into Schedule I of state law.

California, Louisiana, Maine, North Carolina, and Tennessee have enacted other forms of legislation restricting the distribution of the plant.

### **California**

For example, as of January 1, 2009, the sale or distribution of *S. divinorum* or salvinorin A, or any substance or material containing *S. divinorum* or salvinorin A, to any person under 18 years of age became a misdemeanor in the state of California that is now punishable by imprisonment in a county jail for not more than six months, by a fine of no



more than \$1,000, or both.

### **Louisiana**

In 2005, Louisiana passed a bill which prohibits the possession, production, manufacture and distribution of a material, compound, mixture, or preparation intended for human consumption which contains a hallucinogenic plant. A "hallucinogenic plant" is defined as "any part or portion" of the forty plants listed, which includes *S. divinorum*.

### **Maine**

In Maine, *S. divinorum* and salvinorin A are regulated <sup>way similar to</sup> ~~similarly to how~~ tobacco products <sup>in a similar fashion as</sup> are controlled. Adults eighteen years of age or over can legally purchase and use the material, but selling or providing *S. divinorum* or salvinorin A to anyone under the age of eighteen is a criminal offence. Possession by a minor is a civil violation, punishable by a fine, community service, or both.

### **North Carolina**

On February 11, 2009, Senate Bill 138 was introduced to the North Carolina State Legislature which sought to make *Salvia divinorum* and salvinorin A Schedule I controlled substances in that state. This bill was later amended to make possession of *S. divinorum* an infraction, a minor crime punishable by a maximum \$25 fine. A third possession offence would be charged as a misdemeanor. There are no separate penalties for manufacturing or sales. This bill includes two exemptions. One permits growing the plant for aesthetic, landscaping, or decorative purposes; the other allows for university-affiliated medical or pharmacological research. The amended version passed the Senate unanimously on May 14, 2009, the House approved it on August 5, 2009 and it was signed into law on August 28, 2009. The new law came into effect on December 1, 2009.

### **Tennessee**

On July 1, 2006, Tennessee classified the deliberate production, manufacture, distribution, or possession of the active chemical ingredient in the hallucinogenic plant *S. divinorum* as a Class A misdemeanor. It is not however, a criminal offence to possess, plant, cultivate, grow, or harvest *S. divinorum* for aesthetic, landscaping, or decorative purposes. The law also does not apply to any dosage that is legally obtainable from a retail establishment without a prescription when it is recognized by the FDA as a homeopathic drug.

In addition, the U.S. Department of Justice Drug Enforcement Agency (DEA) has also placed *S. divinorum* and salvinorin A on a list of drugs and chemicals "of concern," without legal implications.

### 3.2.2 Chemical and Pharmacological Similarity to Other Substances Listed in the CDSA

The psychoactive ingredient in *Salvia divinorum* is salvinorin A. Other plants which contain psychotropic terpenoids are *Artemisia absinthium* (wormwood) and *Cannabis sativa*. Salvinorin A is considered by some as the most potent natural hallucinogen ever isolated.<sup>5</sup>

Unlike all other hallucinogens, salvinorin A is structurally distinct and does not interact with the serotonin-2A receptor or any other molecular target of classical hallucinogens. It thus affects the brain in a way that is quite unique.<sup>6</sup> Recent pharmacological screenings of receptors have found it to be a highly potent and selective  $\kappa$ -opioid receptor (KOR) agonist.<sup>7</sup>

The psychomimetic effects of *S. divinorum* closely resemble schizophrenia symptoms induced by lysergic acid diethylamide (LSD) or phencyclidine (PCP).<sup>8</sup> Yet, it is said to have only weak influence on the prevailing mood of the user which differentiates it from other hallucinogens such as LSD and psilocybin.<sup>9</sup> Its strong dissociative effects are often compared to those of ketamine. Users have reported that the psychedelic effects of *S. divinorum* were most similar to those caused by psilocybin mushrooms.<sup>10</sup> However, users familiar with the effects of other hallucinogens agree that despite certain similarities to classical hallucinogens, the visions and overall experience is quite unique.<sup>11</sup>

In addition, the psychedelic effects of *S. divinorum* are similar to those of classical psychedelics regarding changes in perception and somatic sensations. *S. divinorum* causes an unusually high degree of sedation, weakness and fatigue, while the increased de-realization is not commonly reported for classical psychedelics.<sup>12</sup> The combination of these effects seems to correlate with that of other KOR agonists such as pentazocine.<sup>13</sup>

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<sup>5</sup> Ott J. Ethnopharmacognosy and human pharmacology of *Salvia divinorum* and salvinorin A. *Curare*. 1995 18: 103-129. Unofficial transcription available online. URL <http://www.sagewisdom.org/ott2.html>

<sup>6</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>7</sup> Roth BL, Baner K, Westkaemper R, Siebert D, Rice KC, Steinberg S, Ernsberger P, Rothman RB. Salvinorin A: a potent naturally occurring nonnitrogenous kappa opioid selective agonist. *Proc Natl Acad Sci U S A*. 2002 Sep 3;99(18):11934-9.

<sup>8</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>9</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>10</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>11</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6 and González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>12</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>13</sup> Arasteh K, Poudevida S, Farre M, Roset PN, Cami J. Response patterns of the Spanish version of the 49-item short form of the Addiction Research Center Inventory after the use of sedatives, stimulants, and opioids. *Drug Alcohol Depend*. 1999 Jun 1;55(1-2):117-25.

### 3.2.3 Legitimate Uses of Salvia Divinorum

presently

There are no legitimate medical or industrial uses for *S. divinorum* in Canada.

*Salvia divinorum* has traditionally been used for spiritual and medicinal purposes by the Mazatec Indians in Oaxaca, Mexico,<sup>14</sup> where an infusion of the leaves or the leaves themselves are ingested to treat gastrointestinal problems, headaches, rheumatism, anemia and swelling of the stomach.<sup>15</sup> Its main use is however for its psychoactive properties in the aid of producing “mystical” or hallucinogenic experiences as part of spiritual rituals.<sup>16</sup>

Although selective kappa receptor agonists have been shown to produce analgesic effects, adverse effects such as psychotomimesis, dysphoria and diuresis have been observed in studies investigating their therapeutic use.<sup>17</sup> It has been speculated that KOR agonists may prove to be useful in the treatment of certain psychiatric disorders including Alzheimer’s disease, schizophrenia, dementia and bipolar disorder.<sup>18</sup> However, much more research is needed in order to substantiate these hypotheses. Another study has suggested that chemical analogues of salvinorin A may be a useful treatment for addiction to other substances.<sup>19</sup>

those suffering from

### 3.2.4 Potential for Abuse Liability and/or Addiction Liability of the Substance

Most clinically used opioid analgesics (e.g. codeine, oxycodone, morphine) are selective for the  $\mu$ -opioid receptor (MOR) and can be habit-forming<sup>23</sup> because activation of the MORs causes euphoria, which makes the user want to take them again. As previously mentioned, salvinorin A

<sup>14</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>15</sup> Munro, T. The Chemistry of Salvia divinorum. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

<sup>16</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage Salvia divinorum. Life Sci. 2005 Dec 22;78(5):527-31.

<sup>17</sup> Barker RL, Fawcett J, Barkin SJ. 2002. Chronic pain management with a focus on the role of newer antidepressants and centrally acting agents. In: Pain Management: A Practical Guide for Clinicians, 6th edition, Weiner RS ed. CRC Press, Boca Raton, FL. pp. 415-34 and Tidgewell et al., 2004. A facile method for the preparation of deuterium labelled salvinorin A: Biorganic & Medicinal Chemistry Letters, 14: 5099-5102.

<sup>18</sup> Sheffler DJ & Roth BL. Salvinorin A: the ‘magic mint’ hallucinogen finds a molecular target in the kappa opioid receptor. Trends Pharmacol Sci. 2003 Mar;24(3):107-109.

<sup>19</sup> Prisinzano TE. Natural products as tools for neuroscience: discovery and development of novel agents to treat drug abuse. J Nat Prod. 2009 Mar 27;72(3):581-7.

<sup>23</sup> Gustein HB & Akil H. Opioid Analgesics. In: Goodman and Gilman’s The Pharmacological Basis of Therapeutics 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.

is a potent, selective agonist of the  $\kappa$ -opioid receptor (KOR), and in contrast to the euphoria produced by MOR agonists, the KOR agonists are negatively reinforcing and aversive.<sup>24</sup> In addition, KOR agonists have analgesic properties but are not associated with respiratory depression like MOR agonists. Initially, these effects provided hope for the development of an analgesic absent of addiction liability and respiratory depression. However, it was soon discovered that KOR agonists produced dysphoria and psychomimetic effects such as confusion, hallucinations and depersonalization.<sup>25</sup> Finally, while MOR increases the release of dopamine, the activation of KOR decreases dopamine release in the nucleus accumbens.<sup>26</sup>

The onset and intensity of the effects of *Salvia divinorum* appear to be related to the route of administration. Traditional uses generally produce mild effects because the leaves are rolled and chewed or crushed and prepared as a foamy infusion whereby the salvinorin A is degraded in the gastrointestinal system before being absorbed into the bloodstream. These methods rely on contact with the oral mucosa for absorption and the level of effect relates quite closely to the length of time the material spends in the mouth. The onset of effect generally takes 5-10 minutes. The effects build over the next hour and last for another hour before they begin to subside.<sup>27</sup>

Routes of administration that avoid the hepatic first-pass effect are the quickest and most intense.<sup>28</sup> Salvinorin A can be isolated from the plant to make a powder which can be vaporized and inhaled. This method of administration is the most powerful and only requires 200-500 micrograms of salvinorin A powder to produce the same effects as those of fresh leaves. The onset of effect felt from vaporizing salvinorin A powder occurs in about 30 seconds and effects last for about 5-10 minutes and then subside over the next 30 minutes.<sup>29</sup>

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<sup>24</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590, Cooper S. Interactions between endogenous opioids and dopamine: Implications for reward and aversion. In: *The Mesolimbic Dopamine System: From Motivation to Action*. Willner P and Scheel-Kruger J (editors) Wiley, Chester, England, 1991, pp. 331-366, and Shippenberg TS, Herz A, Spanagel R, Bals-Kubik R, Stein C. Conditioning of opioid reinforcement: neuroanatomical and neurochemical substrates. *Ann N Y Acad Sci*. 1992 Jun 28;654:347-56.

<sup>25</sup> Pfeiffer A, Brantl V, Herz A, Emrich HM. Psychotomimesis mediated by kappa opiate receptors. *Science*. 1986 Aug 15;233(4765):774-6, Rimoy GH, Wright DM, Bhaskar NK, Rubin PC. The cardiovascular and central nervous system effects in the human of U-62066E. A selective opioid receptor agonist. *Eur J Clin Pharmacol*. 1994;46(3):203-7, and Walsh SL, Strain EC, Abreu ME, Bigelow GE. Enadoline, a selective kappa opioid agonist: comparison with butorphanol and hydromorphone in humans. *Psychopharmacology (Berl)*. 2001 Sep;157(2):151-62.

<sup>26</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.

<sup>27</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>28</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

<sup>29</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

Smoking is by far the most popular method of administration<sup>30</sup> and this is accomplished by smoking the dried leaves or a concentrated extract using a pipe or bong. Dried leaves may also be fortified with a concentrated extract of salvinorin A, and/or a concentrated extract can also be used sublingually. Neither *S. divinorum* nor salvinorin A are injected because the powder is insoluble in water.<sup>31</sup>

The various modes of administration of *S. divinorum* lead to the variable onset and duration of its effects. These effects are generally accepted to be: sensation of becoming an object, visions of various two-dimensional surfaces, films and membranes, revisiting places of the past (particularly childhood), <sup>perceived</sup> loss of the body and/or identity, various sensations of motion (being pulled or twisted by a force of some kind), uncontrollable hysterical laughter, and overlapping realities (perceptions of being in more than one place).<sup>32</sup> Laughter, happiness, sense of well-being and dissociative effects were deemed the best aspects of *S. divinorum* by users, second only to the "trip" that the drug elicits.<sup>33</sup> Depersonalization, speaking gibberish, widening of consciousness, subjective illusions of rapid movement, flying or hovering have also been reported.<sup>34</sup>

The aversive effects of previously studied KOR agonists predict that the risk of addiction to *S. divinorum* is negligible. However, very few controlled scientific studies of the physical and psychotropic effects of *Salvia divinorum* on humans have been carried out. Therefore, <sup>it is difficult</sup> using <sup>these studies</sup> these studies to predict its potential for addiction and abuse is difficult. In studies that have been conducted, there is conflicting information around the addiction liability of *S. divinorum* in both animals and humans. Some users have noted that they require increasing doses of salvinorin A in order to achieve the desired effect, and the stimulated cerebral KOR may act as a mechanism of tolerance.<sup>35</sup> More controlled systematic research in this area is needed. Further studies on the mediated decrease of dopamine as well as the impact of dose on the rewarding and aversive effects are also warranted.

Another aspect of the *S. divinorum* abuse potential stems from its availability. As previously mentioned, it is widely available for purchase on the Internet through drug promotional sites and

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<sup>30</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62 and Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>31</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs.* 1994 Jul-Sep;26(3):277-83.

<sup>32</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>33</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>34</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry.* 2005 Jan;38(1):1-5 and Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>35</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry.* 2005 Jan;38(1):1-5.

it is also sold in various "head shops" and corner stores. In addition, the potential for high yields and ease of extraction may make buying and selling ~~the drug~~ <sup>this substance</sup> quite affordable and attractive. Originally the concerns for the abuse potential were minimal since it was concluded that 1 kg of dried leaves yielded only 3 to 6 human doses of salvinorin A. However, it was discovered that vaporizing and inhaling 200-500 micrograms had profound hallucinogenic effects.<sup>36</sup> The extraction of salvinorin A from the plant is very easy and with care, approximately 1.5 grams of pure salvinorin A per kilogram of dried leaves (8kg of fresh leaves) can be isolated. Therefore, ~~even poor yields of a gram per kilograms of dried leaves would provide enough salvinorin A for~~ <sup>despite for</sup> 2000 human doses.<sup>37</sup> It is <sup>also</sup> believed to be easier to obtain salvinorin A than to extract LSD or produce PCP derivatives.<sup>38</sup> <sup>is enough</sup>

### 3.2.5 Extent of Actual Abuse in Canada and Internationally

Very limited data exists regarding the actual ~~population~~ use of *Salvia divinorum* across the Canadian population. To address this lack of data, questions about the use of *S. divinorum* were included in the 2008-2009 Youth Smoking Survey, the 2009 Canadian Alcohol and Drug Use Monitoring Survey and the 2009 Ontario Student Drug Use and Health Survey.

The results from the 2009 Ontario Student Drug Use and Health Survey were published on November 18, 2009 and indicate that:

- Among all responding students in Ontario, 4.4% report using *Salvia divinorum* at least once in the past year. In comparison, 58.2% indicated they had used alcohol, 25.6% indicated they had used cannabis and 5.0% indicated they had used hallucinogens other than LSD and PCP in the past year;
- Males (6.2%) <sup>are</sup> significantly more likely than females (2.3%) to use *Salvia divinorum*;
- There is significant grade variation, with *Salvia divinorum* use most likely among 11<sup>th</sup> graders (8.6%) and 12<sup>th</sup> graders (8.4%); and
- There are significant regional variations, with students in Northern Ontario (9.2%) most likely to use *Salvia divinorum*.

The results of the 2008-2009 Youth Smoking Survey were <sup>published</sup> ~~released~~ on May 31, 2010 and indicate that:

- 4.9% of students indicated that they had used *S. divinorum* in the last twelve months. In comparison, 53.0% indicated they had used alcohol, 27.3% indicated they had used cannabis and 6.9% indicated they had used other hallucinogens in the last twelve months;
- 2.6% of students in Grades 7-9, <sup>and</sup> 7.0% of students in Grades 10-12 had used *S. divinorum* in the last twelve months; and

<sup>36</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>37</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs.* 1994 Jul-Sep;26(3):277-83.

<sup>38</sup> Bucheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry.* 2005 Jan;38(1):1-5.

- Males (6.6%) <sup>were</sup> are more likely to have used *S. divinorum* in the past twelve months compared to females (3.2%).

The scope of the previously mentioned studies did not provide for any explanations regarding differences in usage between ages, genders and regions. *Given the lack of information surrounding S.d. it is difficult to speculate what may have caused such differences.*

*Additional* Further data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey, will be available in the summer of 2010.

As far as law enforcement is concerned, the Department has only received a limited number of communications indicating concern with respect to *S. divinorum* and none of these have advised that the use of *S. divinorum* poses any threat to public safety.

Health Canada's Drug Analysis Services (DAS) has collected some raw data regarding the number of samples identified as containing salvinorin A in the DAS labs, however, as the plant and/or substance is not in the CDS druglist, it is not possible to have records of any seizures of it in the database. However, there have been a number of samples submitted to DAS for analysis that have been confirmed to contain salvinorin A.

**NUMBER OF SAMPLES FOUND TO CONTAIN SALVINORIN A**

Year Return Completed	Count
2006	6
2007	8
2008	6
2009	To be updated

The National Forensic Laboratory Information System (NFLIS) and the System to Retrieve Information from Drug Evidence (STRIDE) in the United States is a Drug Enforcement Agency (DEA) database that collects scientifically verified data on analyzed samples in state and local forensic labs as well as samples from DEA labs. The following table shows the quantity of *S. divinorum* products that were seized from 2000 through to 2009.

**ANALYZED SALVIA DIVINORUM or SALVINORIN A SEIZURES**

(Number of items/Exhibits)

Source	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009*
NFLIS-State/Local <sup>1</sup>	0	0	0	0	1	8	12	12	70	34
STRIDE <sup>2</sup>	0	0	1	1	1	0	0	0	N/A	N/A
<b>TOTAL</b>	0	0	1	1	2	8	12	12	70	34

Data Source: NFLIS & STRIDE, 2008 data queried 11/24/08, updated 06/10/2010

<sup>1</sup> NFLIS reported seizures of *Salvia divinorum* and/or salvinorin A

<sup>2</sup> STRIDE reported items of *Salvia divinorum*.

\* Includes only January – May data in 2009.

*A few* Two reports regarding the use of *S. divinorum* have been published in the academic literature.

~~The first was~~ <sup>One was</sup> an international case report in which a <sup>19-year-old</sup> young man (~~19 years of age~~) described his perceptions after inhaling smoke from *S. divinorum*. The peak psychotropic effects, including prickling of the skin, fever-like hot flashes, muscular tremor, and depersonalization, were reached in less than five minutes after inhalation of an unknown amount of smoke from burning dried leaves.<sup>40</sup> ~~The second case~~ <sup>Another report</sup> involved a 15-year-old male who presented to psychiatric emergency services with acute onset of paranoia, déjà vu, blunted affect, difficulties in thought processing and slowed speech, after smoking *Salvia divinorum* over an unknown period of time. During his hospitalization all symptoms improved significantly except the feeling of déjà vu. Based on this case presentation, the author suggested that the feelings of déjà vu may be ~~considered~~ long-term effects of *S. divinorum* use.<sup>41</sup> However, given that this is the only case report in which déjà vu was associated with the use of *S. divinorum*, more reports are needed to substantiate this finding.

In addition to the above-mentioned reports, in 2006, a case was reported in the U.S. in which a 17-year-old boy committed suicide after smoking *S. divinorum* for an unknown period of time.<sup>42</sup> It should be noted that alcohol and general depression were the main confounders in this case. After this case was reported, the state of Delaware passing a law which classified *S. divinorum* as a Schedule I controlled substance along with other hallucinogenic substances.

It is difficult to determine the extent of actual abuse of *S. divinorum* as there appear to be inconsistencies in the literature regarding risk aversion. For example, one author states: "Many who have used salvinorin A find the experience extremely unnerving, frightening and overly intense and most have no desire to repeat the experience."<sup>43</sup> However, another study suggested that this is ~~certainly~~ not the experience of all recreational users of *S. divinorum*.<sup>44</sup> ~~Moreover,~~ <sup>Over</sup> eighty percent of users surveyed on a web-based questionnaire about their *S. divinorum* use said that they would probably or definitely use *S. divinorum* again.<sup>45</sup> Users have reported the negative effects of *S. divinorum* as: the short duration of action, lack of control over the experience, persisting negative effects (most often anxiety)<sup>46</sup> sweating, chills, increased diuresis, impaired vigilance,<sup>47</sup> and negative after-effects including tiredness, feeling head heavy, dizziness, physical exhaustion, and some degree of malaise or 'hangover' as they 'comedown' from the drug.<sup>48</sup> However, it is difficult to determine the influence these effects have on the use of *S.*

<sup>41</sup> Singh S. (2007) Adolescent salvia substance abuse. *Addiction*. 102, 823-824.

<sup>42</sup> <http://www.kvbc.com/Global/story.asp?S=4893692>

<sup>43</sup> Turner DM. *Salvinorin - The Psychedelic Essence of Salvia Divinorum*. Panther Press, San Francisco, CA 1996.

<sup>44</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62, Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5, and Valdés LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs*. 1994 Jul-Sep;26(3):277-83.

<sup>45</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>46</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>47</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>48</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia*



*divinorum*.

### 3.2.6 Overall Risk to Public Health and Safety of Canadians

The increase in both the number of enquiries from various municipalities and members of the public and in the amount of media interest regarding the availability of *Salvia divinorum* in Canada may be an indication that the recreational use of *S. divinorum* as a hallucinogen is on the rise in Canada. However, there are no available statistics that indicate there has been a significant increase in *S. divinorum* use in the Canadian population and, in comparison to the use of other drugs such as alcohol and cannabis, the actual use of *S. divinorum* is quite low.

The potential for harm to the user and/or other individuals is primarily related to the hallucinogenic properties of the substance. Users may get up and walk around without apparent awareness of their movements, behaviour or surroundings, and distinction between self and surroundings is often lost. At doses greater than 1mg of salvinorin A, out of body experiences are frequent and loss of consciousness has been reported.<sup>49</sup> There is little information regarding the social behaviours of persons under the influence of *S. divinorum* products, and what risks their activities, such as operating a motorized vehicle, may pose to the general public. There is also very little data regarding the toxicity, teratogenicity and long-term effects of *S. divinorum* use.<sup>50</sup>

As stated earlier, there are no approved medical uses for *S. divinorum* in Canada. Health Canada has also neither received nor approved any submissions for natural health products for sale in Canada. Therefore, products that claim to contain this substance have not been extensively reviewed by Health Canada and as such, may be counterfeit or may contain other ingredients that may pose risks to health. For example, like many drugs of abuse, the users are often unaware of the potency and adulterants in the products they are purchasing. A study by Wolowich *et al.* (2006)<sup>51</sup>, showed that the salvinorin A content in five out of five *S. divinorum* products were ~~were~~ falsely indicated on the label and 4 out of 5 products contained unidentified adulterants (i.e. vitamin E, caffeine).

Health Canada has only anecdotal information about the use and abuse of *S. divinorum* in Canada as well as the threat *S. divinorum* poses to the health and safety of Canadians. Although reports of domestic adverse reactions related to the use of *S. divinorum* as a hallucinogen have been received through the Canada Vigilance database, it is important to note that the number of reports and the nature of reactions reported are not adequate to characterize the risk to the general population. This data can also not be used to determine incidence of use in the general Canadian population.

## 4. ASSESSMENT OF RISKS AND BENEFITS

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*divinorum* among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>49</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>50</sup> Grundmann O, Phipps SM, Zadezensky I, Butterweck V. *Salvia divinorum* and Salvinorin A: An Update on Pharmacology and Analytical Methodology. Planta Med 2007 Jun;73:1039-1046.

<sup>51</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. Pharmacotherapy. 2006 Sep;26(9):1268-72.

s.21(1)(a)

s.21(1)(b)

*Salvia divinorum* is a substance with unknown long term effects that is currently not scheduled under the CDSA. It can be imported and sold legally in Canada to anyone of any age, anywhere in Canada provided it is not represented as a health product, and the *S. divinorum* sold in Canada is currently not subject to any specific quality or safety standards. The available scientific evidence indicates a low potential for abuse of this substance.

There are certain risks associated with ~~the~~ scheduling *Salvia divinorum* and/or salvinorin A under the CDSA. In particular, scheduling *S. divinorum* and/or salvinorin A under the CDSA without sufficient defensible evidence according to the established criteria for scheduling could be precedent-setting in that Health Canada might then have to look at scheduling other plants with psychoactive properties, e.g. Jimsonweed, Datura.

Health Canada only has anecdotal information about the risks associated with the use of *S. divinorum* and/or salvinorin A. However, there is scientific evidence which suggests that this plant and its active ingredient may have the potential to create risks to individual and public health and safety resulting from the unsupervised use of a hallucinogenic substance (i.e. driving under the influence, injuries caused by disassociation with surroundings, loss of consciousness, etc.). In the absence of any type of mechanism of control of these substances, the safety and well-being of Canadians could be at risk.

## 5. IDENTIFICATION AND ANALYSIS OF OPTIONS

**Page(s) 000832 to\à 000833**

**Is(Are) exempted pursuant to section(s)  
est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**

s.21(1)(a)

s.21(1)(b)

7. **CONSIDERATIONS** ← HPFB recommendations.

*S. divinorum*'s KOR-mediated aversive and dysphoric effects do not appear to be hampering its use. Young adults have begun smoking the leaves and leaf extract recreationally.<sup>55</sup> It can be purchased through online botanical companies and other drug promotional sites and is often touted as a legal alternative to substances such as cannabis and mescaline.<sup>56</sup> Interestingly, after being widely available for over a decade, the drug has not had any extreme social impact as did LSD or MDMA.<sup>57</sup>

Over the past few years, there has been an increase in the number of enquiries that Health Canada is receiving from various municipalities and members of the public regarding the availability of *Salvia divinorum* as a hallucinogen. Health Canada has also observed a steady increase in the amount of media interest regarding the availability of *S. divinorum* in Canada. According to currently available statistics, the reported use of *S. divinorum* by young Canadians is much lower than that of alcohol or cannabis.

*Salvia divinorum* meets the definition of a natural health product (NHP) under the *Natural Health Product Regulations* (NHPR). This means that products containing *S. divinorum* must be approved by Health Canada prior to sale in Canada and that product's that are not in compliance with the NHPR may be subject to compliance and enforcement actions. As Health Canada has yet to receive and/or approve any applications for natural health products containing *S. divinorum* for sale on the Canadian market, the sale of such products is illegal. Several challenges also arise with respect to the importation and domestic movement of *S. divinorum* products as they are often declared as incense and therefore cannot be considered unapproved natural health products. r seized.

In addition, compliance and enforcement actions, such as voluntary stop-sales, forfeiture, destruction, and administrative seizure, cannot be implemented unless the labeling of the product indicates that it is to be used for consumption and/or pharmacological effects. The NHPR are therefore limited in their capacity to control the availability of *S. divinorum* beyond the scope of scenarios listed above.

*S. divinorum* and salvinorin A are not structurally similar or even pharmacologically similar to other substances included in the schedules to the CDSA. The abuse liability and potential for dependence of *S. divinorum* is not known as very few controlled scientific studies of the physical

<sup>55</sup> Hazelden Foundation, 2004. Drug Abuse Trends. June 2004. URL: [www.research.hazelden.org](http://www.research.hazelden.org).

<sup>56</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

<sup>57</sup> Munro, T. The Chemistry of *Salvia divinorum*. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

s.21(1)(a)

s.21(1)(b)

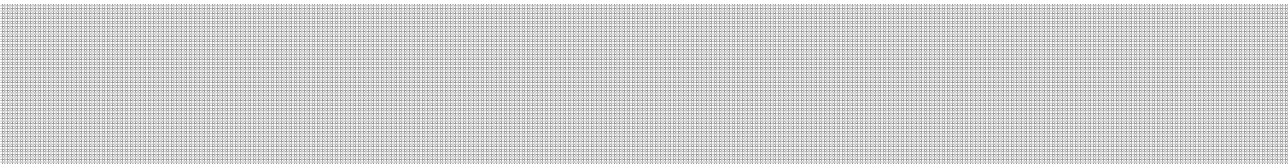
and psychotropic effects of *S. divinorum* have been carried out on humans. More controlled systematic research in this area is needed. Health Canada has only received a limited number of communications regarding *Salvia divinorum* from law enforcement agencies, and none of these have advised that the use of *Salvia divinorum* poses any particular threat to public safety. Evidence of a risk to public health and safety is anecdotal in nature and not quantified in any way as there is a lack of information regarding usage in Canada.

Health Canada is currently finalizing media lines regarding *S. divinorum* as well as an "It's Your Health" article to be published on the Health Canada website. These documents are designed to address the recurrent media attention regarding *S. divinorum* as well as increase public awareness of the risks associated with this substance as well as what Health Canada is doing to safeguard the health of Canadians.

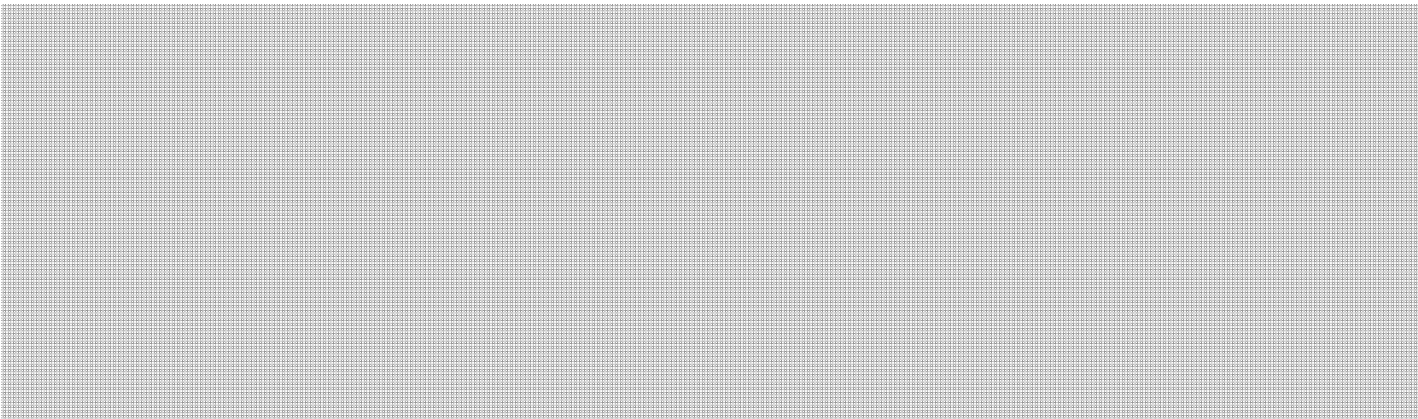
**8. SELECTED STRATEGY**



**9. IMPLEMENTATION AND EVALUATION**



**10. OUTCOME EVALUATION**



(NOT CIRCULATED)

# Issue Analysis Summary

DRAFT

## Scheduling *Salvia Divinorum* and/or *Salvinorin A* under the CDSA

Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Controlled Substances and Tobacco and Directorate

June 11, 2010

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10. OUTCOME EVALUATION

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#### 1. ISSUE

In Canada, neither the herb *Salvia divinorum* (*S. divinorum*) nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA). Health Canada has received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *S. divinorum*, particularly given reports from scientific and media sources suggesting that *S. divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has also noted an ongoing media interest regarding the availability of *S. divinorum* in Canada.

#### 2. PURPOSE

To assess *Salvia divinorum* and/or salvinorin A against the criteria for the addition of a substance to one of the Schedules of the CDSA, and determine whether or not they should be regulated as controlled substances in Canada.

#### 3. CONTEXT

*Salvia divinorum* is a species of sage which belongs to the mint family, and which is found in the form of dried leaves, extract and plant cuttings. Also known as "diviner's sage", the plant is

known to induce illusions and hallucinations when chewed or smoked. Salvinorin A, the psychoactive ingredient in *S. divinorum* (also referred to chemically as a neoclerodane diterpene) is found primarily in the leaves, and to a lesser extent in the stems.<sup>1</sup>

*S. divinorum* is widely touted as a "legal" alternative to street drugs on the Internet, and has also been reported to be one of the most prevalent herbal products available for use as an alternative to illicit drugs of abuse among adolescents and young adults.<sup>2</sup> While very little is known about how and where *S. divinorum* is sold in Canada, it is suspected that it is mainly purchased over the Internet and/or bought at head shops, and alternative life style stores, etc.

The use of *S. divinorum* as a psychotropic agent first came to Health Canada's attention in 2002. In 2004, Health Canada received four adverse drug reaction (ADR) reports associated with the use of *S. divinorum* as a hallucinogen, with three being considered non-serious (requiring no medical attention) and the fourth being considered serious (medical intervention was required), and involving the concomitant use of alcohol in a person diagnosed with Attention Deficit Disorder.

re serious ADR report

Further to the receipt of the aforementioned ADRs, the Marketed Health Products Directorate (MHPD) and the Natural Health Products Directorate (NHPD) of the Health Products and Food Branch (HPFB) prepared an issue analysis summary (IAS), which recommended that *S. divinorum* and its active ingredient salvinorin A be regulated as a controlled substance (a recommendation that was maintained when the IAS was updated in November 2006).

Later, in December 2005, MHPD and NHPD prepared a Signal Assessment (SA) (updated in June 2007) that eventually led to the preparation of a Health Risk Assessment (HRA), which concluded that *S. divinorum* or salvinorin A-containing health products should be restricted from over-the-counter use. Should any such (unauthorized) health products be found on the Canadian market, they should be removed from sale. Such products would constitute a Type II Health Risk according to the Health Hazard Classification of the Recall Policy of the Health Products and Food Branch Inspectorate (HPFBI). Such a risk is defined as "a situation in which the use of, or exposure to, a product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote".

Further to an Assistant Deputy Minister (ADM) discussion in April 2007, the Drug Strategy and Controlled Substances Directorate (DSCSD) organized a meeting with MHPD, NHPD and the Inspectorate of HPFB (HPFBI) to discuss *S. divinorum*. At that time, it was decided that *S. divinorum* would be classified by HPFBI as a Type II substance based on its Health Hazard Classification. HPFBI was to determine appropriate compliance activities regarding *S. divinorum* and check with Canada Border Services Agency (CBSA) to determine if any further

<sup>1</sup> U.S. Department of Justice Drug Enforcement Administration. 2002. Drugs and Chemicals of Concern: Salvia Divinorum (salvinorin A, divinorin A) URL:

[http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm) Nov 2008

<sup>2</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.

information regarding *S. divinorum* shipments was available.

On September 13, 2007, a meeting was organized between DSCSD, MHDP, NHPD and HPFBI to discuss what was known about *S. divinorum* from a regulatory perspective and to reach consensus on the next steps. It was determined that DSCSD would conduct a scheduling assessment of *S. divinorum* to explore the possibility of scheduling this substance under the CDSA.

The Director Generals of DSCSD, MHPD, TPD and the HPFBI also met on September 26, 2008 to discuss an update on issues relating to *S. divinorum* and to determine an agreed upon approach for subsequent steps. It was decided that media lines and a proposal for an "It's Your Health" article on *S. divinorum* would be prepared.

### **3.1 Legislative Frameworks for Drug Control in Canada**

#### **3.1.1 Food and Drug Regulations (under the Food and Drug Act)**

The *Food and Drug Regulations* (F&DR) serve to ensure the safety, efficacy, and quality of health products offered for sale in Canada, including drugs and medical devices. Prior to being given market authorization, a manufacturer must present substantive scientific evidence of a product's safety, efficacy and quality. Health Canada reviews this information carefully and, if the review is satisfactory, a Notice of Compliance (NOC) is issued and appropriate Drug Identification Numbers (DINs) are assigned.

A "drug" is defined under the F&DR as any substance or mixture of substances manufactured, sold or represented for use in :

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
- (b) restoring, correcting or modifying organic functions in human beings or animals, or
- (c) disinfection in premises in which food is manufactured, prepared or kept;

As no products containing *S. divinorum* or its extracts have been reviewed and approved by Health Canada as of January 2010, it is illegal to market *S. divinorum* when it is represented as a drug.

#### **3.1.2 Natural Health Product Regulations (under the Food and Drug Act)**

The *Natural Health Products Regulations* (NHPR) came into force in January 2004 to provide Canadians with ready access to natural health products (NHPs) that are safe, effective, and of high quality, while respecting freedom of choice and philosophical and cultural diversity. The NHPR contain a product licensing system that requires that all licensed products display a



Natural Product Number (NPN), or, in the case of a homeopathic medicine, Drug Identification Number - Homeopathic Medicine (DIN-HM), on their labels. The number is issued once a (NHPR) product is authorized for sale in Canada by the Natural Health Products Directorate. Product authorization requires either reference to a *natural health product monograph* or submission of other evidence of safety and health claim. A system of site licensing is also included in the NHPR which requires that all manufacturers, packagers, labellers, and importers be licensed; sites have procedures in place respecting distribution records and product recalls; where applicable, sites have procedures in place for the handling, storage and delivery of their products, and sites meet good manufacturing practice requirements.

The definition of an NHP under the NHPR has both a function and substance component. The function component refers to those substances that are manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
- (b) restoring or correcting organic functions in humans; or
- (c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

The substance component refers to whether the product or medicinal ingredient therein is safe for consideration as an over-the-counter product, can be available for self-care and self-selection, and does not require a prescription to be sold. To be considered a NHP, no direct health claims need to be made regarding the substance. In the case of *S. divinorum*, it is generally marketed for its hallucinogenic properties which are considered a modification of an organic function. Therefore such products would be considered NHPs.

As of January 2010, no products containing *S. divinorum* have been reviewed and approved by Health Canada and no NPNs or DIN-HMs have been issued. Therefore sale of an unlicensed hallucinogen such as *S. divinorum* is illegal under the NHPR.

### 3.1.3 Controlled Drugs and Substances Act and its Regulations

The CDSA provides a legislative framework for the control of substances that can alter mental processes and that may produce harm to the health of an individual or to society when diverted or misused. Except as authorized under its regulations, activities such as possession, possession for the purposes of trafficking, trafficking, importation, exportation, possession for the purposes of exportation and production of controlled substances are prohibited under the CDSA.

The substances regulated under the CDSA are grouped into eight Schedules, and each Schedule is associated with particular penalties as described in Part I of the CDSA.

In determining whether a substance should be regulated as a controlled substance, and into which Schedule of the CDSA it should be placed, Health Canada considers the following factors:

- International requirements and trends in control/scheduling;
- Chemical and pharmacological similarity to other substances already scheduled under the CDSA;
- Legitimate uses of the substance (i.e. therapeutic, industrial or commercial);
- Potential for abuse and/or addiction liability of the substance;
- Extent of actual abuse in Canada and internationally; and
- Overall risk to public health and safety of Canadians.

### **3.2 Assessment of *Salvia Divinorum* for Scheduling Purposes**

#### **3.2.1 International Requirements and Trends in Control/Scheduling**

At the present time, neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and therefore do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these conventions.

#### ***Australia***

In June 2002, Australia became the first country to prohibit *S. divinorum* and salvinorin A. Although both *S. divinorum* and salvinorin A are listed on Schedule 9 of Australia's Standard for the Uniform Scheduling of Drugs and Poisons on the basis of "high potential for abuse and risk to public health and safety", no substantiation of this risk was provided at the time of this scheduling decision.<sup>3</sup> Schedule 9 is Australia's most restrictive drug schedule, and includes "substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities."<sup>4</sup>

#### ***Belgium***

A decree was passed in Belgium on October 22, 2006 which added *S. divinorum* to the list of controlled substances which includes substances such as psilocybin mushrooms, khat and peyote cactus.<sup>5</sup>

#### ***Denmark***

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<sup>3</sup> <http://www.tga.gov.au/ndpsc/record/rr200111.pdf>

<sup>4</sup> [http://www.cognitiveliberty.org/news/salvia\\_australia.htm](http://www.cognitiveliberty.org/news/salvia_australia.htm)

<sup>5</sup>

<http://eldd.emcdda.europa.eu/html.cfm/index5176EN.html?pluginMethod=eldd.shownewsdetails&id=20/12/2006BELGIUM.%20New%20substances%20controlled%20include%20mCPP%20and%20khat>

In 2003, Denmark prohibited *S. divinorum* and salvinorin A by adding them to their list of "category B" controlled substances, a category which also includes psilocybin mushrooms, cocaine, amphetamine, and several others substances that are only legal for medicinal and scientific purposes. Illegal possession carries a penalty of up to two years in prison.

### ***Germany***

*S. divinorum* (plant and plant parts) was added to Appendix I of the *Narcotics Act* in Germany on March 1, 2008, making it illegal to produce, traffic, or possess. The law does not specifically mention salvinorin A.

### ***Italy***

On June 25, 2004, the Italian Ministry of Health issued an ordinance prohibiting the sale of *S. divinorum* and its active constituent salvinorin A. On January 11, 2005, the Ministry of Health made possession of *S. divinorum* and salvinorin A illegal by placing them in "Tabella 1" of the *Tabella Sostanze Stupefacenti o Psicotrope*.

### ***Japan***

On November 9, 2006, the Japanese government added a group of thirty-three drugs to its list of controlled substances, including salvinorin A. The drugs will be banned under a revised pharmaceutical law, under which persons involved in their illegal import, production, and sale (that beyond medical treatment or research purposes) will be subject to up to five years imprisonment or to a fine of up to five million yen.

### ***Spain***

On January 28, 2004 the Spanish Ministry of Health and Consumption issued an order prohibiting the sale of *S. divinorum*, along with a long list of other allegedly toxic herbs. The regulation went into effect on May 6, 2004 and only prohibits activities related to commerce. Possession and/or use are not considered to be criminal offences.

### ***Other Countries***

*Salvia divinorum* is illegal to possess or sell in Croatia, Latvia, Lithuania, Poland, Romania, South Korea and Sweden. In Russia it is illegal to grow or sell *S. divinorum*, but it is legal to possess it. In Estonia, Finland, Iceland and Norway, *S. divinorum* is treated as a medicinal herb and it is illegal to import it without a relevant prescription from a doctor.

### ***United States of America***

*S. divinorum* and salvinorin A are not included in the Schedules of the United States *Controlled Substances Act*, although some individual states have implemented laws restricting its use, sale

and/or distribution. As of May 2010, nineteen states have enacted legislation placing regulatory controls on *S. divinorum* and/or salvinorin A. Delaware, Florida, Hawaii, Illinois, Kansas, Kentucky, Mississippi, Missouri, Nebraska, North Dakota, Ohio, Oklahoma, South Dakota and Virginia have placed *S. divinorum* and/or salvinorin A into Schedule I of state law.

California, Louisiana, Maine, North Carolina, and Tennessee have enacted other forms of legislation restricting the distribution of the plant.

### ***California***

As of January 1, 2009, the sale or distribution of *S. divinorum* or salvinorin A, or any substance or material containing *S. divinorum* or salvinorin A, to any person under 18 years of age became a misdemeanor in the state of California that is now punishable by imprisonment in a county jail for not more than six months, by a fine of no more than \$1,000, or both.

### ***Louisiana***

In 2005, Louisiana passed a bill which prohibits the possession, production, manufacture and distribution of a material, compound, mixture, or preparation intended for human consumption which contains a hallucinogenic plant. A "hallucinogenic plant" is defined as "any part or portion" of the forty plants listed, which includes *S. divinorum*.

### ***Maine***

In Maine, *S. divinorum* and salvinorin A are regulated in a way similar to how tobacco products are controlled. Adults eighteen years of age or over can legally purchase and use the material, but selling or providing *S. divinorum* or salvinorin A to anyone under the age of eighteen is a criminal offence. Possession by a minor is a civil violation, punishable by a fine, community service, or both.

### ***North Carolina***

On February 11, 2009, Senate Bill 138 was introduced to the North Carolina State Legislature which sought to make *Salvia divinorum* and salvinorin A Schedule I controlled substances in that state. This bill was later amended to make possession of *S. divinorum* an infraction, a minor crime punishable by a maximum \$25 fine. A third possession offence would be charged as a misdemeanor. There are no separate penalties for manufacturing or sales. This bill includes two exemptions. One permits growing the plant for aesthetic, landscaping, or decorative purposes; the other allows for university-affiliated medical or pharmacological research. ~~The amended version passed the Senate unanimously on May 14, 2009, the House approved it on August 5, 2009 and it was signed into law on August 28, 2009.~~ The new law came into effect on December 1, 2009.

## *Tennessee*

On July 1, 2006, Tennessee classified the deliberate production, manufacture, distribution, or possession of the active chemical ingredient in the hallucinogenic plant *S. divinorum* as a Class A misdemeanor. It is not, however, a criminal offence to possess, plant, cultivate, grow, or harvest *S. divinorum* for aesthetic, landscaping, or decorative purposes. The law also does not apply to any dosage that is legally obtainable from a retail establishment without a prescription when it is recognized by the Food and Drug Administration as a homeopathic drug.

In addition, the U.S. Department of Justice Drug Enforcement Agency (DEA) has ~~also~~ placed *S. divinorum* and salvinorin A on a list of drugs and chemicals "of concern," without legal implications.

### 3.2.2 Chemical and Pharmacological Similarity to Other Substances Listed in the CDSA

The psychoactive ingredient in *Salvia divinorum* is salvinorin A. Other plants which contain psychotropic terpenoids are *Artemisia absinthium* (wormwood) and *Cannabis sativa*. Salvinorin A is considered by some as the most potent natural hallucinogen ever isolated.<sup>6</sup>

Unlike all other hallucinogens, salvinorin A is structurally distinct and does not interact with the serotonin-2A receptor or any other molecular target of classical hallucinogens. It thus affects the brain in a way that is quite unique.<sup>7</sup> Recent pharmacological screenings of receptors have found it to be a highly potent and selective  $\kappa$ -opioid receptor (KOR) agonist.<sup>8</sup>

The psychomimetic effects of *S. divinorum* closely resemble schizophrenia symptoms induced by lysergic acid diethylamide (LSD) or phencyclidine (PCP).<sup>9</sup> Yet, it is said to have only weak influence on the prevailing mood of the user which differentiates it from other hallucinogens such as LSD and psilocybin.<sup>10</sup> Its strong dissociative effects are often compared to those of ketamine. Users have reported that the psychedelic effects of *S. divinorum* were most similar to

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<sup>6</sup> Ott J. Ethnopharmacognosy and human pharmacology of *Salvia divinorum* and salvinorin A. *Curare*. 1995 18: 103-129. Unofficial transcription available online. URL <http://www.sagewisdom.org/ott2.html>

<sup>7</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>8</sup> Roth BL, Baner K, Westkaemper R, Siebert D, Rice KC, Steinberg S, Ernsberger P, Rothman RB. Salvinorin A: a potent naturally occurring nonnitrogenous kappa opioid selective agonist. *Proc Natl Acad Sci U S A*. 2002 Sep 3;99(18):11934-9.

<sup>9</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>10</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

those caused by psilocybin mushrooms.<sup>11</sup> However, users familiar with the effects of other hallucinogens agree that despite certain similarities to classical hallucinogens, the visions and overall experience is quite unique.<sup>12</sup>

In addition, the psychedelic effects of *S. divinorum* are similar to those of classical psychedelics regarding changes in perception and somatic sensations. *S. divinorum* causes an unusually high degree of sedation, weakness and fatigue, while the increased de-realization is not commonly reported for classical psychedelics.<sup>13</sup> The combination of these effects seems to correlate with that of other KOR agonists such as pentazocine.<sup>14</sup>

### 3.2.3 Legitimate Uses of Salvia Divinorum

There are presently no legitimate medical or industrial uses for *S. divinorum* in Canada.

*Salvia divinorum* has traditionally been used for spiritual and medicinal purposes by the Mazatec Indians in Oaxaca, Mexico,<sup>15</sup> where an infusion of the leaves or the leaves themselves are ingested to treat gastrointestinal problems, headaches, rheumatism, anemia and swelling of the stomach.<sup>16</sup> Its main use is, however, for its psychoactive properties in the aid of producing “mystical” or hallucinogenic experiences as part of spiritual rituals.<sup>17</sup>

Although selective kappa receptor agonists have been shown to produce analgesic effects, adverse effects such as psychotomimesis, dysphoria and diuresis have been observed in studies investigating their therapeutic use.<sup>18</sup> It has been speculated that KOR agonists may prove to be useful in the treatment of certain psychiatric disorders including Alzheimer’s disease, schizophrenia, dementia and bipolar disorder.<sup>19</sup> However, much more research is needed in

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<sup>11</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>12</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6 and González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>13</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>14</sup> Arasteh K, Poudevida S, Farre M, Roset PN, Cami J. Response patterns of the Spanish version of the 49-item short form of the Addiction Research Center Inventory after the use of sedatives, stimulants, and opioids. Drug Alcohol Depend. 1999 Jun 1;55(1-2):117-25.

<sup>15</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>16</sup> Munro, T. The Chemistry of Salvia divinorum. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

<sup>17</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage Salvia divinorum. Life Sci. 2005 Dec 22;78(5):527-31.

<sup>18</sup> Barker RL, Fawcett J, Barkin SJ. 2002. Chronic pain management with a focus on the role of newer antidepressants and centrally acting agents. In: Pain Management: A Practical Guide for Clinicians, 6th edition, Weiner RS ed. CRC Press, Boca Raton, FL. pp. 415-34 and Tidgewell et al., 2004. A facile method for the preparation of deuterium labelled salvinorin A: Biorganic & Medicinal Chemistry Letters, 14: 5099-5102.

<sup>19</sup> Sheffler DJ & Roth BL. Salvinorin A: the ‘magic mint’ hallucinogen finds a molecular target in the kappa opioid receptor. Trends Pharmacol Sci. 2003 Mar;24(3):107-109.

order to substantiate these hypotheses. Another study has suggested that chemical analogues of salvinorin A may be a useful treatment for those suffering from addiction to other substances.<sup>20</sup>

### 3.2.4 Potential for Abuse Liability and/or Addiction Liability of the Substance

Most clinically used opioid analgesics (e.g. codeine, oxycodone, morphine) are selective for the  $\mu$ -opioid receptor (MOR) and can be habit-forming<sup>24</sup> because activation of the MORs causes euphoria, which makes the user want to take them again. As previously mentioned, salvinorin A is a potent, selective agonist of the  $\kappa$ -opioid receptor (KOR), and in contrast to the euphoria produced by MOR agonists, the KOR agonists are negatively reinforcing and aversive.<sup>25</sup> In addition, KOR agonists have analgesic properties but are not associated with respiratory depression like MOR agonists. Initially, these effects provided hope for the development of an analgesic absent of addiction liability and respiratory depression. However, it was soon discovered that KOR agonists produced dysphoria and psychomimetic effects such as confusion, hallucinations and depersonalization.<sup>26</sup> Finally, while MOR increases the release of dopamine, the activation of KOR decreases dopamine release in the nucleus accumbens.<sup>27</sup>

The onset and intensity of the effects of *Salvia divinorum* appear to be related to the route of administration. Traditional uses generally produce mild effects because the leaves are rolled and

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<sup>20</sup> Prisinzano TE. Natural products as tools for neuroscience: discovery and development of novel agents to treat drug abuse. *J Nat Prod*. 2009 Mar 27;72(3):581-7.

<sup>24</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.

<sup>25</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590, Cooper S. Interactions between endogenous opioids and dopamine: Implications for reward and aversion. In: *The Mesolimbic Dopamine System: From Motivation to Action*. Willner P and Scheel-Kruger J (editors) Wiley, Chester, England, 1991, pp. 331-366, and Shippenberg TS, Herz A, Spanagel R, Bals-Kubik R, Stein C. Conditioning of opioid reinforcement: neuroanatomical and neurochemical substrates. *Ann N Y Acad Sci*. 1992 Jun 28;654:347-56.

<sup>26</sup> Pfeiffer A, Brantl V, Herz A, Emrich HM. Psychotomimesis mediated by kappa opiate receptors. *Science*. 1986 Aug 15;233(4765):774-6, Rimoy GH, Wright DM, Bhaskar NK, Rubin PC. The cardiovascular and central nervous system effects in the human of U-62066E. A selective opioid receptor agonist. *Eur J Clin Pharmacol*. 1994;46(3):203-7, and Walsh SL, Strain EC, Abreu ME, Bigelow GE. Enadoline, a selective kappa opioid agonist: comparison with butorphanol and hydromorphone in humans. *Psychopharmacology (Berl)*. 2001 Sep;157(2):151-62.

<sup>27</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.

chewed or crushed and prepared as a foamy infusion whereby the salvinorin A is degraded in the gastrointestinal system before being absorbed into the bloodstream. These methods rely on contact with the oral mucosa for absorption and the level of effect relates quite closely to the length of time the material spends in the mouth. The onset of effect generally takes 5-10 minutes. The effects build over the next hour and last for another hour before they begin to subside.<sup>28</sup>

Routes of administration that avoid the hepatic first-pass effect are the quickest and most intense.<sup>29</sup> Salvinorin A can be isolated from the plant to make a powder which can be vaporized and inhaled. This method of administration is the most powerful and only requires 200-500 micrograms of salvinorin A powder to produce the same effects as those of fresh leaves. The onset of effects felt from vaporizing salvinorin A powder occurs in about 30 seconds and effects last for about 5-10 minutes and then subside over the next 30 minutes.<sup>30</sup> Smoking is by far the most popular method of administration<sup>31</sup> and this is accomplished by smoking the dried leaves or a concentrated extract using a pipe or bong. Dried leaves may also be fortified with a concentrated extract of salvinorin A. A concentrated extract can also be used sublingually. Neither *S. divinorum* nor salvinorin A are injected because the powder is insoluble in water.<sup>32</sup>

The various modes of administration of *S. divinorum* lead to the variable onset and duration of its effects. These effects are generally accepted to be: sensation of becoming an object, visions of various two-dimensional surfaces, films and membranes, revisiting places of the past (particularly childhood), perceived loss of the body and/or identity, various sensations of motion (being pulled or twisted by a force of some kind), uncontrollable hysterical laughter, and overlapping realities (perceptions of being in more than one place).<sup>33</sup> Laughter, happiness, sense of well-being and dissociative effects were deemed the best aspects of *S. divinorum* by users, second only to the "trip" that the drug elicits.<sup>34</sup> Depersonalization, speaking gibberish, widening of consciousness, subjective illusions of rapid movement, flying or hovering have also been reported.<sup>35</sup>

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<sup>28</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>29</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.

<sup>30</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>31</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62 and Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>32</sup> Valdés LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs.* 1994 Jul-Sep;26(3):277-83.

<sup>33</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>34</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>35</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage).



The aversive effects of previously studied KOR agonists predict that the risk of addiction to *S. divinorum* is negligible. However, very few controlled scientific studies of the physical and psychotropic effects of *Salvia divinorum* on humans have been carried out. Therefore, it is difficult to predict its potential for addiction and abuse. In studies that have been conducted, there is conflicting information around the addiction liability of *S. divinorum* in both animals and humans. Some users have noted that they require increasing doses of salvinorin A in order to achieve the desired effect and the stimulated cerebral KOR may act as a mechanism of tolerance.<sup>36</sup> More controlled systematic research in this area is needed. Further studies on the mediated decrease of dopamine as well as the impact of dose on the rewarding and aversive effects are also warranted.

Another aspect of the *S. divinorum* abuse potential stems from its availability. As previously mentioned, it is widely available for purchase on the Internet through drug promotional sites and it is also sold in various "head shops" and corner stores. In addition, the potential for high yields and ease of extraction may make buying and selling this substance quite affordable and attractive. Originally the concerns for the ~~abuse potential~~<sup>for abuse</sup> were minimal ~~since~~<sup>as</sup> it was concluded that 1 kg of dried leaves yielded only 3 to 6 human doses of salvinorin A. However, it was discovered that vaporizing and inhaling 200-500 micrograms had profound hallucinogenic effects.<sup>37</sup> The extraction of salvinorin A from the plant is very easy and with care, approximately 1.5 grams of pure salvinorin A per kilogram of dried leaves (8kg of fresh leaves) can be isolated. ~~Therefore, despite poor yields,~~<sup>to provide</sup> a gram of salvinorin A is enough substance for 2000 human doses.<sup>38</sup> It is also believed to be easier to obtain salvinorin A than to extract LSD or produce PCP derivatives.<sup>39</sup>

### 3.2.5 Extent of Actual Abuse in Canada and Internationally

Very limited data exists regarding the population use of *Salvia divinorum* across the Canadian population. To address this lack of data, questions about the use of *S. divinorum* were included in the 2008-2009 Youth Smoking Survey, the 2009 Canadian Alcohol and Drug Use Monitoring Survey and the 2009 Ontario Student Drug Use and Health Survey.

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Pharmacopsychiatry. 2005 Jan;38(1):1-5 and Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>36</sup> Bucheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5.

<sup>37</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>38</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. J Psychoactive Drugs. 1994 Jul-Sep;26(3):277-83.

<sup>39</sup> Bucheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5.

The results from the 2009 Ontario Student Drug Use and Health Survey were published on November 18, 2009 and indicate that:

- Among all responding students in Ontario, 4.4% reported using *Salvia divinorum* at least once in the past year. In comparison, 58.2% indicated they had used alcohol, 25.6% indicated they had used cannabis and 5.0% indicated they had used hallucinogens other than LSD and PCP in the past year;
- Males (6.2%) were significantly more likely than females (2.3%) to report using *Salvia divinorum*;
- There is significant grade variation, with *Salvia divinorum* use most likely among 11<sup>th</sup> graders (8.6%) and 12<sup>th</sup> graders (8.4%); and
- There are significant regional variations, with students in Northern Ontario (9.2%) most likely to use *Salvia divinorum*.

The results of the 2008-2009 Youth Smoking Survey were published on May 31, 2010 and indicate that:

- 4.9% of students <sup>stated</sup> indicated that they had used *S. divinorum* in the last twelve months. In comparison, 53.0% indicated they had used alcohol, 27.3% indicated they had used cannabis and 6.9% indicated they had used other hallucinogens in the last twelve months;
- 2.6% of students in Grades 7-9 and 7.0% of students in Grades 10-12 had used *S. divinorum* in the last twelve months; and
- Males (6.6%) were more likely to have used *S. divinorum* in the past twelve months compared to females (3.2%).

The scope of the previously mentioned studies did not provide for any explanations regarding differences in usage between ages, genders and regions. Given the lack of information surrounding *S. divinorum*, it is difficult to speculate on the causality of such differences.

Additional data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey will be available in the summer of 2010.

As far as law enforcement is concerned, the Department has only received a limited number of communications indicating concern with respect to *S. divinorum* and none of these have advised that the use of *S. divinorum* poses any threat to public safety.

Health Canada's Drug Analysis Services (DAS) has collected some raw data regarding the number of samples identified as containing salvinorin A in the DAS labs, however, as the plant and/or substance is not in the Controlled Drugs and Substances Database (CDS) druglist, it is not possible to have records of any seizures of it in the database. However, there have been a number of samples submitted to DAS for analysis that have been confirmed to contain salvinorin A.

**NUMBER OF SAMPLES FOUND TO CONTAIN SALVINORIN A**

Year Return Completed	Count
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2006	6
2007	8
2008	6
2009	To be updated

The National Forensic Laboratory Information System (NFLIS) and the System to Retrieve Information from Drug Evidence (STRIDE) in the United States is a Drug Enforcement Agency (DEA) database that collects scientifically verified data on analyzed samples in state and local forensic labs as well as samples from DEA labs. The following table shows the quantity of *S. divinorum* products that were seized from 2000 through to 2009.

**ANALYZED SALVIA DIVINORUM or SALVINORIN A SEIZURES**

(Number of items/Exhibits)

Source	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009*
NFLIS-State/Local <sup>1</sup>	0	0	0	0	1	8	12	12	70	34
STRIDE <sup>2</sup>	0	0	1	1	1	0	0	0	N/A	N/A
<b>TOTAL</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>1</b>	<b>2</b>	<b>8</b>	<b>12</b>	<b>12</b>	<b>70</b>	<b>34</b>

Data Source: NFLIS & STRIDE, 2008 data queried 11/24/08, updated 06/10/2010

<sup>1</sup> NFLIS reported seizures of *Salvia divinorum* and/or salvinorin A

<sup>2</sup> STRIDE reported items of *Salvia divinorum*.

\* Includes only January – May data in 2009.

A handful of case reports regarding the use of *S. divinorum* have been published in the academic literature. One report was an international case report in which a young man (19 years of age) described his perceptions after inhaling smoke from *S. divinorum*. The peak psychotropic effects, including prickling of the skin, fever-like hot flashes, muscular tremor, and depersonalization, were reached in less than five minutes after inhalation of an unknown amount of smoke from burning dried leaves.<sup>41</sup> Another report involved a 15-year-old male who presented to psychiatric emergency services with acute onset of paranoia, déjà vu, blunted affect, difficulties in thought processing and slowed speech after smoking *Salvia divinorum* over an unknown period of time. During his hospitalization all symptoms improved significantly except the feeling of déjà vu. Based on this case presentation, the author suggested that the feelings of déjà vu may be a long-term effect of *S. divinorum* use.<sup>42</sup> However, given that this is the only case report in which déjà vu was associated with the use of *S. divinorum*, more reports are needed to substantiate this finding.

In addition to the above-mentioned reports, in 2006, a case was reported in the U.S. in which a 17-year-old boy committed suicide after smoking *S. divinorum* for an unknown period of time.<sup>43</sup> It should be noted that alcohol and general depression were the main confounders in this case. After this case was reported, the state of Delaware passing a law which classified *S. divinorum* as a Schedule I controlled substance along with other hallucinogenic substances.

<sup>42</sup> Singh S. (2007) Adolescent salvia substance abuse. *Addiction*. 102, 823-824.

<sup>43</sup> <http://www.kvbc.com/Global/story.asp?S=4893692>

It is difficult to determine the extent of actual abuse of *S. divinorum* as there appear to be inconsistencies in the literature regarding risk aversion. For example, one author states: "Many who have used salvinorin A find the experience extremely unnerving, frightening and overly intense and most have no desire to repeat the experience."<sup>44</sup> However, another study suggested that this is not the experience of all recreational users of *S. divinorum*.<sup>45</sup> Over eighty percent of users surveyed on a web-based questionnaire about their *S. divinorum* use said that they would probably or definitely use *S. divinorum* again.<sup>46</sup> Users have reported the negative effects of *S. divinorum* as: the short duration of action, lack of control over the experience, persisting negative effects (most often anxiety)<sup>47</sup> sweating, chills, increased diuresis, impaired vigilance,<sup>48</sup> and negative after-effects including tiredness, feeling head heavy, dizziness, physical exhaustion, and some degree of malaise or 'hangover' as they 'comedown' from the drug.<sup>49</sup> However, it is difficult to determine the influence these effects have on the use of *S. divinorum*.

### 3.2.6 Overall Risk to Public Health and Safety of Canadians

The increase in both the number of enquiries from various municipalities and members of the public and in the amount of media interest regarding the availability of *Salvia divinorum* in Canada may be an indication that the recreational use of *S. divinorum* as a hallucinogen is on the rise in Canada. However, there are no available statistics that indicate there has been a significant increase in *S. divinorum* use in the Canadian population and, in comparison to the use of other drugs such as alcohol and cannabis, the actual use of *S. divinorum* is quite low.

The potential for harm to the user and/or other individuals is primarily related to the hallucinogenic properties of the substance. Users may get up and walk around without apparent awareness of their movements, behaviour or surroundings, and distinction between self and surroundings is often lost. At doses greater than 1mg of salvinorin A, out of body experiences are frequent and loss of consciousness has been reported.<sup>50</sup> There is little information regarding the social behaviours of persons under the influence of *S. divinorum* products, and what risks their activities such as operating a motorized vehicle may pose to the general public. There is also very little data regarding the toxicity, teratogenicity and long-term effects of *S. divinorum*

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<sup>44</sup> Turner DM. Salvinorin - The Psychedelic Essence of Salvia Divinorum. Panther Press, San Francisco, CA 1996.

<sup>45</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62, Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5, and Valdès LJ 3rd. Salvia divinorum and the unique diterpene hallucinogen, Salvinorin (divinorin) A. J Psychoactive Drugs. 1994 Jul-Sep;26(3):277-83.

<sup>46</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>47</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>48</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5.

<sup>49</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>50</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

use.<sup>51</sup>

As stated earlier, there are no approved medical uses for *S. divinorum* in Canada. Health Canada has also neither received nor approved any submissions for natural health products for sale in Canada. Therefore, products that claim to contain this substance have not been extensively reviewed by Health Canada and as such, may be counterfeit or may contain other ingredients that may pose risks to health. For example, like many drugs of abuse, the users are often unaware of the potency and adulterants in the products they are purchasing. A study by Wolowich *et al.* (2006)<sup>52</sup>, showed that the salvinorin A content in five out of five *S. divinorum* products were ~~were~~ <sup>were</sup> falsely indicated on the label and 4 out of 5 products contained unidentified adulterants (i.e. vitamin E, caffeine).

Health Canada has only anecdotal information about the use and abuse of *S. divinorum* in Canada as well as the threat *S. divinorum* may pose to the health and safety of Canadians. Although reports of domestic adverse reactions related to the use of *S. divinorum* as a hallucinogen have been received through the Canada Vigilance database, it is important to note that the number of reports and the nature of reactions reported are not adequate to characterize the risk to the general population. This data can also not be used to determine incidence of use in the Canadian population.

#### 4. ASSESSMENT OF RISKS AND BENEFITS

*Salvia divinorum* is a substance with unknown long term effects that is currently not scheduled under the CDSA. It can be imported and sold legally in Canada to anyone of any age, anywhere in Canada provided it is not represented as a health product. The *S. divinorum* sold in Canada is currently not subject to any specific quality or safety standards. The available scientific evidence indicates a low potential for abuse of this substance.

There are certain risks associated with scheduling *Salvia divinorum* and/or salvinorin A under the CDSA. In particular, scheduling *S. divinorum* and/or salvinorin A under the CDSA without sufficient defensible evidence <sup>in accordance with</sup> according to the established criteria for scheduling could be precedent-setting in that Health Canada might then have to look at scheduling other plants with psychoactive properties, e.g. Jimsonweed, Datura.

Health Canada only has anecdotal information about the risks associated with the use of *S. divinorum* and/or salvinorin A. However, there is scientific evidence which suggests that this plant and its active ingredient may have the potential to create risks to individual and public health and safety resulting from the unsupervised use of a hallucinogenic substance (i.e. driving under the influence, injuries caused by disassociation with surroundings, loss of consciousness, etc.). In the absence of any type of mechanism of control of these substances, the safety and well-being of Canadians could be at risk.

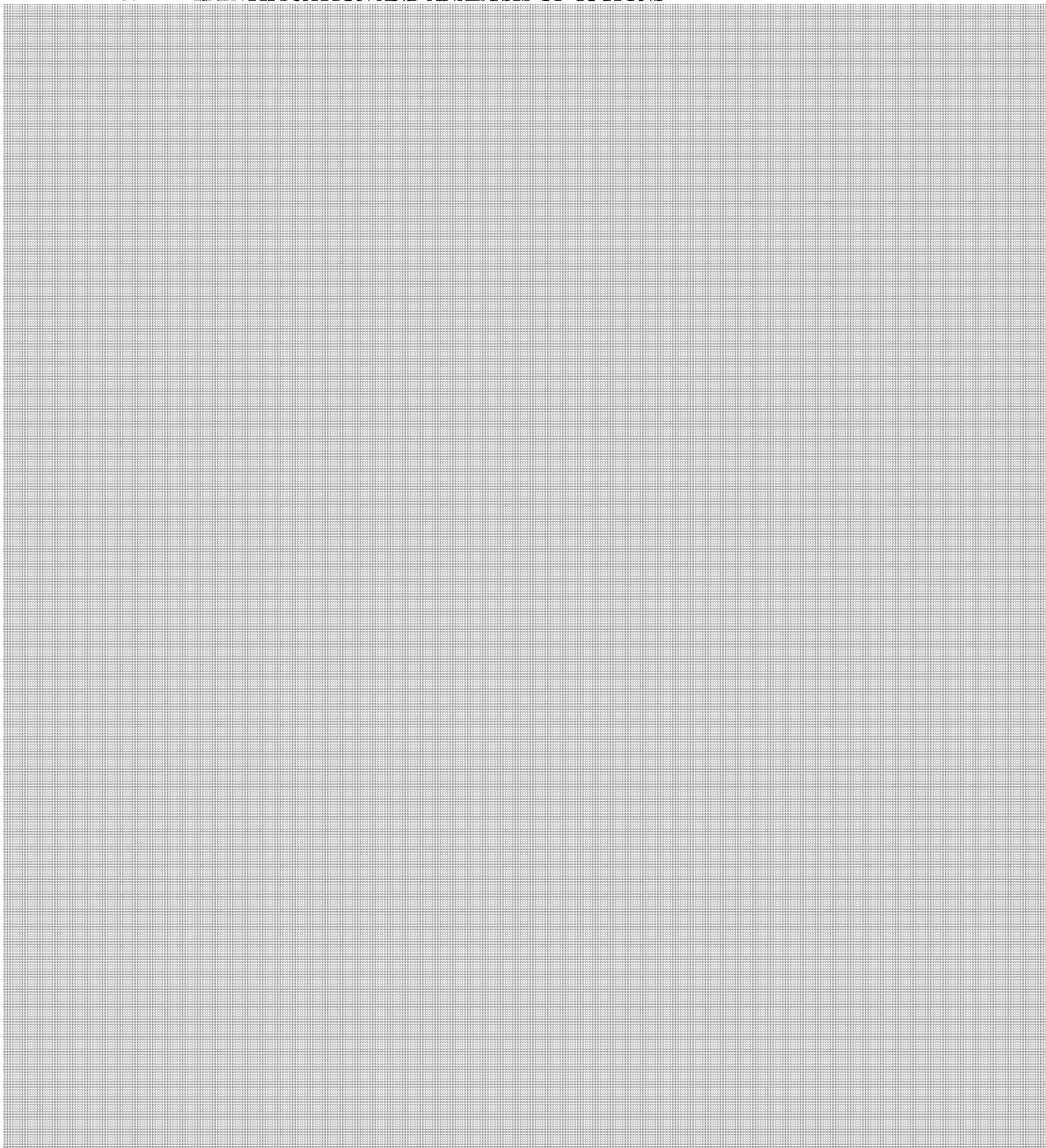
<sup>51</sup> Grundmann O, Phipps SM, Zadezensky I, Butterweck V. *Salvia divinorum* and Salvinorin A: An Update on Pharmacology and Analytical Methodology. *Planta Med* 2007 Jun;73:1039-1046.

<sup>52</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

s.21(1)(a)

s.21(1)(b)

**5. IDENTIFICATION AND ANALYSIS OF OPTIONS**

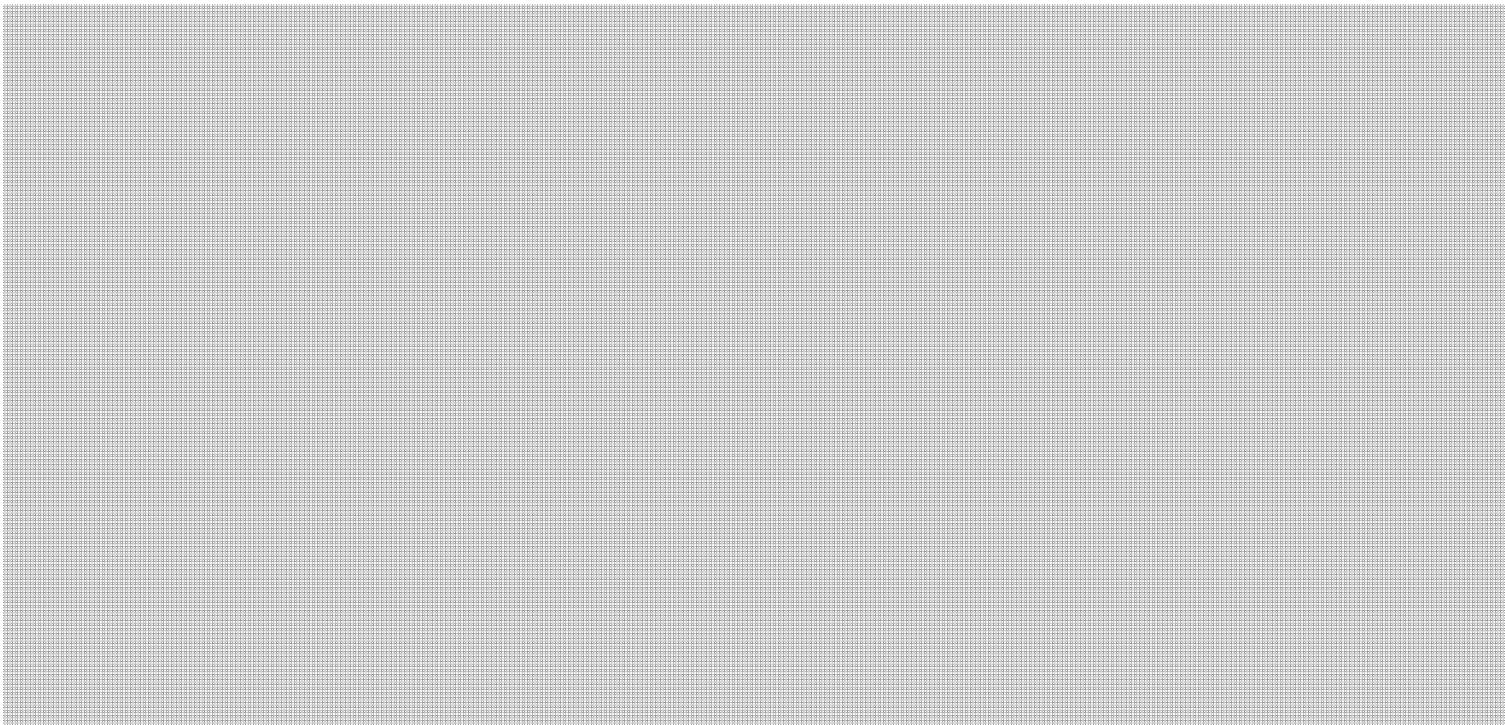


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**Is(Are) exempted pursuant to section(s)  
est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**



## 6. CONSULTATIONS

The Drug Analysis Services (DAS) was contacted in order to provide any data available regarding the prevalence of *S. divinorum* in Canada. Though DAS did not have a record of seizures of the substance, it did provide information regarding the number of samples DAS tested which contained salvinorin A.

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The OCS contacted the Royal Canadian Mounted Police (RCMP) in order to establish their views on *S. divinorum* use in Canada. The RCMP indicated that *Salvia divinorum* is not yet a known substance in the majority of Canada (with the exception of Ontario), and that it does not pose a significant concern for public safety at this time. An RCMP document prepared by Sgt. Doug Culver stated that scheduling of *S. divinorum* under the CDSA was not currently warranted due to its low potential for abuse and potential medical significance.

OCS has received a number of correspondences from Canada Border Service Agency (CBSA) officers concerning a lack of information regarding the status of *S. divinorum* and how the substance should be treated at the border. Officers also expressed concern regarding the substances hallucinogenic properties and increased media attention. At present, only shipments of *S. divinorum* that are represented as health products/ hallucinogens can be refused for import under the NHPR.

## 7. CONSIDERATIONS

*S. divinorum*'s KOR-mediated aversive and dysphoric effects do not appear to be hampering its use. Young adults have begun smoking the leaves and leaf extract recreationally.<sup>56</sup> It can be purchased

<sup>56</sup> Hazelden Foundation, 2004. Drug Abuse Trends. June 2004. URL: [www.reserach.hazelden.org](http://www.reserach.hazelden.org).



**Page(s) 000855 to/à 000855**

**is(are) not reviewed  
n'est (ne sont) pas révisée(s)**

**s.21(1)(a)**

**s.21(1)(b)**

**9. IMPLEMENTATION AND EVALUATION**

**10. OUTCOME EVALUATION**

# SALVIA

If we are to use references in the IAS,

I would prefer that we use the appropriate reference system and add a reference section at the end. Using footnote ~~can lead to~~ in this case leads to multiple instances of the same reference.

As it stands it looks like we reviewed 50 documents/papers for this IAS where in fact we did not.

A reference section also can be easily consulted as opposed to foot notes.

# Issue Analysis Summary

DRAFT

## Scheduling *Salvia Divinorum* and/or *Salvinorin A* under the CDSA

Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Controlled Substances and Tobacco and Directorate

June 15, 2010

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  2. PURPOSE
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  10. OUTCOME EVALUATION
- 

#### 1. ISSUE

In Canada, neither the herb *Salvia divinorum* (*S. divinorum*) nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA). Health Canada has received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *S. divinorum*, particularly given reports from scientific and media sources suggesting that *S. divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has also noted an ongoing media interest regarding the availability of *S. divinorum* in Canada.

#### 2. PURPOSE

To assess *Salvia divinorum* and/or salvinorin A against the criteria for the addition of a substance to one of the Schedules of the CDSA, and determine whether or not they should be regulated as controlled substances in Canada.

#### 3. CONTEXT

*Salvia divinorum* is a species of sage which belongs to the mint family, and which is found in the form of dried leaves, extract and plant cuttings. Also known as "diviner's sage", the plant is

known to induce illusions and hallucinations when chewed or smoked. Salvinorin A, the psychoactive ingredient in *S. divinorum* (also referred to chemically as a neoclerodane diterpene) is found primarily in the leaves, and to a lesser extent in the stems.<sup>1</sup>

*S. divinorum* is widely touted as a "legal" alternative to street drugs on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs among adolescents and young adults.<sup>2</sup> While very little is known about how and where *S. divinorum* is sold in Canada, it is suspected that it is mainly purchased over the Internet and/or bought at head shops, and alternative life style stores, etc.

The use of *S. divinorum* as a psychotropic agent first came to Health Canada's attention in 2002. In 2004, Health Canada received four adverse drug reaction (ADR) reports associated with the use of *S. divinorum* as a hallucinogen, with three being considered non-serious (requiring no medical attention) and the fourth being considered serious (medical intervention was required). The serious ADR report involved the concomitant use of alcohol in a person diagnosed with Attention Deficit Disorder.

Further to the receipt of the aforementioned ADRs, the Marketed Health Products Directorate (MHPD) and the Natural Health Products Directorate (NHPD) of the Health Products and Food Branch (HPFB) prepared an issue analysis summary (IAS), which recommended that *S. divinorum* and its active ingredient salvinorin A be regulated as controlled substances (a recommendation that was maintained when the IAS was updated in November 2006).

Later, in December 2005, MHPD and NHPD prepared a Signal Assessment (SA) (updated in June 2007) that eventually led to the preparation of a Health Risk Assessment (HRA), which concluded that *S. divinorum* or salvinorin A-containing health products should be restricted from over-the-counter use. Should any such (unauthorized) health products be found on the Canadian market, they should be removed from sale. Such products would constitute a Type II Health Risk according to the Health Hazard Classification of the Recall Policy of the Health Products and Food Branch Inspectorate (HPFBI). Such a risk is defined as "a situation in which the use of, or exposure to, a product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote".

Further to an Assistant Deputy Minister (ADM) discussion in April 2007, the Drug Strategy and Controlled Substances Directorate (DSCSD) organized a meeting with MHPD, NHPD and the Inspectorate of HPFB (HPFBI) to discuss *S. divinorum*. At that time, it was decided that *S. divinorum* would be classified by HPFBI as a Type II substance based on its Health Hazard Classification. HPFBI was to determine appropriate compliance activities regarding *S. divinorum* and check with Canada Border Services Agency (CBSA) to determine if any further

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<sup>1</sup> U.S. Department of Justice Drug Enforcement Administration. 2002. Drugs and Chemicals of Concern: Salvia Divinorum (salvinorin A, divinorin A) URL:

[http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm) Nov 2008

<sup>2</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.

information regarding *S. divinorum* shipments was available.

On September 13, 2007, a meeting was organized between DSCSD, MHDP, NHPD and HPFBI to discuss what was known about *S. divinorum* from a regulatory perspective and to reach a consensus on the next steps. It was determined that DSCSD would conduct a scheduling assessment of *S. divinorum* to explore the possibility of scheduling this substance under the CDSA.

The Director Generals of DSCSD, MHPD, TPD and the HPFBI also met on September 26, 2008 to discuss an update on issues relating to *S. divinorum* and to determine an agreed upon approach for subsequent steps. It was decided that media lines and a proposal for an "It's Your Health" article on *S. divinorum* would be prepared.

### **3.1 Legislative Frameworks for Drug Control in Canada**

#### **3.1.1 Food and Drug Regulations (under the Food and Drug Act)**

The *Food and Drug Regulations* (F&DR) serve to ensure the safety, efficacy, and quality of health products offered for sale in Canada, including drugs and medical devices. Prior to being given market authorization, a manufacturer must present substantive scientific evidence of a product's safety, efficacy and quality. Health Canada reviews this information carefully and, if the review is satisfactory, a Notice of Compliance (NOC) is issued and appropriate Drug Identification Numbers (DINs) are assigned.

A "drug" is defined under the F&DR as any substance or mixture of substances manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
- (b) restoration, correction or modification of organic functions in human beings or animals, or
- (c) disinfection in premises in which food is manufactured, prepared or kept;

As no products containing *S. divinorum* or its extracts have been reviewed and approved by Health Canada as of January 2010, it is illegal to market *S. divinorum* when it is represented as a drug.

#### **3.1.2 Natural Health Product Regulations (under the Food and Drug Act)**

The *Natural Health Products Regulations* (NHPR) came into force in January 2004 to provide Canadians with ready access to natural health products (NHPs) that are safe, effective, and of high quality, while respecting freedom of choice and philosophical and cultural diversity. The NHPR contain a product licensing system that requires that all licensed products display a

Natural Product Number (NPN), or, in the case of a homeopathic medicine, Drug Identification Number - Homeopathic Medicine (DIN-HM), on their labels. The number is issued once a product is authorized for sale in Canada by the Natural Health Products Directorate (NHPD). Product authorization requires either reference to a *natural health product monograph* or submission of other evidence of safety and health claim. A system of site licensing is also included in the NHPR which requires that all manufacturers, packagers, labellers, and importers be licensed; sites have procedures in place respecting distribution records and product recalls; where applicable, sites have procedures in place for the handling, storage and delivery of their products, and sites meet good manufacturing practice requirements.

The definition of an NHP under the NHPR has both a function and substance component. The function component refers to those substances that are manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
- (b) restoring or correcting organic functions in humans; or
- (c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

The substance component refers to whether the product or medicinal ingredient therein is safe for consideration as an over-the-counter product, can be available for self-care and self-selection, and does not require a prescription to be sold. To be considered a NHP, no direct health claims need to be made regarding the substance. In the case of *S. divinorum*, it is generally marketed for its hallucinogenic properties which are considered a modification of an organic function. Therefore such products would be considered NHPs.

As of January 2010, no products containing *S. divinorum* have been reviewed and approved by Health Canada and no NPNs or DIN-HMs have been issued. Therefore sales of an unlicensed hallucinogen such as *S. divinorum* is illegal under the NHPR if claims are made regarding its hallucinogenic properties or other similar claims for human consumption (e.g. modification of an organic function).

### 3.1.3 Controlled Drugs and Substances Act and its Regulations

The CDSA provides a legislative framework for the control of substances that can alter mental processes and that may produce harm to the health of an individual or to society when diverted or misused. Except as authorized under its regulations, activities such as possession, possession for the purposes of trafficking, trafficking, importation, exportation, possession for the purposes of exportation and production of controlled substances are prohibited under the CDSA.

The substances regulated under the CDSA are grouped into eight Schedules, and each Schedule is associated with particular penalties as described in Part I of the CDSA.

offences and.

In determining whether a substance should be regulated as a controlled substance, and into which Schedule of the CDSA it should be placed, Health Canada considers the following factors:

- International requirements and trends in control/scheduling;
- Chemical and pharmacological similarity to other substances already scheduled under the CDSA;
- Legitimate uses of the substance (i.e. therapeutic, industrial or commercial);
- Potential for abuse and/or addiction liability of the substance;
- Extent of actual abuse in Canada and internationally; and
- Overall risk to public health and safety of Canadians.

### **3.2 Assessment of *Salvia Divinorum* for Scheduling Purposes**

#### **3.2.1 International Requirements and Trends in Control/Scheduling**

At the present time, neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and therefore do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these conventions.

#### ***Australia***

In June 2002, Australia became the first country to prohibit *S. divinorum* and salvinorin A. Although both *S. divinorum* and salvinorin A are listed on Schedule 9 of Australia's Standard for the Uniform Scheduling of Drugs and Poisons on the basis of "high potential for abuse and risk to public health and safety", no substantiation of this risk was provided at the time of this scheduling decision.<sup>3</sup> Schedule 9 is Australia's most restrictive drug schedule, and includes "substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities."<sup>4</sup>

#### ***Belgium***

A decree was passed in Belgium on October 22, 2006 which added *S. divinorum* to the list of controlled substances which includes substances such as psilocybin mushrooms, khat and peyote cactus.<sup>5</sup>

#### ***Denmark***

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<sup>3</sup> <http://www.tga.gov.au/ndpsc/record/tr200111.pdf>

<sup>4</sup> [http://www.cognitiveliberty.org/news/salvia\\_australia.htm](http://www.cognitiveliberty.org/news/salvia_australia.htm)

<sup>5</sup>

<http://eldd.emcdda.europa.eu/html.cfm/index5176EN.html?pluginMethod=eldd.shownewsdetails&id=20/12/2006BELGIUM:%20New%20substances%20controlled%20include%20mCPP%20and%20khat>



In 2003, Denmark prohibited *S. divinorum* and salvinorin A by adding them to their list of “category B” controlled substances, a category which also includes psilocybin mushrooms, cocaine, amphetamine, and several others substances that are only legal for medicinal and scientific purposes. Illegal possession carries a penalty of up to two years in prison.

### ***Germany***

*S. divinorum* (plant and plant parts) was added to Appendix I of the *Narcotics Act* in Germany on March 1, 2008, making it illegal to produce, traffic, or possess. The law does not specifically mention salvinorin A.

### ***Italy***

On June 25, 2004, the Italian Ministry of Health issued an ordinance prohibiting the sale of *S. divinorum* and its active constituent salvinorin A. On January 11, 2005, the Ministry of Health made possession of *S. divinorum* and salvinorin A illegal by placing them in “*Tabella 1*” of the *Tabella Sostanze Stupefacenti o Psicotrope*.

### ***Japan***

On November 9, 2006, the Japanese government added a group of thirty-three drugs to its list of controlled substances, including salvinorin A. The drugs are banned under a revised pharmaceutical law, under which persons involved in their illegal import, production, and sale (that beyond medical treatment or research purposes) will be subject to up to five years imprisonment or a fine of up to five million yen.

### ***Spain***

On January 28, 2004 the Spanish Ministry of Health and Consumption issued an order prohibiting the sale of *S. divinorum*, along with a long list of other allegedly toxic herbs. The regulation went into effect on May 6, 2004 and only prohibits activities related to commerce. Possession and/or use are not considered to be criminal offences.

### ***Other Countries***

*Salvia divinorum* is illegal to possess or sell in Croatia, Latvia, Lithuania, Poland, Romania, South Korea and Sweden. In Russia it is illegal to grow or sell *S. divinorum*, but it is legal to possess it. In Estonia, Finland, Iceland and Norway, *S. divinorum* is treated as a medicinal herb and it is illegal to import it without a relevant prescription from a doctor.

### ***United States of America***

*S. divinorum* and salvinorin A are not included in the Schedules of the United States *Controlled Substances Act*, although some individual states have implemented laws restricting its use, sale

and/or distribution. As of May 2010, nineteen states have enacted legislation placing regulatory controls on *S. divinorum* and/or salvinorin A. Delaware, Florida, Hawaii, Illinois, Kansas, Kentucky, Mississippi, Missouri, Nebraska, North Dakota, Ohio, Oklahoma, South Dakota and Virginia have placed *S. divinorum* and/or salvinorin A into Schedule I of state law.

California, Louisiana, Maine, North Carolina, and Tennessee have enacted other forms of legislation restricting the distribution of the plant.

### ***California***

As of January 1, 2009, the sale or distribution of *S. divinorum* or salvinorin A, or any substance or material containing *S. divinorum* or salvinorin A, to any person under 18 years of age became a misdemeanor in the state of California that is now punishable by imprisonment in a county jail for not more than six months, by a fine of no more than \$1,000, or both.

### ***Louisiana***

In 2005, Louisiana passed a bill which prohibits the possession, production, manufacture and distribution of a material, compound, mixture, or preparation intended for human consumption which contains a hallucinogenic plant. A "hallucinogenic plant" is defined as "any part or portion" of the forty plants listed, which includes *S. divinorum*.

### ***Maine***

In Maine, *S. divinorum* and salvinorin A are regulated in a way similar to how tobacco products are controlled. Adults eighteen years of age or over can legally purchase and use the material, but selling or providing *S. divinorum* or salvinorin A to anyone under the age of eighteen is a criminal offence. Possession by a minor is a civil violation, punishable by a fine, community service, or both.

### ***North Carolina***

On February 11, 2009, Senate Bill 138 was introduced to the North Carolina State Legislature which sought to make *Salvia divinorum* and salvinorin A Schedule I controlled substances in that state. This bill was later amended to make possession of *S. divinorum* an infraction, a minor crime punishable by a maximum \$25 fine. A third possession offence would be charged as a misdemeanor. There are no separate penalties for manufacturing or sales. This bill includes two exemptions. One permits growing the plant for aesthetic, landscaping, or decorative purposes; the other allows for university-affiliated medical or pharmacological research. The new law came into effect on December 1, 2009.

### ***Tennessee***

On July 1, 2006, Tennessee classified the deliberate production, manufacture, distribution, or possession of the active chemical ingredient in the hallucinogenic plant *S. divinorum* as a Class A misdemeanor. It is not, however, a criminal offence to possess, plant, cultivate, grow, or harvest *S. divinorum* for aesthetic, landscaping, or decorative purposes. The law also does not apply to any dosage that is legally obtainable from a retail establishment without a prescription when it is recognized by the Food and Drug Administration as a homeopathic drug.

In addition, the U.S. Department of Justice Drug Enforcement Agency (DEA) has placed *S. divinorum* and salvinorin A on a list of drugs and chemicals "of concern," without legal implications.

### 3.2.2 Chemical and Pharmacological Similarity to Other Substances Listed in the CDSA

The psychoactive ingredient in *Salvia divinorum* is salvinorin A. Other plants which contain psychotropic terpenoids are *Artemisia absinthium* (wormwood) and *Cannabis sativa*. Salvinorin A is considered by some as the most potent natural hallucinogen ever isolated.<sup>6</sup>

Unlike all other hallucinogens, salvinorin A is structurally distinct and does not interact with the serotonin-2A receptor or any other molecular target of classical hallucinogens. It thus affects the brain in a way that is quite unique.<sup>7</sup> Recent pharmacological screenings of receptors have found it to be a highly potent and selective  $\kappa$ -opioid receptor (KOR) agonist.<sup>8</sup>

The psychomimetic effects of *S. divinorum* closely resemble schizophrenia symptoms induced by lysergic acid diethylamide (LSD) or phencyclidine (PCP).<sup>9</sup> Yet, it is said to have only weak influence on the prevailing mood of the user which differentiates it from other hallucinogens such as LSD and psilocybin.<sup>10</sup> Its strong dissociative effects are often compared to those of ketamine. Users have reported that the psychedelic effects of *S. divinorum* were most similar to those caused by psilocybin mushrooms.<sup>11</sup> However, users familiar with the effects of other hallucinogens agree that despite certain similarities to classical hallucinogens, the visions and

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<sup>6</sup> Ott J. Ethnopharmacognosy and human pharmacology of *Salvia divinorum* and salvinorin A. *Curare*. 1995 18: 103-129. Unofficial transcription available online. URL <http://www.sagewisdom.org/ott2.html>

<sup>7</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>8</sup> Roth BL, Baner K, Westkaemper R, Siebert D, Rice KC, Steinberg S, Ernsberger P, Rothman RB. Salvinorin A: a potent naturally occurring nonnitrogenous kappa opioid selective agonist. *Proc Natl Acad Sci U S A*. 2002 Sep 3;99(18):11934-9.

<sup>9</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>10</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>11</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

overall experience is quite unique.<sup>12</sup>

In addition, the psychedelic effects of *S. divinorum* are similar to those of classical psychedelics regarding changes in perception and somatic sensations. *S. divinorum* causes an unusually high degree of sedation, weakness and fatigue, while the increased de-realization is not commonly reported for classical psychedelics.<sup>13</sup> The combination of these effects seems to correlate with that of other KOR agonists such as pentazocine.<sup>14</sup>

### 3.2.3 Legitimate Uses of Salvia *Divinorum*

There are presently no legitimate medical or industrial uses for *S. divinorum* in Canada.

*Salvia divinorum* has traditionally been used for spiritual and medicinal purposes by the Mazatec Indians in Oaxaca, Mexico,<sup>15</sup> where an infusion of the leaves or the leaves themselves are ingested to treat gastrointestinal problems, headaches, rheumatism, anemia and swelling of the stomach.<sup>16</sup> Its main use is, however, for its psychoactive properties in the aid of producing “mystical” or hallucinogenic experiences as part of spiritual rituals.<sup>17</sup>

Although selective kappa receptor agonists have been shown to produce analgesic effects, adverse effects such as psychotomimesis, dysphoria and diuresis have been observed in studies investigating their therapeutic use.<sup>18</sup> It has been speculated that KOR agonists may prove to be useful in the treatment of certain psychiatric disorders including Alzheimer’s disease, schizophrenia, dementia and bipolar disorder.<sup>19</sup> However, much more research is needed in order to substantiate these hypotheses. Another study has suggested that chemical analogues of salvinorin A may be a useful treatment for those suffering from addiction to other substances.<sup>20</sup>

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<sup>12</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6 and González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>13</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>14</sup> Arasteh K, Poudevida S, Farre M, Roset PN, Cami J. Response patterns of the Spanish version of the 49-item short form of the Addiction Research Center Inventory after the use of sedatives, stimulants, and opioids. *Drug Alcohol Depend.* 1999 Jun 1;55(1-2):117-25.

<sup>15</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>16</sup> Munro, T. The Chemistry of *Salvia divinorum*. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

<sup>17</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage *Salvia divinorum*. *Life Sci.* 2005 Dec 22;78(5):527-31.

<sup>18</sup> Barker RL, Fawcett J, Barkin SJ. 2002. Chronic pain management with a focus on the role of newer antidepressants and centrally acting agents. In: *Pain Management: A Practical Guide for Clinicians*, 6th edition, Weiner RS ed. CRC Press, Boca Raton, FL. pp. 415-34 and Tidgewell et al., 2004. A facile method for the preparation of deuterium labelled salvinorin A: *Biorganic & Medicinal Chemistry Letters*, 14: 5099-5102.

<sup>19</sup> Sheffler DJ & Roth BL. Salvinorin A: the ‘magic mint’ hallucinogen finds a molecular target in the kappa opioid receptor. *Trends Pharmacol Sci.* 2003 Mar;24(3):107-109.

<sup>20</sup> Prisinzano TE. Natural products as tools for neuroscience: discovery and development of novel agents to treat drug abuse. *J Nat Prod.* 2009 Mar 27;72(3):581-7.

### 3.2.4 Potential for Abuse Liability and/or Addiction Liability of the Substance

Most clinically used opioid analgesics (e.g. codeine, oxycodone, morphine) are selective for the  $\mu$ -opioid receptor (MOR) and can be habit-forming<sup>24</sup> because activation of the MORs causes euphoria, which makes the user want to take them again. As previously mentioned, salvinorin A is a potent, selective agonist of the  $\kappa$ -opioid receptor (KOR), and in contrast to the euphoria produced by MOR agonists, the KOR agonists are negatively reinforcing and aversive.<sup>25</sup> In addition, KOR agonists have analgesic properties but are not associated with respiratory depression like MOR agonists. Initially, these effects provided hope for the development of an analgesic absent of addiction liability and respiratory depression. However, it was soon discovered that KOR agonists produced dysphoria and psychomimetic effects such as confusion, hallucinations and depersonalization.<sup>26</sup> Finally, while MOR increases the release of dopamine, the activation of KOR decreases dopamine release in the nucleus accumbens.<sup>27</sup>

The onset and intensity of the effects of *Salvia divinorum* appear to be related to the route of administration. Traditional uses generally produce mild effects because the leaves are rolled and chewed or crushed and prepared as a foamy infusion whereby the salvinorin A is degraded in the gastrointestinal system before being absorbed into the bloodstream. These methods rely on contact with the oral mucosa for absorption and the level of effect relates quite closely to the length of time

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<sup>24</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.

<sup>25</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590, Cooper S. Interactions between endogenous opioids and dopamine: Implications for reward and aversion. In: *The Mesolimbic Dopamine System: From Motivation to Action*. Willner P and Scheel-Kruger J (editors) Wiley, Chester, England, 1991, pp. 331-366, and Shippenberg TS, Herz A, Spanagel R, Bals-Kubik R, Stein C. Conditioning of opioid reinforcement: neuroanatomical and neurochemical substrates. *Ann N Y Acad Sci*. 1992 Jun 28;654:347-56.

<sup>26</sup> Pfeiffer A, Brantl V, Herz A, Emrich HM. Psychotomimesis mediated by kappa opiate receptors. *Science*. 1986 Aug 15;233(4765):774-6, Rimoy GH, Wright DM, Bhaskar NK, Rubin PC. The cardiovascular and central nervous system effects in the human of U-62066E. A selective opioid receptor agonist. *Eur J Clin Pharmacol*. 1994;46(3):203-7, and Walsh SL, Strain EC, Abreu ME, Bigelow GE. Enadoline, a selective kappa opioid agonist: comparison with butorphanol and hydromorphone in humans. *Psychopharmacology (Berl)*. 2001 Sep;157(2):151-62.

<sup>27</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.

the material spends in the mouth. The onset of effect generally takes 5-10 minutes. The effects build over the next hour and last for another hour before they begin to subside.<sup>28</sup>

Routes of administration that avoid the hepatic first-pass effect are the quickest and most intense.<sup>29</sup> Salvinorin A can be isolated from the plant to make a powder which can be vaporized and inhaled. This method of administration is the most powerful and only requires 200-500 micrograms of salvinorin A powder to produce the same effects as those of fresh leaves. The onset of effects felt from vaporizing salvinorin A powder occurs in about 30 seconds and effects last for about 5-10 minutes and then subside over the next 30 minutes.<sup>30</sup> Smoking is by far the most popular method of administration<sup>31</sup> and this is accomplished by smoking the dried leaves or a concentrated extract using a pipe or bong. Dried leaves may also be fortified with a concentrated extract of salvinorin A. A concentrated extract can also be used sublingually. Neither *S. divinorum* nor salvinorin A are injected because the powder is insoluble in water.<sup>32</sup>

The various modes of administration of *S. divinorum* lead to the variable onset and duration of its effects. These effects are generally accepted to be: sensation of becoming an object, visions of various two-dimensional surfaces, films and membranes, revisiting places of the past (particularly childhood), perceived loss of the body and/or identity, various sensations of motion (being pulled or twisted by a force of some kind), uncontrollable hysterical laughter, and overlapping realities (perceptions of being in more than one place).<sup>33</sup> Laughter, happiness, sense of well-being and dissociative effects were deemed the best aspects of *S. divinorum* by users, second only to the "trip" that the drug elicits.<sup>34</sup> Depersonalization, speaking gibberish, widening of consciousness, subjective illusions of rapid movement, flying or hovering have also been reported.<sup>35</sup>

The aversive effects of previously studied KOR agonists predict that the risk of addiction to *S. divinorum* is negligible. However, very few controlled scientific studies of the physical and

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<sup>28</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>29</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.

<sup>30</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>31</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62 and Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>32</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs.* 1994 Jul-Sep;26(3):277-83.

<sup>33</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>34</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>35</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry.* 2005 Jan;38(1):1-5 and Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

psychotropic effects of *Salvia divinorum* on humans have been carried out. Therefore, it is difficult to predict its potential for addiction and abuse. In studies that have been conducted, there is conflicting information around the addiction liability of *S. divinorum* in both animals and humans. Some users have noted that they require increasing doses of salvinorin A in order to achieve the desired effect and the stimulated cerebral KOR may act as a mechanism of tolerance.<sup>36</sup> More controlled systematic research in this area is needed. Further studies on the mediated decrease of dopamine as well as the impact of dose on the rewarding and aversive effects are also warranted.

Another aspect of the *S. divinorum* abuse potential stems from its availability. As previously mentioned, it is widely available for purchase on the Internet through drug promotional sites and it is also sold in various "head shops" and corner stores. In addition, the potential for high yields and ease of extraction may make buying and selling this substance quite affordable and attractive. Originally, the concerns for the potential of abuse were minimal as it was concluded that 1 kg of dried leaves yielded only 3 to 6 human doses of salvinorin A. However, it was discovered that vaporizing and inhaling 200-500 micrograms had profound hallucinogenic effects.<sup>37</sup> The extraction of salvinorin A from the plant is very easy and with care, approximately 1.5 grams of pure salvinorin A per kilogram of dried leaves (8kg of fresh leaves) can be isolated. Therefore, a gram of salvinorin A is enough substance to provide for 2000 human doses.<sup>38</sup> It is also believed to be easier to obtain salvinorin A than to extract LSD or produce PCP derivatives.<sup>39</sup>

### 3.2.5 Extent of Actual Abuse in Canada and Internationally

Very limited data exists regarding the population use of *Salvia divinorum* across the Canadian population. To address this lack of data, questions about the use of *S. divinorum* were included

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<sup>36</sup> Bucheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>37</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>38</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs*. 1994 Jul-Sep;26(3):277-83.

<sup>39</sup> Bucheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

in the 2008-2009 Youth Smoking Survey, the 2009 Canadian Alcohol and Drug Use Monitoring Survey and the 2009 Ontario Student Drug Use and Health Survey.

The results from the 2009 Ontario Student Drug Use and Health Survey were published on November 18, 2009 and indicate that:

- Among all responding students in Ontario, 4.4% reported using *Salvia divinorum* at least once in the past year. In comparison, 58.2% indicated they had used alcohol, 25.6% indicated they had used cannabis and 5.0% indicated they had used hallucinogens other than LSD and PCP in the past year;
- Males (6.2%) were significantly more likely than females (2.3%) to report using *Salvia divinorum*;
- There is significant grade variation, with *Salvia divinorum* use most likely among 11<sup>th</sup> graders (8.6%) and 12<sup>th</sup> graders (8.4%); and
- There are significant regional variations, with students in Northern Ontario (9.2%) most likely to use *Salvia divinorum*.

The results of the 2008-2009 Youth Smoking Survey were published on May 31, 2010 and indicate that:

- 4.9% of students stated that they had used *S. divinorum* in the last twelve months. In comparison, 53.0% indicated they had used alcohol, 27.3% indicated they had used cannabis and 6.9% indicated they had used other hallucinogens in the last twelve months;
- 2.6% of students in Grades 7-9 and 7.0% of students in Grades 10-12 had used *S. divinorum* in the last twelve months; and
- Males (6.6%) were more likely to have used *S. divinorum* in the past twelve months compared to females (3.2%).

The scope of the previously mentioned studies did not provide for any explanations regarding differences in usage between ages, genders and regions. Given the lack of information surrounding *S. divinorum*, it is difficult to speculate on the causality of such differences.

Additional data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey will be available in the summer of 2010.

As far as law enforcement is concerned, the Department has only received a limited number of communications indicating concern with respect to *S. divinorum* and none of these have advised that the use of *S. divinorum* poses any threat to public safety.

*Should we qualify this? Significant?*

Health Canada's Drug Analysis Services (DAS) has collected some raw data regarding the number of samples identified as containing salvinorin A in the DAS labs, however, as the plant and/or substance is not in the Controlled Drugs and Substances Database (CDS) druglist, it is not possible to have records of any seizures of it in the database. However, there have been a number of samples submitted to DAS for analysis that have been confirmed to contain salvinorin A.



**NUMBER OF SAMPLES FOUND TO CONTAIN SALVINORIN A**

Year Return Completed	Count
2006	6
2007	8
2008	6
2009	To be updated

The National Forensic Laboratory Information System (NFLIS) and the System to Retrieve Information from Drug Evidence (STRIDE) in the United States is a Drug Enforcement Agency (DEA) database that collects scientifically verified data on analyzed samples in state and local forensic labs as well as samples from DEA labs. The following table shows the quantity of *S. divinorum* products that were seized from 2000 through to 2009.

**ANALYZED SALVIA DIVINORUM or SALVINORIN A SEIZURES**

(Number of items/Exhibits)

Source	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009*
NFLIS-State/Local <sup>1</sup>	0	0	0	0	1	8	12	12	70	34
STRIDE <sup>2</sup>	0	0	1	1	1	0	0	0	N/A	N/A
<b>TOTAL</b>	0	0	1	1	2	8	12	12	70	34

Data Source: NFLIS & STRIDE, 2008 data queried 11/24/08, updated 06/10/2010

<sup>1</sup> NFLIS reported seizures of *Salvia divinorum* and/or salvinorin A

<sup>2</sup> STRIDE reported items of *Salvia divinorum*.

\* Includes only January – May data in 2009.

A handful of case reports regarding the use of *S. divinorum* have been published in the academic literature. One report was an international case report in which a young man (19 years of age) described his perceptions after inhaling smoke from *S. divinorum*. The peak psychotropic effects, including prickling of the skin, fever-like hot flashes, muscular tremor, and depersonalization, were reached in less than five minutes after inhalation of an unknown amount of smoke from burning dried leaves.<sup>41</sup> Another report involved a 15-year-old male who presented to psychiatric emergency services with acute onset of paranoia, déjà vu, blunted affect, difficulties in thought processing and slowed speech after smoking *Salvia divinorum* over an unknown period of time. During his hospitalization all symptoms improved significantly except the feeling of déjà vu. Based on this case presentation, the author suggested that the feelings of déjà vu may be a long-term effect of *S. divinorum* use.<sup>42</sup> However, given that this is the only case report in which déjà vu was associated with the use of *S. divinorum*, more reports are needed to substantiate this finding.

In addition to the above-mentioned reports, in 2006, a case was reported in the U.S. in which a 17-year-old boy committed suicide after smoking *S. divinorum* for an unknown period of time.<sup>43</sup> It should be noted that alcohol and general depression were the main confounders in this case.

<sup>42</sup> Singh S. (2007) Adolescent salvia substance abuse. *Addiction*. 102, 823-824.

<sup>43</sup> <http://www.kvbc.com/Global/story.asp?S=4893692>

After this case was reported, the state of Delaware passed a law which classified *S. divinorum* as a Schedule I controlled substance along with other hallucinogenic substances.

It is difficult to determine the extent of actual abuse of *S. divinorum* as there appear to be inconsistencies in the literature regarding risk aversion. For example, one author states: "Many who have used salvinorin A find the experience extremely unnerving, frightening and overly intense and most have no desire to repeat the experience."<sup>44</sup> However, another study suggested that this is not the experience of all recreational users of *S. divinorum*.<sup>45</sup> Over eighty percent of users surveyed on a web-based questionnaire about their *S. divinorum* use said that they would probably or definitely use *S. divinorum* again.<sup>46</sup> Users have reported the negative effects of *S. divinorum* as: the short duration of action, lack of control over the experience, persisting negative effects (most often anxiety)<sup>47</sup> sweating, chills, increased diuresis, impaired vigilance,<sup>48</sup> and negative after-effects including tiredness, feeling head heavy, dizziness, physical exhaustion, and some degree of malaise or 'hangover' as they 'comedown' from the drug.<sup>49</sup> However, it is difficult to determine the influence these effects have on the use of *S. divinorum*.

### 3.2.6 Overall Risk to Public Health and Safety of Canadians

The increase in both the number of enquiries from various municipalities and members of the public and in the amount of media interest regarding the availability of *Salvia divinorum* in Canada may be an indication that the recreational use of *S. divinorum* as a hallucinogen is on the rise in Canada. However, there are no available statistics that indicate there has been a significant increase in *S. divinorum* use in the Canadian population and, in comparison to the use of other drugs such as alcohol and cannabis, the actual use of *S. divinorum* is quite low.

The potential for harm to the user and/or other individuals is primarily related to the hallucinogenic properties of the substance. Users may get up and walk around without apparent awareness of their movements, behaviour or surroundings, and distinction between self and surroundings is often lost. At doses greater than 1mg of salvinorin A, out of body experiences are frequent and loss of consciousness has been reported.<sup>50</sup> There is little information regarding

<sup>44</sup> Turner DM. Salvinorin - The Psychedelic Essence of Salvia Divinorum. Panther Press, San Francisco, CA 1996.

<sup>45</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62, Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5, and Valdès LJ 3rd. Salvia divinorum and the unique diterpene hallucinogen, Salvinorin (divinorin) A. J Psychoactive Drugs. 1994 Jul-Sep;26(3):277-83.

<sup>46</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>47</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>48</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5.

<sup>49</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>50</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

the social behaviours of persons under the influence of *S. divinorum* products, and what risks their activities such as operating a motorized vehicle may pose to the general public. There is also very little data regarding the toxicity, teratogenicity and long-term effects of *S. divinorum* use.<sup>51</sup>

As stated earlier, there are no approved medical uses for *S. divinorum* in Canada. Health Canada has also neither received nor approved any submissions for natural health products for sale in Canada. Therefore, products that claim to contain this substance have not been extensively reviewed by Health Canada and as such, may be counterfeit or may contain other ingredients that may pose health risks. Like many drugs of abuse, the users are often unaware of the potency and adulterants in the products they are purchasing. A study by Wolowich *et al.* (2006)<sup>52</sup>, showed that the salvinin A content in five out of five *S. divinorum* products was falsely indicated on the label and 4 out of 5 products contained unidentified adulterants (i.e. vitamin E, caffeine).

Health Canada has only anecdotal information about the use and abuse of *S. divinorum* in Canada as well as the threat *S. divinorum* may pose to the health and safety of Canadians. Although reports of domestic adverse reactions related to the use of *S. divinorum* as a hallucinogen have been received through the Canada Vigilance database, it is important to note that the number of reports and the nature of reactions reported are not adequate to characterize the risk to the general population. This data can also not be used to determine incidence of use in the Canadian population.

#### 4. ASSESSMENT OF RISKS AND BENEFITS

*Salvia divinorum* is a substance with unknown long term effects that is currently not scheduled under the CDSA. It can be imported and sold legally in Canada to anyone of any age, anywhere in Canada provided it is not represented as a health product. The *S. divinorum* sold in Canada is currently not subject to any specific quality or safety standards. The available scientific evidence indicates a low potential for abuse of this substance.

There are certain risks associated with scheduling *Salvia divinorum* and/or salvinin A under the CDSA. In particular, scheduling *S. divinorum* and/or salvinin A under the CDSA without sufficient defensible evidence in accordance with the established criteria for scheduling could be precedent-setting in that Health Canada might then have to look at scheduling other plants with psychoactive properties, e.g. Jimsonweed, Datura.

Health Canada only has anecdotal information about the risks associated with the use of *S. divinorum* and/or salvinin A. However, there is scientific evidence which suggests that this plant and its active ingredient may have the potential to create risks to individual and public health and safety resulting from the unsupervised use of a hallucinogenic substance (i.e. driving under the influence, and injuries caused by disassociation with surroundings, loss of consciousness, etc.). In the absence of any type of mechanism of control of these substances, the

<sup>51</sup> Grundmann O, Phipps SM, Zadezensky I, Butterweck V. *Salvia divinorum* and Salvinin A: An Update on Pharmacology and Analytical Methodology. *Planta Med* 2007 Jun;73:1039-1046.

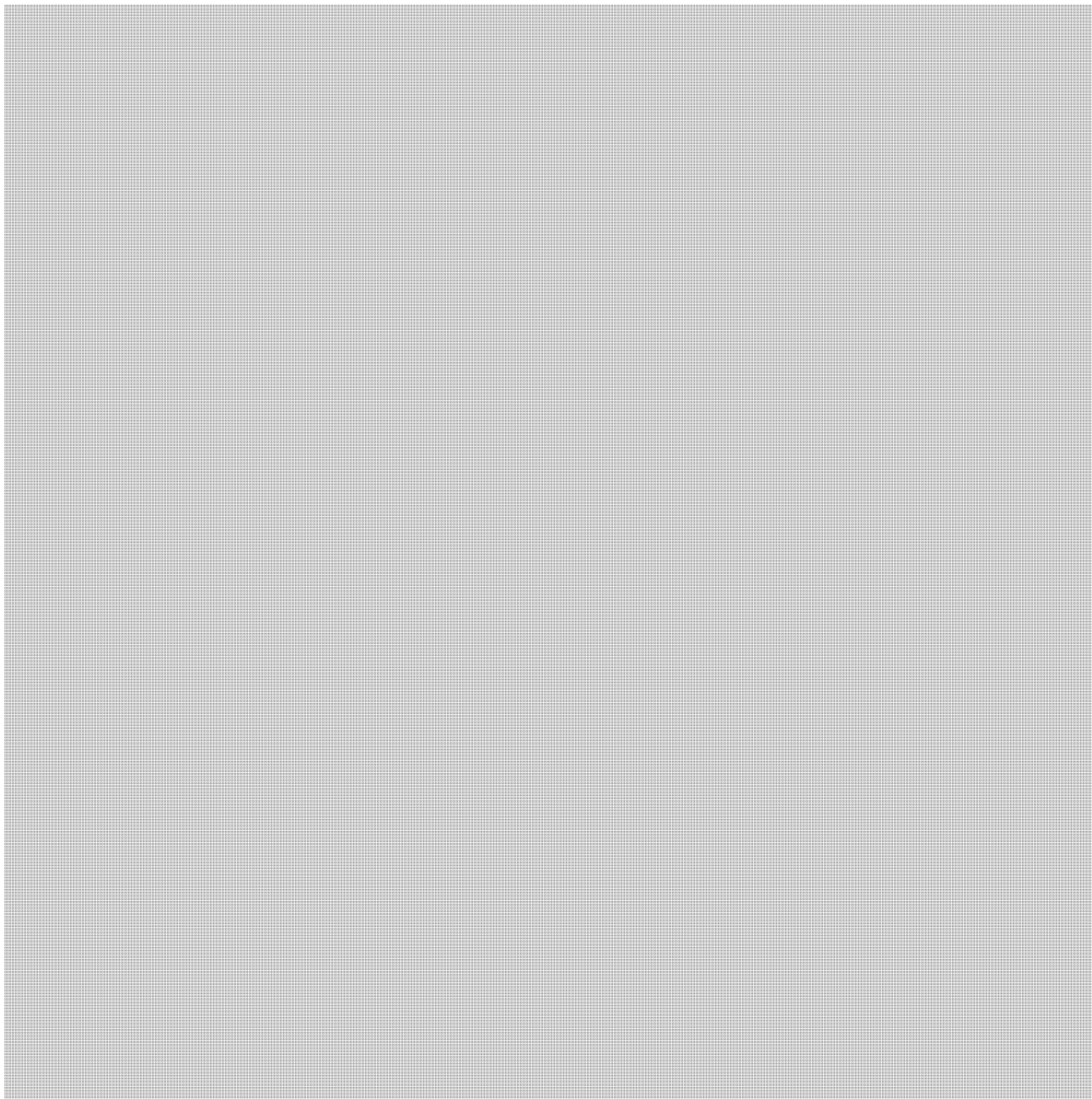
<sup>52</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

safety and well-being of Canadians could be at risk.

**s.21(1)(a)**

**s.21(1)(b)**

**5. IDENTIFICATION AND ANALYSIS OF OPTIONS**



**Page(s) 000875 to\à 000875**

**Is(Are) exempted pursuant to section(s)  
est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**

## 6. CONSULTATIONS

The Drug Analysis Services (DAS) was contacted in order to provide any data available regarding the prevalence of *S. divinorum* in Canada. Though DAS did not have a record of seizures of the substance, it did provide information regarding the number of samples DAS tested which contained salvinorin A.

???

The OCS contacted the Royal Canadian Mounted Police (RCMP) in order to establish their views on *S. divinorum* use in Canada. The RCMP indicated that *Salvia divinorum* is not yet a known substance in the majority of Canada (with the exception of Ontario), and that it does not pose a significant concern for public safety at this time. An RCMP document prepared by Sgt. Doug Culver stated that scheduling of *S. divinorum* under the CDSA was not currently warranted due to its low potential for abuse and potential medical significance.

OCS has received a number of correspondences from Canada Border Service Agency (CBSA) officers concerning a lack of information regarding the status of *S. divinorum* and how the substance should be treated at the border. Officers also expressed concern regarding the substances hallucinogenic properties and increased media attention. At present, only shipments of *S. divinorum* that are represented as health products/ hallucinogens can be refused for import under the NHPR.

## 7. CONSIDERATIONS

*S. divinorum*'s KOR-mediated aversive and dysphoric effects do not appear to be hampering its use. Young adults have begun smoking the leaves and leaf extract recreationally.<sup>56</sup> It can be purchased

<sup>56</sup> Hazelden Foundation, 2004. Drug Abuse Trends. June 2004. URL: [www.research.hazelden.org](http://www.research.hazelden.org).

**Page(s) 000877 to/à 000877**

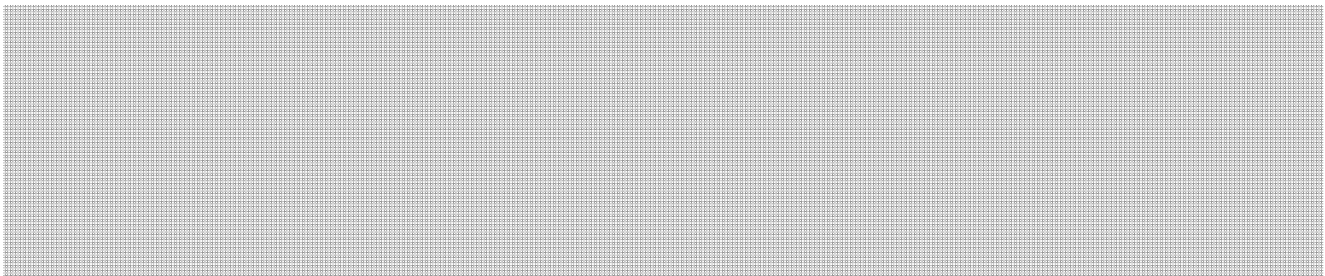
**is(are) not reviewed  
n'est (ne sont) pas révisée(s)**

Health Canada is currently finalizing media lines regarding *S. divinorum* as well as an “It’s Your Health” article to be published on the Health Canada website. These documents are designed to address the recurrent media attention regarding *S. divinorum* as well as increase public awareness of the risks associated with this substance.

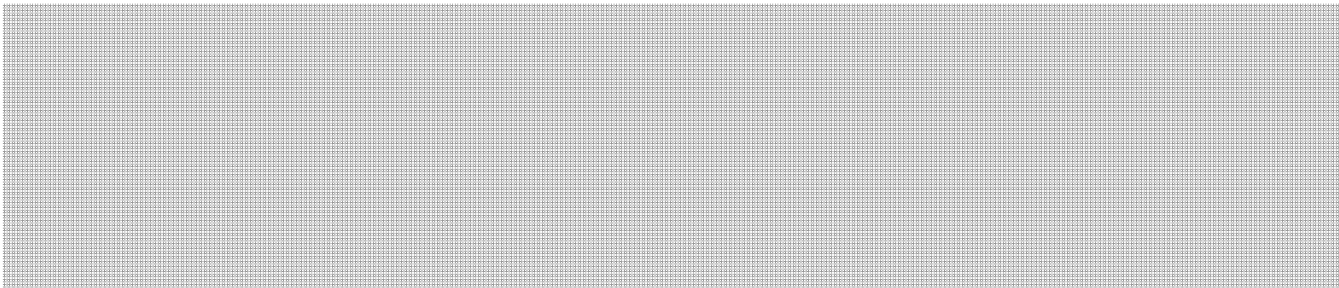
**8. SELECTED STRATEGY**



**9. IMPLEMENTATION AND EVALUATION**



**10. OUTCOME EVALUATION**





s.21(1)(a)

s.21(1)(b)

## Proposed Changes to Issue Analysis Summary for *Salvia divinorum*

- Template to be adjusted (based on IAS for BZP and TFMPP)

### CONTEXT

- Too detailed ✓
- Remove American statistics *or add new data.*
- Remove meeting action items (re-work into a few sentences)

### Legislative Framework

- Include how current FDR and NHPR are already controlling *S. divinorum* -

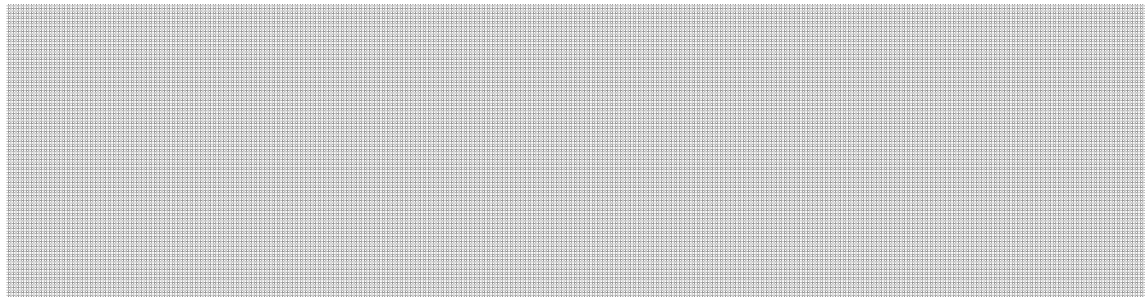
### Assessment of *Salvia divinorum* for Scheduling Purposes

- Update international requirements, legitimate uses, potential for abuse and risk to public health sections ✓

### ASSESSMENT OF RISKS AND BENEFITS

- Re-work (in context of options)
- Add current controls in place (FDR, NHPR)

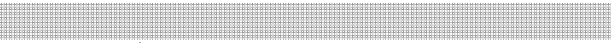
### IDENTIFICATION AND ANALYSIS OF OPTIONS




### CONSULTATIONS

- Change to sentences instead of bullet points (and expand slightly).

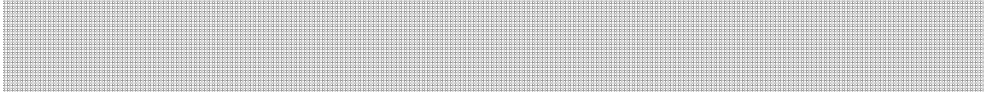

### CONSIDERATIONS

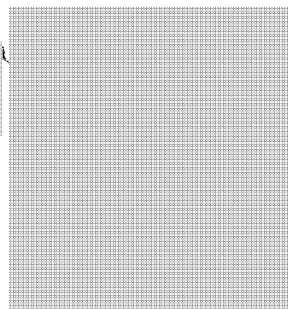
- Re-work (in context of options)
- 
- Sentences instead of bullets

### SELECTED STRATEGY

- 

### IMPLEMENTATION AND EVALUATION

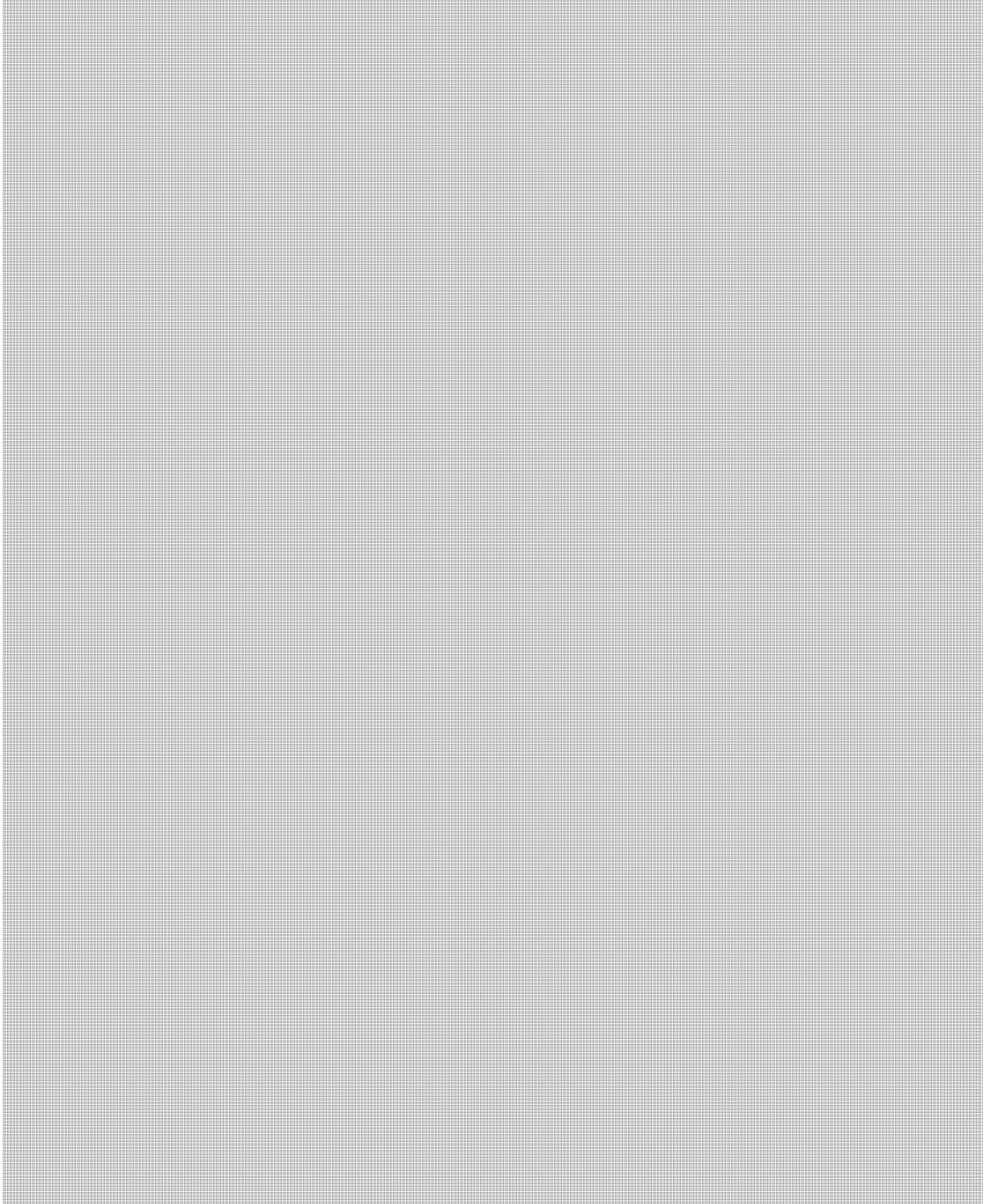
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s.21(1)(a)

s.21(1)(b)

## 6. IDENTIFICATION AND ANALYSIS OF OPTIONS



**Page(s) 000881 to\à 000882**

**Is(Are) exempted pursuant to section(s)  
est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**

References OK as is

# Issue Analysis Summary

DRAFT

## Scheduling *Salvia Divinorum* and/or *Salvinorin A* under the CDSA

Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Controlled Substances and Tobacco and Directorate

June 17, 2010

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10. OUTCOME EVALUATION

shld use template under L.1005 Templates

has an approvals section and Recommendation vs. Selected strategy I think

1. ISSUE *neither of which are currently*

In Canada, neither the herb *Salvia divinorum* (*S. divinorum*) nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA). Health Canada has received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *S. divinorum* and/or its particularly given reports from scientific and media sources suggesting that *S. divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has also noted an ongoing media interest regarding the availability of *S. divinorum* in Canada.

② These requests are largely based on further to

2. PURPOSE

To assess *Salvia divinorum* and/or salvinorin A against the criteria for the addition of a substance to one of the Schedules of the CDSA, and determine whether ~~or not they~~ should be regulated as controlled substances in Canada.

*one or both*

3. CONTEXT

*Salvia divinorum* is a species of sage which belongs to the mint family, and which is found in the form of dried leaves, extract and plant cuttings. Also known as "diviner's sage", the plant is

known to induce illusions and hallucinations when chewed or smoked. Salvinorin A, the psychoactive ingredient in *S. divinorum* (also referred to chemically as a neoclerodane diterpene) is found primarily in the leaves, and to a lesser extent in the stems.<sup>1</sup>

*S. divinorum* is widely touted as a "legal" alternative to street drugs on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs among adolescents and young adults.<sup>2</sup> While very little is known about how and where *S. divinorum* is sold in Canada, it is suspected that it is mainly purchased over the Internet and/or bought at head shops ~~and~~ <sup>or</sup> alternative life style stores, etc.

The use of *S. divinorum* as a psychotropic agent first came to Health Canada's attention in 2002. In 2004, Health Canada received four adverse drug reaction (ADR) reports associated with the use of *S. divinorum* as a hallucinogen, with three being considered non-serious (requiring no medical attention) and the fourth being considered serious (medical intervention was required). The serious ADR report involved the concomitant use of alcohol in a person diagnosed with Attention Deficit Disorder.

Further to the receipt of the aforementioned ADRs, the Marketed Health Products Directorate (MHPD) and the Natural Health Products Directorate (NHPD) of the Health Products and Food Branch (HPFB) prepared an issue analysis summary (IAS), which recommended that *S. divinorum* and its active ingredient salvinorin A be regulated as controlled substances. ~~That~~ <sup>This</sup> recommendation ~~that~~ was maintained when the IAS was updated in November 2006.

Later, in December 2005, MHPD and NHPD prepared a Signal Assessment (SA) (updated in June 2007) that eventually led to the preparation of a Health Risk Assessment (HRA), which concluded that *S. divinorum* or salvinorin A-containing health products ~~should be restricted from over-the-counter use. Should any such (unauthorized) health products be found on the Canadian market, they should be removed from sale.~~ Such products would constitute a Type II Health Risk according to the Health Hazard Classification of the Recall Policy of the Health Products and Food Branch Inspectorate (HBFBI). Such a risk is defined as "a situation in which the use of, or exposure to, a product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote".

Further to an Assistant Deputy Minister (ADM) discussion in April 2007, the Drug Strategy and Controlled Substances Directorate (DSCSD) organized a meeting with MHPD, NHPD and the ~~Inspectorate of HPFB (HPFBI)~~ to discuss *S. divinorum*. ~~At that time, it was decided that *S. divinorum* would be classified by HPFB as a Type II substance based on its Health Hazard Classification.~~ HPFBI was to determine appropriate compliance activities regarding *S. divinorum* and ~~check with the Canada Border Services Agency (CBSA) to determine if any~~ <sup>consult</sup> ~~regarding the~~

<sup>1</sup> U.S. Department of Justice Drug Enforcement Administration. 2002. Drugs and Chemicals of Concern: Salvia Divinorum (salvinorin A, divinorin A) URL:

[http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm) Nov 2008

<sup>2</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.

~~movement of products containing further information regarding *S. divinorum* shipments was available.~~ <sup>into and out of Canada.</sup>

~~On September 13, 2007, a meeting was organized between DSCSD, MHDP, NHPD and HPFBI to discuss what was known about *S. divinorum* from a regulatory perspective and to reach a consensus on the next steps. It was determined that DSCSD would conduct a scheduling assessment of *S. divinorum* to explore the possibility of scheduling this substance under the CDSA.~~ <sup>a further</sup>

led to the conclusion that in September, 2008,

~~The Director Generals of DSCSD, MHPD, TPD and the HPFBI also met on September 26, 2008 to discuss an update on issues relating to *S. divinorum* and to determine an agreed upon approach for subsequent steps. It was decided that media lines and a proposal for an "It's Your Health" article on *S. divinorum* would be prepared.~~ <sup>in order</sup>

<sup>Relevant</sup>  
3.1 ~~Legislative Frameworks for Drug Control in Canada~~

Act is "drugs"  
Regs are "drug"

3.1.1 Food and Drug Regulations (under the Food and Drug Act)

The *Food and Drug Regulations* (F&DR) serve to ensure the safety, efficacy, and quality of health products offered for sale in Canada, including drugs and medical devices. Prior to being given market authorization, a manufacturer must present substantive scientific evidence of ~~that a~~ <sup>is</sup> product's safety, efficacy <sup>is of high</sup> and quality. Health Canada reviews this information carefully and, if the review is satisfactory, a Notice of Compliance (NOC) is issued and appropriate Drug Identification Numbers (DINs) are assigned. <sup>For drugs,</sup>

A "drug" is defined under the F&DR as any substance or mixture of substances manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
- (b) restoration, correction or modification of organic functions in human beings or animals, or
- (c) disinfection in premises in which food is manufactured, prepared or kept;

As no products containing *S. divinorum* or its extracts have been reviewed and approved by Health Canada as of ~~January~~ <sup>July</sup> 2010, it is illegal to market *S. divinorum* when it is represented as a drug.

3.1.2 Natural Health Product Regulations (under the Food and Drug Act)

The *Natural Health Products Regulations* (NHPR) ~~came into force in January 2004~~ <sup>in</sup> to provide Canadians with ready access to natural health products (NHPs) that are safe, effective, and of high quality, while respecting freedom of choice and philosophical and cultural diversity. The NHPR contain a product licensing system that requires that all licensed products display a

These  
for the  
Natural Product Number (NPN), or, in the case of a homeopathic medicine, Drug Identification Number - Homeopathic Medicine (DIN-HM), on their labels. The number is issued once a product is authorized for sale in Canada by the Natural Health Products Directorate (NHPD). Product authorization requires either reference to a natural health product monograph or submission of other evidence of safety and health claim. A system of site licensing is also included in the NHPR which requires that all manufacturers, packagers, labellers, and importers be licensed; sites have procedures in place respecting distribution records, and product recalls; where applicable, sites have procedures in place for the handling, storage and delivery of their products, and sites meet good manufacturing practice requirements.

which in turn requires the presence of  
The definition of an NHP under the NHPR has both a function and substance component. The function component refers to those substances that are manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
- (b) restoring or correcting organic functions in humans; or
- (c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

The substance component refers to whether the product or medicinal ingredient therein is safe for consideration as an over-the-counter product, can be available for self-care and self-selection, and does not require a prescription to be sold. To be considered a NHP, no direct health claims need to be made regarding the substance. In the case of *S. divinorum*, it is generally marketed for its hallucinogenic properties which are considered a modification of an organic function. Therefore such products would be considered NHPs.

containing it meet the definition of an  
As of January 2010, no products containing *S. divinorum* have been reviewed and approved by Health Canada and no NPNs or DIN-HMs have been issued. Therefore sales of *S. divinorum* are illegal under the NHPR if it is represented for use as a hallucinogen or if other health claims such as modifying of organic functions are made.

### 3.1.3 Controlled Drugs and Substances Act and its Regulations

The CDSA provides a legislative framework for the control of substances that can alter mental processes and that may produce harm to the health of an individual or to society when diverted or misused. Except as authorized under its regulations, activities such as possession, possession for the purposes of trafficking, trafficking, importation, exportation, possession for the purposes of exportation and production of controlled substances are prohibited under the CDSA.

The substances regulated under the CDSA are grouped into eight Schedules, and each Schedule is associated with particular offences and penalties as described in Part I of the CDSA.

In determining whether a substance should be regulated as a controlled substance, and into which Schedule of the CDSA it should be placed, Health Canada considers the following factors:

- International requirements and trends in control/scheduling;
- Chemical and pharmacological similarity to other substances already scheduled under the CDSA;
- Legitimate uses of the substance (i.e. therapeutic, industrial or commercial);
- Potential for abuse and/or addiction liability of the substance;
- Extent of actual abuse in Canada and internationally; and
- Overall risk to public health and safety of Canadians.

pls confir that these are later factor (Trans-Schedulr policy - doc)

### 3.2 Assessment of *Salvia Divinorum* for Scheduling Purposes

#### 3.2.1 International Requirements and Trends in Control/Scheduling

At the present time, neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and therefore do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

#### *Australia*

In June 2002, Australia became the first country to prohibit *S. divinorum* and salvinorin A. Although both *S. divinorum* and salvinorin A are listed on Schedule 9 of Australia's Standard for the Uniform Scheduling of Drugs and Poisons on the basis of "high potential for abuse and risk to public health and safety", no substantiation of this risk was provided at the time of this scheduling decision.<sup>3</sup> Schedule 9 is Australia's most restrictive drug schedule, and includes "substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities."<sup>4</sup>

prohibit what sale, import?

#### *Belgium*

A decree was passed in Belgium on October 22, 2006 which added *S. divinorum* to the list of controlled substances, which includes substances such as psilocybin mushrooms, khat and peyote cactus.<sup>5</sup>

This list

#### Denmark

move to next page so not removed from text

<sup>3</sup> <http://www.tga.gov.au/ndpsc/record/rr200111.pdf>

<sup>4</sup> [http://www.cognitiveliberty.org/news/salvia\\_australia.htm](http://www.cognitiveliberty.org/news/salvia_australia.htm)

<sup>5</sup>

<http://eldd.emcdda.europa.eu/html.cfm/index5176EN.html?pluginMethod=eldd.shownewsdetails&id=20/12/2006BELGIUM:%20New%20substances%20controlled%20include%20mCPP%20and%20khat>



In 2003, Denmark <sup>added</sup> ~~prohibited~~ *S. divinorum* and salvinorin A ~~by adding them~~ to their list of "category B" controlled substances, a category which also includes psilocybin mushrooms, cocaine, amphetamine, and several others substances that are only legal for medicinal and scientific purposes. Illegal possession carries a penalty of up to two years in prison.

### **Germany**

*S. divinorum* (plant and plant parts) was added to Appendix I of the *Narcotics Act* in Germany on March 1, 2008, making it illegal to produce, traffic, or possess. The law does not specifically mention salvinorin A.

### **Italy**

On June 25, 2004, the Italian Ministry of Health issued an ordinance prohibiting the sale of *S. divinorum* and its active constituent salvinorin A. On January 11, 2005, the Ministry of Health made possession of *S. divinorum* and salvinorin A illegal by placing them in "Tabella 1" of the *Tabella Sostanze Stupefacenti o Psicotrope*.

### **Japan**

On November 9, 2006, the Japanese government added a group of thirty-three drugs to its list of controlled substances, including salvinorin A. The drugs are banned under a revised pharmaceutical law, under which persons involved in their illegal import, production, and sale, *i.e.*, ~~that~~ beyond medical treatment or research purposes, will be subject to up to five years imprisonment or a fine of up to five million yen.

### **Spain**

On January 28, 2004 the Spanish Ministry of Health and Consumption issued an order prohibiting the sale of *S. divinorum*, ~~along with a long list of other allegedly toxic herbs~~. The regulation went into effect on May 6, 2004 and only prohibits activities related to commerce. Possession and/or use are not considered to be criminal offences.

### **Other Countries**

*Salvia divinorum* is illegal to possess or sell in Croatia, Latvia, Lithuania, Poland, Romania, South Korea and Sweden. In Russia it is illegal to grow or sell *S. divinorum*, but it is legal to possess it. In Estonia, Finland, Iceland and Norway, *S. divinorum* is treated as a medicinal herb and it is illegal to import it without a relevant prescription from a doctor.

### **United States of America**

*S. divinorum* and salvinorin A are not included in the Schedules of the United States *Controlled*

although it has added ~~it to a list of chemicals~~ *Salvia divinorum* A  
do we need to update this:

In addition

*Wisconsin*  
Substances Act, although some individual states have implemented laws restricting its use, sale and/or distribution. As of May 2010, nineteen states have enacted legislation placing regulatory controls on *S. divinorum* and/or salvinorin A, <sup>including</sup> Delaware, Florida, Hawaii, Illinois, Kansas, Kentucky, Mississippi, Missouri, Nebraska, North Dakota, Ohio, Oklahoma, South Dakota and Virginia have placed *S. divinorum* and/or salvinorin A into Schedule I of state law.

of iron which has no legal implicat

California, Louisiana, Maine, North Carolina, and Tennessee have enacted other forms of legislation restricting the distribution of the plant.

More details on the regulations *Salvia Divinorum* in these last five states is provided below

**California**

As of January 1, 2009, the sale or distribution of *S. divinorum* or salvinorin A, or any substance or material containing *S. divinorum* or salvinorin A, to any person under 18 years of age became a misdemeanor in the state of California that is now punishable by imprisonment in a county jail for not more than six months, by a fine of no more than \$1,000, or both.

**Louisiana**

and that

In 2005, Louisiana passed a bill which prohibits the possession, production, manufacture and distribution of a material, compound, mixture, or preparation intended for human consumption which contains a hallucinogenic plant. A "hallucinogenic plant" is defined as "any part or portion" of the forty plants listed, which includes *S. divinorum*.

a plant on a list of

**Maine**

In Maine, *S. divinorum* and salvinorin A are regulated in a way similar to how tobacco products are controlled. Adults eighteen years of age or over can legally purchase and use the material, but selling or providing *S. divinorum* or salvinorin A to anyone under the age of eighteen is a criminal offence. Possession by a minor is a civil violation, punishable by a fine, community service, or both.

the same way as

**North Carolina**

December 1, 2009

the possession of

On February 11, 2009, Senate Bill 138 was introduced to the North Carolina State Legislature which sought to make *Salvia divinorum* and salvinorin A Schedule I controlled substances in that state. This bill was later amended to make possession of *S. divinorum* an infraction, a minor crime punishable by a maximum \$25 fine. A third possession offence would be charged as a misdemeanor. There are no separate penalties for manufacturing or sales. This bill includes two exemptions. One permits growing the plant for aesthetic, landscaping, or decorative purposes, the other allows for university-affiliated medical or pharmacological research. The new law came into effect on December 1, 2009.

illegal

brought a new law into force which

The only legal activities with *S. divinorum* are the growing for

## Tennessee

On July 1, 2006, Tennessee classified the deliberate production, manufacture, distribution, or possession of the active chemical ingredient in the hallucinogenic plant *S. divinorum* as a Class A misdemeanor. It is not, however, a criminal offence to possess, plant, cultivate, grow, or harvest *S. divinorum* for aesthetic, landscaping, or decorative purposes. The law also does not apply to any dosage that is legally obtainable from a retail establishment without a prescription when it is recognized by the Food and Drug Administration as a homeopathic drug.

*moved to earlier* In addition, the U.S. Department of Justice Drug Enforcement Agency (DEA) has placed *S. divinorum* and salvinorin A on a list of drugs and chemicals "of concern" without legal implications.

### 3.2.2 Chemical and Pharmacological Similarity to Other Substances Listed in the CDSA

The psychoactive ingredient in *Salvia divinorum* is salvinorin A. Other plants which contain psychotropic terpenoids are *Artemisia absinthium* (wormwood) and *Cannabis sativa*. Salvinorin A is considered by some as the most potent natural hallucinogen ever isolated.<sup>6</sup>

Unlike all other hallucinogens, salvinorin A is structurally distinct and does not interact with the serotonin-2A receptor or any other molecular target of classical hallucinogens. It thus affects the brain in a way that is quite unique.<sup>7</sup> Recent pharmacological screenings of receptors have found it to be a highly potent and selective  $\kappa$ -opioid receptor (KOR) agonist.<sup>8</sup>

The psychomimetic effects of *S. divinorum* closely resemble schizophrenia symptoms induced by lysergic acid diethylamide (LSD) or phencyclidine (PCP).<sup>9</sup> Yet, it is said to have only weak influence on the prevailing mood of the user which differentiates it from other hallucinogens such as LSD and psilocybin.<sup>10</sup> Its strong dissociative effects are often compared to those of ketamine. Users have reported that the psychedelic effects of *S. divinorum* were most similar to those caused by psilocybin mushrooms.<sup>11</sup> However, users familiar with the effects of other

<sup>6</sup> Ott J. Ethnopharmacognosy and human pharmacology of *Salvia divinorum* and salvinorin A. *Curare*. 1995 18: 103-129. Unofficial transcription available online. URL <http://www.sagewisdom.org/ott2.html>

<sup>7</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>8</sup> Roth BL, Baner K, Westkaemper R, Siebert D, Rice KC, Steinberg S, Ernsberger P, Rothman RB. Salvinorin A: a potent naturally occurring nonnitrogenous kappa opioid selective agonist. *Proc Natl Acad Sci U S A*. 2002 Sep 3;99(18):11934-9.

<sup>9</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>10</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>11</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

hallucinogens agree that despite certain similarities to classical hallucinogens, the visions and overall experience is quite unique.<sup>12</sup>

In addition, the <sup>a</sup>psychedelic effects of *S. divinorum* are similar to those of classical psychedelics regarding changes in perception and somatic sensations. *S. divinorum* causes an unusually <sup>a</sup>high degree of sedation, weakness and fatigue, while the increased de-realization is not commonly reported for classical psychedelics.<sup>13</sup> The combination of these effects seems to correlate with that of other KOR agonists such as pentazocine.<sup>14</sup>

### 3.2.3 Legitimate Uses of Salvia Divinorum

3 That said,

There are presently no legitimate medical ~~or industrial uses~~ for *S. divinorum* in Canada.

1 *Salvia divinorum* has traditionally been used for spiritual and medicinal purposes by the Mazatec Indians in Oaxaca, Mexico,<sup>15</sup> where an infusion of the leaves or the leaves themselves are ingested to treat gastrointestinal problems, headaches, rheumatism, anemia and swelling of the stomach.<sup>16</sup> Its main use ~~is~~ however, for its psychoactive properties in the aid of producing "mystical" or hallucinogenic experiences as part of spiritual rituals.<sup>17</sup>

2 Although selective kappa receptor agonists have been shown to produce analgesic effects, adverse effects such as psychotomimesis, dysphoria and diuresis have been observed in studies investigating their therapeutic use.<sup>18</sup> <sup>today is</sup> It has been speculated that KOR agonists may prove to be useful in the treatment of certain psychiatric disorders including Alzheimer's disease, schizophrenia, dementia and bipolar disorder.<sup>19</sup> <sup>In addition, while</sup> However, much more research is needed in order to substantiate these hypotheses. <sup>Similarly,</sup> Another study has suggested that chemical analogues of salvinorin A may be a useful treatment for those suffering from addiction to other substances.<sup>20</sup>

<sup>12</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6 and González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>13</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>14</sup> Arasteh K, Poudevida S, Farre M, Roset PN, Cami J. Response patterns of the Spanish version of the 49-item short form of the Addiction Research Center Inventory after the use of sedatives, stimulants, and opioids. *Drug Alcohol Depend.* 1999 Jun 1;55(1-2):117-25.

<sup>15</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>16</sup> Munro, T. The Chemistry of *Salvia divinorum*. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

<sup>17</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage *Salvia divinorum*. *Life Sci.* 2005 Dec 22;78(5):527-31.

<sup>18</sup> Barker RL, Fawcett J, Barkin SJ. 2002. Chronic pain management with a focus on the role of newer antidepressants and centrally acting agents. In: *Pain Management: A Practical Guide for Clinicians*, 6th edition, Weiner RS ed. CRC Press, Boca Raton, FL. pp. 415-34 and Tidgewell et al., 2004. A facile method for the preparation of deuterium labelled salvinorin A: *Biorganic & Medicinal Chemistry Letters*, 14: 5099-5102.

<sup>19</sup> Sheffler DJ & Roth BL. Salvinorin A: the 'magic mint' hallucinogen finds a molecular target in the kappa opioid receptor. *Trends Pharmacol Sci.* 2003 Mar;24(3):107-109.

<sup>20</sup> Prisinzano TE. Natural products as tools for neuroscience: discovery and development of novel agents to treat drug

④ Similarly,

There are no known industrial uses for *S. divinorum* in Canada. The plant is a semi-tropical perennial that can only grow outdoors in a humid climate where it will not encounter frost. Most websites offering *S. divinorum* cuttings and seeds for sale do so in the context of growing the plant for its psychoactive properties, rather than out of horticultural interest or for its esthetic appeal.

### 3.2.4 Potential for Abuse Liability and/or Addiction Liability of the Substance

~~Most clinically used opioid analgesics (e.g. codeine, oxycodone, morphine) are selective for the  $\mu$ -opioid receptor (MOR) and can be habit-forming because activation of the MORs causes euphoria, which makes the user want to take them again. As previously mentioned, Salvinorin A is a potent, selective agonist of the  $\kappa$ -opioid receptor (KOR), and in contrast to the euphoria produced by MOR agonists, the KOR agonists are negatively reinforcing and aversive.<sup>22</sup> In addition, KOR agonists have analgesic properties but are not associated with respiratory depression like MOR agonists. Initially, these effects provided hope for the development of an analgesic absent of addiction liability and respiratory depression. However, it was soon discovered that KOR agonists produced dysphoria and psychomimetic effects such as confusion, hallucinations and depersonalization.<sup>23</sup> Finally, while MOR increases the release of dopamine, the activation of KOR decreases dopamine release in the nucleus accumbens.<sup>24</sup>~~

pull out

not really relevant

agonists

The onset and intensity of the effects of *Salvia divinorum* appear to be related to the route of administration. Traditional uses generally produce mild effects because the leaves are rolled and

Start new para

abuse. *J Nat Prod.* 2009 Mar 27;72(3):581-7.

<sup>22</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590, Cooper S. Interactions between endogenous opioids and dopamine: Implications for reward and aversion. In: *The Mesolimbic Dopamine System: From Motivation to Action*. Willner P and Scheel-Kruger J (editors) Wiley, Chester, England, 1991, pp. 331-366, and Shippenberg TS, Herz A, Spanagel R, Bals-Kubik R, Stein C. Conditioning of opioid reinforcement: neuroanatomical and neurochemical substrates. *Ann N Y Acad Sci.* 1992 Jun 28;654:347-56.

<sup>23</sup> Pfeiffer A, Brantl V, Herz A, Emrich HM. Psychotomimesis mediated by kappa opiate receptors. *Science.* 1986 Aug 15;233(4765):774-6, Rimoy GH, Wright DM, Bhaskar NK, Rubin PC. The cardiovascular and central nervous system effects in the human of U-62066E. A selective opioid receptor agonist. *Eur J Clin Pharmacol.* 1994;46(3):203-7, and Walsh SL, Strain EC, Abreu ME, Bigelow GE. Enadoline, a selective kappa opioid agonist: comparison with butorphanol and hydromorphone in humans. *Psychopharmacology (Berl).* 2001 Sep;157(2):151-62.

<sup>24</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.

chewed or crushed and prepared as a foamy infusion whereby the salvinorin A is degraded in the gastrointestinal system before being absorbed into the bloodstream. ~~These methods rely on contact with the oral mucosa for absorption and~~ the level of effect relates quite closely to the length of time the material spends in the mouth. ~~The~~ onset of effect generally takes 5-10 minutes. The effects build over the next hour and last for another hour before they begin to subside.<sup>25</sup>

Hence

Routes of administration that avoid the hepatic first-pass effect, are the quickest and most intense.<sup>26</sup> [Salvinorin A can be isolated from the plant to make a powder which can be vaporized and inhaled.] ~~This method of administration is the most powerful and only requires 200-500 micrograms of salvinorin A powder to produce the same effects as those of fresh leaves.~~ The onset of effects felt from vaporizing salvinorin A powder occurs in about 30 seconds and effects last for about 5-10 minutes and then subside over the next 30 minutes.<sup>27</sup> Smoking is by far the most popular method of administration<sup>28</sup> and this is accomplished by smoking the dried leaves or a concentrated extract using a pipe or bong. Dried leaves may also be fortified with a concentrated extract of salvinorin A. A concentrated extract can also be used sublingually. Neither *S. divinorum* nor salvinorin A are injected because the powder is insoluble in water.<sup>29</sup>

with the [ ] i.e., there

start new par

~~The various modes of administration of *S. divinorum* lead to the variable onset and duration of its effects.~~ These effects are generally accepted to be: sensation of becoming an object, visions of various two-dimensional surfaces, films and membranes, revisiting places of the past (particularly childhood), perceived loss of the body and/or identity, various sensations of motion (being pulled or twisted by a force of some kind), uncontrollable hysterical laughter, and overlapping realities (perceptions of being in more than one place).<sup>30</sup> Laughter, happiness, sense of well-being and dissociative effects were deemed the best aspects of *S. divinorum* by users, second only to the "trip" that the drug elicits.<sup>31</sup> Depersonalization, speaking gibberish, widening of consciousness, subjective illusions of rapid movement, flying or hovering have also been reported.<sup>32</sup>

out of place as reality more about effects not just addiction liability

<sup>25</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>26</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.

<sup>27</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>28</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62 and Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>29</sup> Valdés LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs.* 1994 Jul-Sep;26(3):277-83.

<sup>30</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>31</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>32</sup> Bücheler R, Gleiter CH, Schworer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry.* 2005 Jan;38(1):1-5 and Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

may be work into 3.2.2

The aversive effects of previously studied KOR agonists predict that the risk of addiction to *S. divinorum* is negligible. However, very few controlled scientific studies of the physical and psychotropic effects of *Salvia divinorum* on humans have been carried out. Therefore, it is difficult to predict its potential for addiction and abuse. In studies that have been conducted, there is conflicting information around the addiction liability of *S. divinorum* in both animals and humans. Some users have noted that they require increasing doses of salvinorin A in order to achieve the desired effect and the stimulated cerebral KOR may act as a mechanism of tolerance.<sup>33</sup> ~~More controlled systematic research in this area is needed.~~ Further studies on the mediated decrease of dopamine as well as the impact of dose on the rewarding and aversive effects are also warranted.

in this area and

required. While

~~Another aspect of the *S. divinorum* abuse potential stems from its availability. As previously mentioned, it is widely available for purchase on the Internet through drug promotional sites and it is also sold in various "head shops" and corner stores. In addition, the potential for high yields and ease of extraction may make buying and selling this substance quite affordable and attractive. Originally, the concerns for the potential of abuse were minimal as it was concluded that 1 kg of dried leaves yielded only 3 to 6 human doses of salvinorin A. However, it was discovered that vaporizing and inhaling 200-500 micrograms had profound hallucinogenic effects.<sup>34</sup> The extraction of salvinorin A from the plant is very easy and with care, approximately 1.5 grams of pure salvinorin A per kilogram of dried leaves (8kg of fresh leaves) can be isolated. Therefore, a gram of salvinorin A is enough substance to provide for 2000 human doses.<sup>35</sup> It is also believed to be easier to obtain salvinorin A than to extract LSD or produce PCP derivatives.<sup>36</sup>~~

but we have no evidence of abuse b/c easy to buy!

which is enough

3.2.5 Extent of Actual Abuse in Canada and Internationally

move to next pg.

have to be honest and say am not sure this info is really relevant (but leave for now)

<sup>33</sup> Bucheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>34</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>35</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs*. 1994 Jul-Sep;26(3):277-83.

<sup>36</sup> Bucheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

All of this is not extent of abuse but use check - ElizD. to see how this info handled for B21

Very limited data exists regarding the ~~population use~~<sup>use</sup> of *Salvia divinorum* ~~across the Canadian population~~<sup>in Canada</sup>. To address this lack of data, questions about the use of *S. divinorum* were included in the 2008-2009 Youth Smoking Survey, the 2009 Canadian Alcohol and Drug Use Monitoring Survey and the 2009 Ontario Student Drug Use and Health Survey.

The results from the 2009 Ontario Student Drug Use and Health Survey were published on November 18, 2009 and indicate that:

- Among all responding students in Ontario, 4.4% reported using *Salvia divinorum* at least once in the past year. In comparison, 58.2% indicated they had used alcohol, 25.6% indicated they had used cannabis and 5.0% indicated they had used hallucinogens other than LSD and PCP in the past year;
- Males (6.2%) were significantly more likely than females (2.3%) to report using *Salvia divinorum*;
- There is significant grade variation, with *Salvia divinorum* use most likely among 11<sup>th</sup> graders (8.6%) and 12<sup>th</sup> graders (8.4%); and
- There are significant regional variations, with students in Northern Ontario (9.2%) most likely to use *Salvia divinorum*.

The results of the 2008-2009 Youth Smoking Survey were published on May 31, 2010 and indicate that:

- 4.9% of students stated that they had used *S. divinorum* in the last twelve months. In comparison, 53.0% indicated they had used alcohol, 27.3% indicated they had used cannabis and 6.9% indicated they had used other hallucinogens in the last twelve months;
- 2.6% of students in Grades 7-9 and 7.0% of students in Grades 10-12 had used *S. divinorum* in the last twelve months; and
- Males (6.6%) were more likely to have used *S. divinorum* in the past twelve months compared to females (3.2%).

The scope of the previously mentioned studies did not provide for any explanations regarding differences in usage between ages, genders and regions. ~~Given the lack of information surrounding *S. divinorum*~~, it is difficult to speculate on the causality of such differences.

In this regard,

Additional data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey will be available in the summer of 2010.

this is on the website raw so its add.

As far as law enforcement is concerned, the Department has only received a limited number of communications indicating concern with respect to *S. divinorum* and none of these ~~have~~<sup>has</sup> advised that the use of *S. divinorum* poses any threat to public safety. ~~Sgt. Doug Culver~~<sup>has</sup> of the Royal Canadian Mounted Police (RCMP) stated that while *S. divinorum* is readily available, it has not become a popular drug in Canada, ~~Sgt. Culver speculated that this may be~~<sup>probably</sup> due to its aversive effects such as anxiety and introversion.

Health Canada's Drug Analysis Services (DAS) has ~~collected some raw data~~<sup>a number of samples</sup> regarding the number of samples identified as containing salvinorin A in the DAS labs, however, ~~as the plant~~<sup>received</sup> seized by

this is step to public safety

raw 000895



and/or substance is not in the Controlled Drugs and Substances Database (CDS) druglist, it is not possible to have records of any seizures of it in the database. However, there have been a number of samples submitted to DAS for analysis that have been confirmed to contain salvinorin A.

**NUMBER OF SAMPLES FOUND TO CONTAIN SALVINORIN A**

Year Return Completed	Count
2006	6
2007	8
2008	6
2009	To be updated

write  
with  
vial  
with  
safety

How will you do this?

The National Forensic Laboratory Information System (NFLIS) and the System to Retrieve Information from Drug Evidence (STRIDE) in the United States is a Drug Enforcement Agency (DEA) database that collects scientifically verified data on analyzed samples in state and local forensic labs as well as samples from DEA labs. The following table shows the quantity of *S. divinorum* products that were seized from 2000 through to 2009.

**ANALYZED SALVIA DIVINORUM or SALVINORIN A SEIZURES**

(Number of items/Exhibits)

Source	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009*
NFLIS-State/Local <sup>1</sup>	0	0	0	0	1	8	12	12	70	34
STRIDE <sup>2</sup>	0	0	1	1	1	0	0	0	N/A	N/A
<b>TOTAL</b>	0	0	1	1	2	8	12	12	70	34

Data Source: NFLIS & STRIDE, 2008 data queried 11/24/08, updated 06/10/2010

<sup>1</sup> NFLIS reported seizures of *Salvia divinorum* and/or salvinorin A

<sup>2</sup> STRIDE reported items of *Salvia divinorum*.

\* Includes only January – May data in 2009.

A handful of case reports regarding the use of *S. divinorum* have been published in the academic literature. One report was an international case report in which a young man (19 years of age) described his perceptions after inhaling smoke from *S. divinorum*. The peak psychotropic effects, including prickling of the skin, fever-like hot flashes, muscular tremor, and depersonalization, were reached in less than five minutes after inhalation of an unknown amount of smoke from burning dried leaves.<sup>37</sup> Another report involved a 15-year-old male who presented to psychiatric emergency services with acute onset of paranoia, déjà vu, blunted affect, difficulties in thought processing and slowed speech after smoking *Salvia divinorum* over an unknown period of time. During his hospitalization all symptoms improved significantly except the feeling of déjà vu. Based on this case presentation, the author suggested that the feelings of déjà vu may be a long-term effect of *S. divinorum* use.<sup>38</sup> However, given that this is the only case report in which déjà vu was associated with the use of *S. divinorum*, more reports are needed to

Again  
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abuse  
per se  
so  
does not  
belong  
here.

<sup>38</sup> Singh S. (2007) Adolescent salvia substance abuse. *Addiction*. 102, 823-824.

substantiate this finding.

In addition to the above-mentioned reports, in 2006, a case was reported in the U.S. in which a 17-year-old boy committed suicide after smoking *S. divinorum* for an unknown period of time.<sup>39</sup> It should be noted that alcohol and general depression were the main confounders in this case. After this case was reported, the state of Delaware passed a law which classified *S. divinorum* as a Schedule I controlled substance along with other hallucinogenic substances.

It is difficult to determine the extent of actual abuse of *S. divinorum* as there appear to be inconsistencies in the literature regarding risk aversion. For example, one author states: "Many who have used salvinorin A find the experience extremely unnerving, frightening and overly intense and most have no desire to repeat the experience."<sup>40</sup> However, another study suggested that this is not the experience of all recreational users of *S. divinorum*.<sup>41</sup> Over eighty percent of users surveyed on a web-based questionnaire about their *S. divinorum* use said that they would probably or definitely use *S. divinorum* again.<sup>42</sup> Users have reported the negative effects of *S. divinorum* as: the short duration of action, lack of control over the experience, persisting negative effects (most often anxiety)<sup>43</sup> sweating, chills, increased diuresis, impaired vigilance,<sup>44</sup> and negative after-effects including tiredness, feeling head heavy, dizziness, physical exhaustion, and some degree of malaise or 'hangover' as they 'comedown' from the drug.<sup>45</sup> ~~However, it is difficult to determine the influence these effects have on the use of *S. divinorum*.~~ *in Canada or elsewhere*

### 3.2.6 Overall Risk to Public Health and Safety of Canadians

The increase in both the number of enquiries from various municipalities and members of the public and in the amount of media interest regarding the availability of *Salvia divinorum* in Canada may be an indication that the recreational use of *S. divinorum* as a hallucinogen is on the rise in Canada. However, there are no available statistics that indicate there has been a significant increase in *S. divinorum* use in the Canadian population and, in comparison to the use of other drugs such as alcohol and cannabis, the actual use of *S. divinorum* is quite low.

The potential for harm to the user and/or other individuals is primarily related to the

<sup>39</sup> <http://www.kvbc.com/Global/story.asp?S=4893692>

<sup>40</sup> Turner DM. Salvinorin - The Psychedelic Essence of Salvia Divinorum. Panther Press, San Francisco, CA 1996.

<sup>41</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62, Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5, and Valdès LJ 3rd. Salvia divinorum and the unique diterpene hallucinogen, Salvinorin (divinorin) A. J Psychoactive Drugs. 1994 Jul-Sep;26(3):277-83.

<sup>42</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>43</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>44</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5.

<sup>45</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

hallucinogenic properties of the substance. Users may get up and walk around without apparent awareness of their movements, behaviour or surroundings, and distinction between self and surroundings is often lost. At doses greater than 1mg of salvinorin A, out of body experiences are frequent and loss of consciousness has been reported.<sup>46</sup> There is little information regarding the social behaviours of persons under the influence of *S. divinorum* products, and what risks their activities such as operating a motorized vehicle may pose to the general public. There is also very little data regarding the toxicity, teratogenicity and long-term effects of *S. divinorum* use.<sup>47</sup>

or other

~~As stated earlier, there are no approved medical uses for *S. divinorum* in Canada. Health Canada has also neither received nor approved any submissions for natural health products for sale in Canada. Therefore, products that claim to contain this substance have not been extensively reviewed by Health Canada and as such, may be counterfeit or may contain other ingredients that may pose health risks. Like many drugs of abuse, the users are often unaware of the potency and adulterants in the products they are purchasing. A study by Wolowich *et al.* (2006)<sup>48</sup>, showed that the salvinorin A content in five out of five *S. divinorum* products was falsely indicated on the label and 4 out of 5 products contained unidentified adulterants (i.e. vitamin E, caffeine).~~

Health Canada has only anecdotal information about the use and abuse of *S. divinorum* in Canada as well as the threat *S. divinorum* may pose to the health and safety of Canadians. Although reports of domestic adverse reactions related to the use of *S. divinorum* as a hallucinogen have been received through the Canada Vigilance database, it is important to note that the number of reports and the nature of reactions reported are not adequate to characterize the risk to the general population. ~~This data can also not be used to determine incidence of use in the Canadian population.~~

stet.

#### 4. ASSESSMENT OF RISKS AND BENEFITS

In addition,

*Salvia divinorum* is a substance with unknown long term effects that is currently not scheduled under the CDSA. It can be imported and sold legally in Canada to anyone of any age, anywhere in Canada provided it is not represented as a health product. The *S. divinorum* sold in Canada is currently not subject to any specific quality or safety standards. The available scientific evidence indicates a low potential for abuse of this substance.

good but put at end of section

There are certain risks associated with scheduling *Salvia divinorum* and/or salvinorin A under the CDSA. In particular, scheduling *S. divinorum* and/or salvinorin A under the CDSA without sufficient defensible evidence in accordance with the established criteria for scheduling could be precedent-setting in that Health Canada might then have to look at scheduling other plants with psychoactive properties, e.g. Jimsonweed, Datura.

Health Canada only has anecdotal information about the risks associated with the use of *S.*

<sup>46</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>47</sup> Grundmann O, Phipps SM, Zadezensky I, Butterweck V. *Salvia divinorum* and Salvinorin A: An Update on Pharmacology and Analytical Methodology. Planta Med 2007 Jun;73:1039-1046.

<sup>48</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. Pharmacotherapy. 2006 Sep;26(9):1268-72.

reward to fows on last sentence ...

however

*divinorum* and/or salvinorin A. ~~However~~, there is scientific evidence which suggests that this plant and its active ingredient may have the potential to create risks to individual and public health and safety resulting from the unsupervised use of a hallucinogenic substance (i.e. driving under the influence, and injuries caused by disassociation with surroundings, loss of consciousness, etc.). In the absence of any type of mechanism of control of these substances, the safety and well-being of Canadians could be at risk.

is shouldn't be statements about this and Risk to Public Safety ?

### 5. IDENTIFICATION AND ANALYSIS OF OPTIONS

Further to the assessment previously described, the following options for the control of *Salvia divinorum* have been identified.

#### Option 1: Status Quo – No Action. *Salvia divinorum* and salvinorin A remain as uncontrolled substances.

~~*S. divinorum* and salvinorin A are considered to be unapproved natural health products according to the NHPR.~~

#### PROS:

- a. Consistent with the fact that *Salvia divinorum* and salvinorin A are not yet scheduled under any of the United Nations Drug Control Conventions
- b. When *S. divinorum* is manufactured, sold or represented for use as a hallucinogen it meets the definition of a drug under the *Food and Drug Act* (FDA) and cannot be sold legally without license authorization. Therefore, the sale of *Salvia divinorum* and salvinorin A is already subject to compliance action when they are represented as hallucinogens

is in itself a pro

- c. ~~A lack of action at this time is~~ consistent with the fact that <sup>very</sup> little is known about *S. divinorum* to ~~make an informed decision regarding changes to its regulation.~~ and for Salvinorin A

#### CONS:

- a. *S. divinorum* can be legally imported and sold in Canada providing it is not represented as a drug product (hallucinogen). This may allow for easier access to the substance by ~~potential abusers~~ and can only be applied
- b. Penalties under the FDA are only administrative in nature, ~~Law enforcement personnel do not have the authority to criminally charge non-compliant retailers~~ in the instance where
- c. ~~By not scheduling *S. divinorum* as a controlled substance, the Canadian mechanism of control differs from that of other countries including Australia, Belgium, Denmark, and Japan~~ <sup>status in</sup> <sub>(e.g.)</sub> a product is active in markets as
- d. ~~Is not~~ in line with the HPFB (MHPD, NHPD) recommendations to schedule *S. divinorum* under the CDSA <sup>as</sup> modifying organic reactions

Out of step with

#### Option 2: Develop and implement an educational campaign regarding the risks associated with the use of *Salvia divinorum*.

#### PROS:

- a. Consistent with the fact that *Salvia divinorum* and salvinorin A are not yet scheduled under any of the UN Drug Control Conventions
- b. Information provided may help individuals make an informed decision based on the

- placement of Salvia use stats

- legitimate use?

- extent of actual abuse?

- placement of DAS seizures &  
DEA info

- currently in extent of abuse

- same as BZP IAS

- specific schedule under CDSA?

- add sentence re: 3-step approach

(to schedule, which schedule, which reg)

- Schedule III - LSD, PCP, mushrooms

- Schedule IV - benzos, steroids (less stringent)

- Schedule I - Narcotics (opium, cocaine)

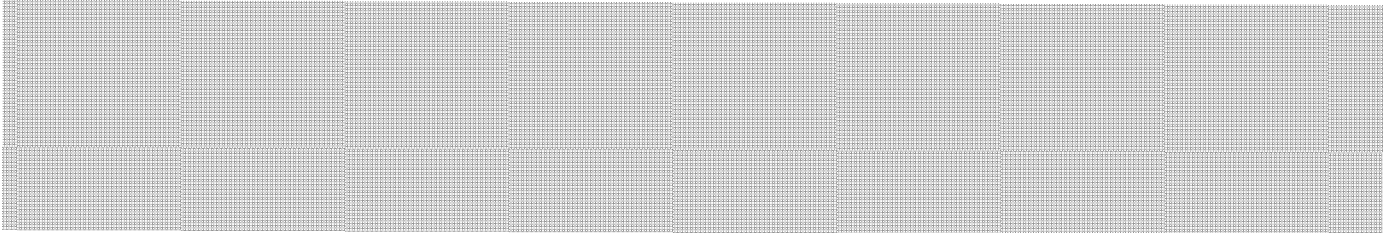
(II - cannabis) (VI - precursor) (V - propylhexedrine)

**Page(s) 000901 to\à 000901**

**Is(Are) exempted pursuant to section(s)  
est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**



6. CONSULTATIONS

The Drug Analysis Services (DAS) was contacted in order to provide any data available regarding the prevalence of *S. divinorum* in Canada. Though DAS did not have a record of seizures of the substance, it did provide information regarding the number of samples DAS tested which contained salvinorin A. *the identity of samples submitted by law enforcement*

The OCS contacted the Royal Canadian Mounted Police (RCMP) in order to establish their views on *S. divinorum* use in Canada. The RCMP indicated that *Salvia divinorum* is not yet a known substance in the majority of Canada (with the exception of Ontario), and that it does not pose a significant concern for public safety at this time. An RCMP document prepared by Sgt. Doug Culver stated that scheduling of *S. divinorum* under the CDSA was not currently warranted due to its low potential for abuse and potential medical significance. *was contacted in order to determine if there was any mention of names of plants*

OCS has received a number of correspondences from Canada Border Service Agency (CBSA) officers concerning a lack of information regarding the status of *S. divinorum* and how the substance should be treated at the border. Officers also expressed concern regarding the substance's hallucinogenic properties and increased media attention. At present, only shipments of *S. divinorum* that are represented as health products/hallucinogens can be refused for import under the NHPR. *plant the plant's CBSA have stick to content from earlier re. RCMP*

7. CONSIDERATIONS

①

The KOR-mediated aversive and dysphoric effects of *Salvia divinorum* do not appear to be hampering its use. *as young* Young adults have begun smoking the leaves and leaf extract recreationally.<sup>49</sup> It can be purchased through online botanical companies and other drug promotional sites and is often touted as a legal alternative to substances such as cannabis and mescaline.<sup>50</sup> Interestingly, after being widely available for over a decade, the drug *does appear to have had the same* has not had any extreme social impact as ~~the~~ LSD or ecstasy.<sup>51</sup>

While

②

Over the past few years, there has been an increase in the number of enquiries that Health Canada is receiving from various municipalities and members of the public regarding the availability of *Salvia divinorum* as a hallucinogen. Health Canada has also observed a steady increase in the amount of media interest regarding the availability of *S. divinorum* in Canada. According to currently available statistics, the reported use of *S. divinorum* by young Canadians is much lower than that of alcohol or cannabis, *according to available statistics.*

<sup>49</sup> Hazelden Foundation, 2004. Drug Abuse Trends. June 2004. URL: [www.research.hazelden.org](http://www.research.hazelden.org).  
<sup>50</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.  
<sup>51</sup> Munro, T. The Chemistry of *Salvia divinorum*. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

s.21(1)(a)

s.21(1)(b)

~~Salvia divinorum~~ meets the definition of a natural health product (NHP) under the *Natural Health Product Regulations* (NHPR). This means that products containing *S. divinorum* must be approved by Health Canada prior to sale in Canada and that products that are not in compliance with the NHPR may be subject to compliance and enforcement actions. As Health Canada has yet to receive and/or approve any applications for natural health products containing *S. divinorum* for sale on the Canadian market, the sale of such products is illegal. Several challenges also arise with respect to the importation and domestic movement of *S. divinorum* products as they are often declared as incense and therefore cannot be considered unapproved natural health products and seized. In addition, compliance and enforcement actions, such as voluntary stop-sales, forfeiture, destruction, and administrative seizure, cannot be implemented unless the labeling of the product indicates that it is to be used for consumption and/or pharmacological effects. The NHPR are therefore limited in their capacity to control the availability of *S. divinorum* beyond the scope of scenarios listed above. *in fact*

Start para here

~~*S. divinorum* and salvininorin A are not structurally similar or even pharmacologically similar to other substances included in the schedules to the CDSA. [The abuse liability and potential for dependence of *S. divinorum* is not known as very few controlled scientific studies of the physical and psychotropic effects of *S. divinorum* have been carried out on humans. More controlled systematic research in this area is needed. Health Canada has only received a limited number of communications regarding *Salvia divinorum* from law enforcement agencies, and none of these have advised that the use of *Salvia divinorum* poses any particular threat to public safety. Evidence of a risk to public health and safety is anecdotal in nature and not quantified in any way, as there is a lack of information regarding usage in Canada.]~~ because we have YSS + CADUMS ...

In regards to the previous HPFB recommendation to schedule *S. divinorum* under the CDSA, ~~this suggestion was deemed inappropriate and~~ likely based on a misunderstanding of the previously-described criteria upon which scheduling is based, ~~it~~ <sup>was</sup> did not consider a number of factors, including ~~namely the lack of evidence of potential for abuse and risk to public health and safety.~~ The Office of Controlled Substances (OCS) was also not consulted by HPFB at the time this recommendation was made. In addition, among countries who have decided to control *S. divinorum* in some way, very little or no substantiation of the risks of *S. divinorum* upon which the decision was based are available.

~~Health Canada is currently finalizing media lines regarding *S. divinorum* as well as an "It's Your Health" article to be published on the Health Canada website. These documents are designed to address the recurrent media attention regarding *S. divinorum* as well as increase public awareness of the risks associated with this substance.~~

8. SELECTED STRATEGY

9. IMPLEMENTATION AND EVALUATION

or call add to implementation + Eval

3  
create  
sub  
bund  
nu  
alvin  
or  
S.A do  
neet  
riterin  
in scheduling

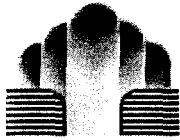


**Page(s) 000904 to\à 000904**

**Is(Are) exempted pursuant to section(s)  
est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**




Jocelyn Kula/HC-SC/GC/CA

2010-06-21 11:52 AM

To Lisa MacKay/HC-SC/GC/CA@HWC

cc Denis Arsenault/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC

bcc

Subject Re: Salvia IYH 

Great news but do we need to see the doc again?.....just that obviously I don't know whether you/ HPFB accepted all the changes we suggested last time.....

Also, do you handle the approvals for the media lines, or do they go back to Comms to handle?

JK

---

Jocelyn Kula

Manager/ Gestionnaire

Policy and Regulatory Affairs Division/ Division des politiques et affaires réglementaires

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs

Health Canada/ Santé Canada

Tel: (613) 946-0125 Fax: (613) 946-4224


Lisa MacKay/HC-SC/GC/CA

Lisa MacKay/HC-SC/GC/CA

2010-06-21 11:50 AM

To Jocelyn Kula/HC-SC/GC/CA@HWC

cc Denis Arsenault/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC

Subject Re: Salvia IYH 

Hi Jocelyn,

I've had some other priorities come up lately but I'm hoping to get it off my desk into formal approvals today or tomorrow.

Thanks

Lisa Mackay

It's Your Health Project Manager/Gestionnaire du projet Votre santé et vous

Strategic Communications and Ministerial Services Division / Division des communications stratégiques et des services ministériels

Public Affairs, Consultation and Communications Branch/ Direction générale des affaires publiques, de la consultation et des communications

Health Canada | Santé Canada

Tel 613.954.0105

Fax 613.952.8644

Lisa\_Mackay@hc-sc.gc.ca

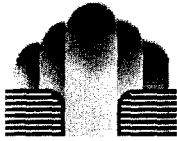
Jocelyn Kula/HC-SC/GC/CA



Jocelyn Kula/HC-SC/GC/CA

2010-06-21 11:40 AM

To Lisa MacKay/HC-SC/GC/CA@HWC



cc Stephanie Chandler/HC-SC/GC/CA@HWC, Denis Arsenault  
Subject Salvia IYH

Hi Lisa

Now it is my turn to ask about status! Just that it came up at a senior management meeting this week and it was left with me to determine where things are at. Any advice you have (and I know we provided lots of input last time round....) as to when it might start moving up the line for approvals and/or come back to programs would be much appreciated.....

Thanks in advance  
Jocelyn

PS Am copying Stephanie Chandler as she has just joined my division and is working on completing the scheduling assessment of Salvia.....

---

Jocelyn Kula  
Manager/ Gestionnaire  
Policy and Regulatory Affairs Division/ Division des politiques et affaires réglementaires  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0125 Fax: (613) 946-4224

Matthew James  
Dann/HC-SC/GC/CA  
2010-06-22 02:47 PM

To Stephanie Chandler/HC-SC/GC/CA@HWC, Judy Snider/HC-SC/GC/CA@HWC  
cc Suzanne Desjardins/HC-SC/GC/CA@HWC  
bcc  
Subject Re: Fw: Data re: Salvia divinorum samples

Hi Stephanie,

Here are the numbers for Salvinorin A from DAS LIMS as of May 7, 2010.

	2005	2006	2007	2008	2009	2010 as May 7
# of exhibits containing salvia	0	9	8	4	20	8

Matthew Dann  
Office of Drugs and Alcohol Research and Surveillance  
Controlled Substances and Tobacco Directorate  
Healthy Environments and Consumer Safety Branch  
MacDonald Building, A.L. 3506A  
123 Slater St., Ottawa, ON  
K1A 0K9

Phone: (613) 948-8908  
Fax: (613) 952-5188

Judy Snider/HC-SC/GC/CA

Judy Snider/HC-SC/GC/CA  
2010-06-22 02:22 PM

To Matthew James Dann/HC-SC/GC/CA@HWC  
cc Suzanne Desjardins/HC-SC/GC/CA@HWC  
Subject Fw: Data re: Salvia divinorum samples

Hi Matt,

Can you please provide the latest info to Stephanie. These numbers have already been created and inserted into the presentation I gave a couple of weeks ago at the CEWG.

Thanks,

Judy

----- Forwarded by Judy Snider/HC-SC/GC/CA on 2010-06-22 02:20 PM -----



Stephanie  
Chandler/HC-SC/GC/CA  
2010-06-22 01:18 PM

To Judy Snider/HC-SC/GC/CA@HWC  
cc  
Subject Data re: Salvia divinorum samples

Hi Judy,

I am currently finalizing a scheduling assessment of *Salvia divinorum* (including Salvinorin A). A search regarding the number of samples which were found to contain these substances by DAS labs was completed in 2008, and I am hoping to be able to update the data to include 2008 to 2010 (if available). I've attached the 2008 email thread and the results of the previous search performed for your information.



Email Salvia 2008-10-10\_DAS.doc Email Salvia 2008-10-10\_DAS Attachment.pdf

I believe you are the correct contact person for this sort of request, however, please let me know if there is someone more appropriate for me to contact.

Thank you,

Stephanie Chandler  
Junior Regulatory Project Officer  
Policy and Regulatory Affairs Division/ Division des politiques et affaires réglementaires  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

Johanne Paquette/HC-  
SC/GC/CA

2008-10-10 09:12 AM

To Cheryl Tremblay/HC-SC/GC/CA@HWC

cc

Subje Re: Fw: Saliva Divinorum  
ct

Good morning Cheyl:

See below the raw data information received.

The psycho-active agent in **salvia divinorum** is **salvinorin A**. As the plant and/or substance is not in the CDSD druglist, it is not possible to have any seizures of it in the database. There have been a number of samples containing the substance identified in the DAS labs.



Salvinorin A.pdf

Should you require futher information, or more statistical analysis, do not hesitate to contact me.

Johanne

*Johanne Paquette*

A / Supervisor, Destruction Unit /

Superviseur par intérim, unité de destruction

Drug Strategy and Controlled Substances (DSCS) /

Stratégie antidrogue et substances contrôlées (SASC)

Drug Analysis Service (DAS) / Service d'analyse des drogues (SAD)

Téléphone: (613) 946-1143

Fax / Télécopieur: (613) 941-4760

Email / courriel: johanne\_paquette@hc-sc.gc.ca

Johanne Paquette/HC-  
SC/GC/CA

2008-10-09 03:12 PM

To Mary-Jane Garnett/HC-SC/GC/CA@HWC

cc

Subje Fw: Saliva Divinorum  
ct

Good afternoon Mary-Jane:

Can you perform a search in CDSD for any seizures from 2002 to 2008 - all police services across Canada and also in LIMS.

Thank you!!

Johanne

*Johanne Paquette*

A / Supervisor, Destruction Unit /  
Superviseur par intérim, unité de destruction  
Drug Strategy and Controlled Substances (DSCS) /  
Stratégie antidrogue et substances contrôlées (SASC)  
Drug Analysis Service (DAS) / Service d'analyse des drogues (SAD)  
Téléphone: (613) 946-1143  
Fax / Télécopieur: (613) 941-4760  
Email / courriel: johanne\_paquette@hc-sc.gc.ca

----- Forwarded by Johanne Paquette/HC-SC/GC/CA on 2008-10-09 03:09 PM -----

**Cheryl Tremblay/HC-  
SC/GC/CA**

2008-10-08 01:59 PM

To Johanne Paquette/HC-SC/GC/CA@HWC

cc

Subje Saliva Divinorum  
ct

Hi Johanne,

I am currently in the process of working on a preliminary scheduling assessment for Salvia  
Divinorum and was just wondering whether DAS has any records of any seizures with respect to  
this plant.

Thank you,

Cheryl Tremblay  
Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Drug Strategy and Controlled Substances Directorate  
Health Canada  
Tel: (613) 954-6527  
Fax: (613) 946-4224

---

Date: 2008/10/10

---

**No of Samples found to contain Salvinorin A**

---

Year Return Completed	Count
2006	6
2007	8
2008	6





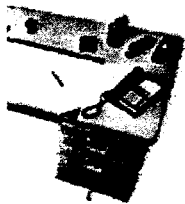
Jocelyn Kula/HC-SC/GC/CA  
2010-06-28 03:54 PM

To Stephanie Chandler/HC-SC/GC/CA@HWC  
cc Daniel Galarneau/HC-SC/GC/CA@HWC  
bcc  
Subject Fw: The use of Salvia as an incense

for the file pls

---

Jocelyn Kula  
Manager/ Gestionnaire  
Policy and Regulatory Affairs Division/ Division des politiques et affaires réglementaires  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0125 Fax: (613) 946-4224  
----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2010-06-28 03:53 PM -----



Robin Marles/HC-SC/GC/CA  
2010-06-28 03:51 PM

To Brook Bertrand/HC-SC/GC/CA@HWC, Jason  
Topping/HC-SC/GC/CA@HWC  
cc CCIM/HC-SC/GC/CA@HWC, Jocelyn  
Kula/HC-SC/GC/CA@HWC  
Subject Re: Fw: The use of Salvia as an incense

Dear colleagues,

Salvia divinorum has traditional medicinal uses among the native peoples of Mexico, e.g. for the treatment of topical ulcers of the feminine organs (Diaz 1976), to help normalize eliminatory functions (diarrhoea/constipation and urination), anemia, headaches, rheumatism, and alcohol addiction, in addition to its use as a hallucinogen in divination rituals (Valdés et al. 1983). The method of preparation is always an infusion of 4 to 120 pairs (10 to 300 g) of fresh leaves crushed and added to boiling water (a tea) -- low doses of fresh or dried leaves for medicinal purposes and doses of 50+ grams of only fresh leaves for divination/hallucination (Valdés et al. 1983).

There is no record in the scientific literature of a history of use of Salvia divinorum as an incense. Burning was not an established method of preparation in traditional uses as a medicine or as a hallucinogenic.

There are a few herbs where burning the leaves produces a very characteristic fragrance (e.g. cured tobacco, Artemisia, cedar).

However, most aromatic plants lose their characteristic fragrance when burned and simply smell like burned leaves. Gum-resins from trees, e.g. frankincense, myrrh, and copal, are much more common incense ingredients because they gradually release their volatile oils into the smoke (Simpson and Ogorzaly 2001).

Therefore, I believe that the production of "incense" from Salvia divinorum leaves or extracts is a recent invention to try to avoid compliance and enforcement actions.

---

Nevertheless, it may be difficult to argue in court that in the absence of any claims regarding hallucinogenic or other actions in humans, use as incense is not "legitimate" even if there is no history of such use and it just smells like burned leaves.

Robin

**References:**

Díaz JL. 1976. Propiedades Terapéuticas Atributas a Plantas Mexicanas, Primera Parte: Nombre Botánico y Usos. Instituto Mexicano para el Estudio de las Plantas Medicinales, Mexico.

Simpson BB and Ogorzally MC. 2001. Economic Botany: Plants in Our World, third edition. New York, NY: McGraw-Hill Co.

Valdés LJ, Días JL, Paul AG. 1983. Ethnopharmacology of Ska María Pastora (Salvia divinorum, Epling and Játiva-M.). J. Ethnopharmacology 7(3): 287-312.

Brook Bertrand/HC-SC/GC/CA



Brook  
Bertrand/HC-SC/GC/CA  
2010-06-25 04:48 PM

To Robin Marles/HC-SC/GC/CA@HWC  
cc Laura Cooney/HC-SC/GC/CA@HWC  
Subject Fw: The use of Salvia as an incense

Hi Robin:

Is this something you can help me with? Any solid sources of evidence we can point to?

Brook Bertrand  
Natural Health Products Directorate /  
Direction des produits de santé naturels  
Health Canada / Santé Canada  
613-948-3537

----- Forwarded by Brook Bertrand/HC-SC/GC/CA on 2010-06-25 04:48 PM -----



Jason  
Topping/HC-SC/GC/CA  
2010-06-25 04:46 PM

To Brook Bertrand/HC-SC/GC/CA@HWC  
cc CCIM/HC-SC/GC/CA@HWC  
Subject Fw: The use of Salvia as an incense

This one has your name all over it!

----- Forwarded by Jason Topping/HC-SC/GC/CA on 2010-06-25 04:46 PM -----

 Health Canada Santé Canada

**NHPD Internal Information Request Form**

000913

## Request Information

Requestor Name: Irshad Mulla Directorate: HPFBI / DGPSA  
Request Type: Compliance Verification / Vérification de conformité  
Urgent?: No / Non  
NHPD Submission #: N/A MECS #: N/A  
Product Name: Salvia  
Ingredient Name: N/A  
Product Licence #: N/A  
Company Name: N/A  
Site Licence #: N/A

Subject: The use of Salvia as an incense

Brief Description of Request or Concern: The Inspectorate has identified multiple situations whereby the seller has indicated that the Salvia (classified as an NHP) being sold was for incense. Could NHPD please look into whether there's any legitimate use of Salvia as incense?

This information will help us to determine how to best revise the action plan that has been developed for Salvia.

Thank you

Attachment(s) or Supporting Documents:

Date Requested: 2010-06-25 04:16 PM

Designated Assignee:

## NHPD Acknowledgement and Response

NHPSAS File #:

Comments/Resolution(s):

Supporting Document(s):

Status: Active / Actif

Completed By :

Reviewed By :

**Concurrence (if applicable)**

BGTD	Reviewed and Concurred by:	<u>Concur</u>
FD	Reviewed and Concurred by:	<u>Concur</u>
HPFBI	Reviewed and Concurred by:	<u>Concur</u>
Legal	Reviewed and Concurred by:	<u>Concur</u>
MHDP	Reviewed and Concurred by:	<u>Concur</u>
PMRA	Reviewed and Concurred by:	<u>Concur</u>
TPD	Reviewed and Concurred by:	<u>Concur</u>
VDD	Reviewed and Concurred by:	<u>Concur</u>

---

**Revision History**

---

Edit History:	<u>Rev.</u>	<u>Editor</u>	<u>Edit Date</u>
	0.	Irshad Mulla	2010-06-25 04:25:01 PM

*\* Only past five edits are shown*

----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2008-04-28 05:37 PM -----

**Ken Moore/HC-  
SC/GC/CA**

2007-08-28 01:02 PM

To Jocelyn Kula/HC-SC/GC/CA@HWC

cc

Subje Fw: salvia divinorum  
ct

Jocelyn; CMLD also gets calls about salvia. Although all our RCOs are aware that it is not scheduled under the CDSA, it is not clear whether HPFB takes compliance action (and after reading the docs below it is still not clear to me whether the approach outlined, to use the NHP regs to intercept at the border is in place or proposed

All this to say, please keep us in the loop  
Thanks  
Ken

----- Forwarded by Ken Moore/HC-SC/GC/CA on 2007-08-28 01:00 PM -----

**Riaz Akhtar/HC-  
SC/GC/CA**

2007-08-28 12:52 PM

To Ken Moore/HC-SC/GC/CA@HWC

cc

Subje re: salvia divinorum  
ct

Ken  
fyi  
This is the status of the product from the NHPD and HPFBI point of view

Riaz

----- Forwarded by Riaz Akhtar/HC-SC/GC/CA on 2007-08-28 12:51 PM -----

**Theresa Hill**

2007-08-28 08:42 AM

To:  
cc:  
Subject:

Riaz Akhtar/HC-SC/GC/CA@HWC  
Brenda Redmond, Evelyn Nugent/HC-SC.  
re: salvia divinorum

Hello Riaz

Further to our telephone conversation this morning. Thank you for responding to the CBSA request regarding the admissibility of the 2gms of salvia divrorum. I will make sure that Brenda and Evelyn know that you would like to be notified if we receive further requests related to shipments of this NHP since it is considered by OCS to be substance of interest. I have also attached the most recent information from the Inspectorate related to this product.

thank you for all of your help

**Request  
Informati**

on

<b>Requestor Name:</b>	Christine Zaczynski	<b>Directorate:</b>	HPFBI / DGPSA
<b>Request Type:</b>			Product Classification / Classification de produit
<b>Urgent?:</b>	No / Non		
<b>NHPD Submission #:</b>	N/A	<b>MECS #:</b>	N/A
<b>Product Name:</b>	N/A		
<b>Ingredient Name:</b>	Salvia divinorum		
<b>Product Licence #:</b>	N/A		
<b>Company Name:</b>	N/A		
<b>Site Licence #:</b>	N/A		
<b>Subject:</b>			Refusal of Salvia divinorum
<b>Brief Description of Request or Concern:</b>			<p>There have been several internal requests regarding Salvia divinorum (links below). This request is being submitted in hopes of tying them up.</p> <p>At a meeting on May 16th 2007 regarding Salvia divinorum (initiated by the OCS), it was decided that NHPD in collaboration with MHPD would work on a HRA (Health Risk Assessment) in order to help support the refusal of Salvia divinorum products which may fall under the Natural Health Products Regulations.</p> <p>The hope of this HRA is that it would extend the definition of "represented for use" such that a product would not need to be labelled with a claim in order to have the "representation for use" (i.e. as a hallucinogen). This could be grounds to refuse bulk Salvia divinorum</p>

shipments which do not  
make a claim.

Currently, bulk shipments are  
being received at the border.  
These products are not  
making a claim however links  
have been established at the  
retailer level for sale as a  
hallucinogen.

We would like confirmation  
that NHPD supports refusal  
of bulk *Salvia divinorum*  
shipments (without a claim)  
under the Natural Health  
Products Regulations?  
(either with established links  
to use, or without)

Note that the issue request  
#2 (below) is regarding bulk  
shipment claiming a non-  
NHP use (incense). This is a  
separate issue which may  
still need to be addressed.

Thank you,

Attachment(s) or  
Supporting Documents:

Previous requests and  
statuses: 1) <sup>(1)</sup>- status-  
"under review by Branch"  
2) <sup>(2)</sup> Until such time as the  
herb and its active constituent  
are scheduled under the  
CDSA or Schedule F to the  
Food and Drug Regulations,  
the NHPD has jurisdiction to  
receive a Product Licence  
Application for a therapeutic  
use.

3) <sup>(3)</sup> *Salvia divinorum* and  
salvinorin A are NHPs  
presenting a risk for abuse  
and thus are subject to  
immediate compliance action  
by the HPFB Inspectorate.

4) <sup>(4)</sup> The IAS was sent out for

review and comment.

**Date Requested:**

31/05/2007 12:33 PM

**Designated Assignee:**

CCIM

Theresa Hill  
Emergency Preparedness Officer  
Health Products and Food Branch  
Inspectorate, Atlantic Operational Centre  
Health Canada  
(902) 426-7704

-----  
(1) -

Notes:///85256FF8004D62E6/00DEAD08908612A185256FA1005699D3/6330D6157FD034F985  
2572420077273C

(2) -

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(3) -

Notes:///85256FF8004D62E6/00DEAD08908612A185256FA1005699D3/63E1B09A0DA023A685  
256F9B004ED52C

(4) -

Notes:///85256FF8004D62E6/00DEAD08908612A185256FA1005699D3/892F04DEC938650785  
257204006C6153



----- Forwarded by Erin Kingdom/HC-SC/GC/CA on 2008-01-30 10:28 AM -----

**Jocelyn Kula/HC-  
SC/GC/CA**

2007-09-06 11:55 AM

To Christine Zaczynski/HC-SC/GC/CA@HWC

cc Jenna Griffiths/HC-SC/GC/CA@HWC, Jenny  
McLaughlin/HC-SC/GC/CA@HWC, Julie Thorpe/HC-  
SC/GC/CA@HWC, Erin Kingdom/HC-  
SC/GC/CA@HWC, Carole Bouchard/HC-  
SC/GC/CA@HWC

Subje Re: Fw: Salvia Divinorum<sup>(1)</sup>  
ct

Hi Christine

While I think Jenny's assessment of the increasing public interest/ scrutiny regarding *Salvia divinorum* in her request for legal opinion is correct, OCS can't really comment on the suitability of issuing a stop sale or refusing shipments at the border as we have no authority to take those kinds of action that are not regulated under the *Controlled Drugs and Substances Act*.

My one concern with your proposed course of action, is that the Department may not be ready to deal with the potential backlash from legitimate business owners who have been selling salvia relatively peacefully for years, and who now find that they can't import the product and/or can't sell it. It is my view that we have not exactly handled all of the communications issues with the greatest of ease (and I am not apportioning blame here just stating the facts) and I fear that in not taking the time to predict the impacts of such action and prepare for them with appropriate media lines/ Q&As or even fact sheets, we will all just be bombarded with everyone that has written to us already, not to mention all those other people out there who didn't know they were doing anything "wrong" until this moment. In this light, I wonder if it might not be prudent to discuss your suggested action at the DG level meeting that has been planned for September 13 (my DG Andrew Adams is coordinating and I believe Chris Turner and Phil Waddington have been invited so far) so that all parties can discuss the impacts of such a step. For your information, we were asked to organize a meeting after Neil Yeates sent the BN prepared by MHPD to our ADM (the one that recommended scheduling), and it was clear that we need to come to some consensus about the status of this plant and agree upon next steps.

Hope this helps, and happy to discuss further.

Jocelyn

PS I was quite interested to read Simon Carvalho's opinion regarding the application of the NHPR, and I wonder if it means the HRA and IAS etc. need to be revised before it can be used as a rationale to support a stop sale etc?

---

Jocelyn Kula  
A/Manager, Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Healthy Environments and Consumer Safety Branch  
Health Canada  
Tel: (613) 946-0125 Fax: (613) 946-4224

**Christine Zaczynski/HC-SC/GC/CA**

2007-09-05 02:45 PM

To Jocelyn Kula/HC-SC/GC/CA@HWC, Jenna Griffiths/HC-SC/GC/CA@HWC  
cc Jenny McLaughlin/HC-SC/GC/CA@HWC, Julie Thorpe/HC-SC/GC/CA@HWC  
Subje Fw: Salvia Divinorum  
ct

Hello,

FYI- Please see below. We plan on moving forward with taking action on bulk Salvia products under the Natural Health Products Regulations.

We hope to use the HRA identifying the risk as a Type II in addition to the legal statement below (representation for use extended to off label).

Please provide us with any questions/comments you may have on this.

Christine

----- Forwarded by Christine Zaczynski/HC-SC/GC/CA on 2007-09-05 02:44 PM -----

**Jenny McLaughlin/HC-SC/GC/CA**

2007-09-05 02:29 PM

To Christine Zaczynski/HC-SC/GC/CA@HWC  
cc Jason Andrus/HC-SC/GC/CA@HWC, Niyi Lawuyi/HC-SC/GC/CA@HWC, Julie Thorpe/HC-SC/GC/CA@HWC, Diane Wai Chung Lai/HC-SC/GC/CA@HWC, Jean Saint Pierre/HC-SC/GC/CA@HWC, Christiane Brown/HC-SC/GC/CA@HWC, Sarah Wiles/HC-SC/GC/CA@HWC, Christine Zaczynski/HC-SC/GC/CA@HWC, Michelle Gillespie/HC-SC/GC/CA@HWC, James Bellis/HC-SC/GC/CA@HWC, Melissa Beauchamp/HC-SC/GC/CA@HWC, Sharon Mullin/HC-SC/GC/CA@HWC, Diana Dowthwaite/HC-SC/GC/CA@HWC  
Subje Fw: Salvia Divinorum  
ct

Hi Christine,

See response from Simon below regarding the classification of salvia divinorum. Based on this and the fact that NHPD has determined that salvia products pose a Type II health hazard, I think the Inspectorate should start taking action (i.e. stop sale, recall, refusal at customs) consistently against salvia products, regardless of whether there are health claims being made.

Jenny

----- Forwarded by Jenny McLaughlin/HC-SC/GC/CA on 2007-09-05 02:25 PM -----

**Simon Carvalho/HC-SC/GC/CA**

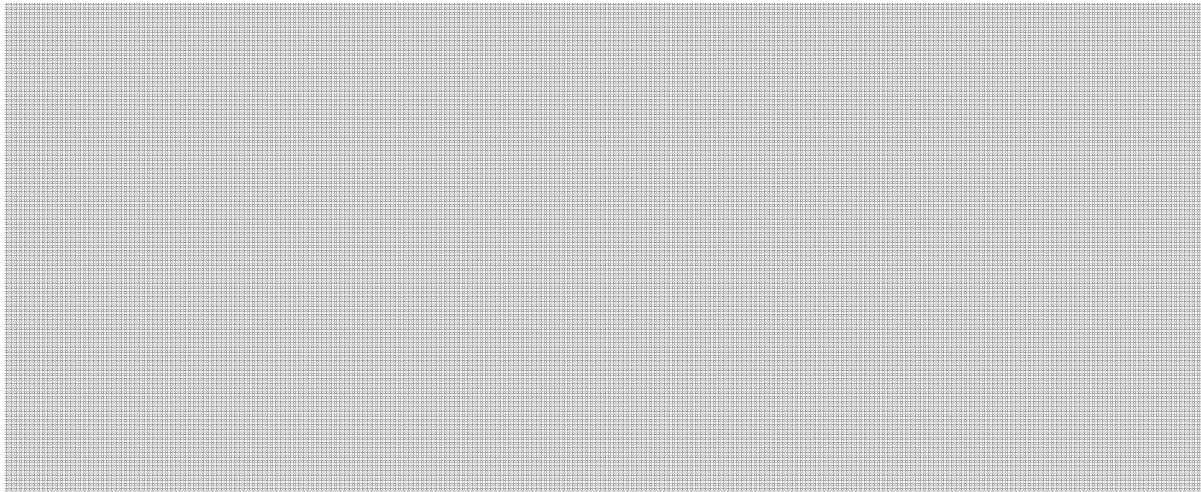
2007-09-05 01:50 PM

To Jenny McLaughlin/HC-SC/GC/CA@HWC

cc Philip Waddington/HC-SC/GC/CA@HWC, Nancy Richards/HC-SC/GC/CA@HWC

Subject Re: Fw: [REDACTED]  
ct

Jenny,



Please let me know if you have any questions.

Simon

**Solicitor-Client Privilege/Protected**

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**Jenny McLaughlin/HC-SC/GC/CA**

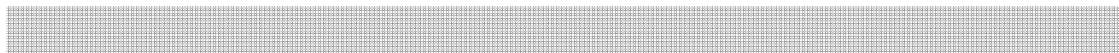
2007-09-05 10:22 AM

To Simon Carvalho/HC-SC/GC/CA@HWC

cc Christine Zaczynski/HC-SC/GC/CA@HWC

Subject Fw: [REDACTED]  
ct

Hi Simon,



**Page(s) 000923 to\à 000923**

**Is(Are) exempted pursuant to section(s)  
est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**23**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**

**CCIM/HC-SC/GC/CA**

2007-08-08 05:59 PM

To Jenny McLaughlin/HC-SC/GC/CA@HWC  
cc CCIM/HC-SC/GC/CA@HWC, Erica Daley/HC-  
SC/GC/CA@HWC  
Subject Re: Salvia Divinorum<sup>(3)</sup>  
ct

Salut Jenny,

As per our discussion, given the Branch discussions on this product, at this time we are not able to process this request.

Please do not hesitate to call me to discuss.

Merci,  
Maggie

**Jenny McLaughlin**

2007-08-07 04:38 PM

To:  
cc:  
CCIM/HC-SC/GC/CA@HWC  
Subject:

Ruby Yang/HC-SC/GC/CA@HWC  
Christine Zaczynski/HC-SC/GC/CA@HW

Re: Salvia Divinorum<sup>(4)</sup>

Hi Ruby,

Based on the label instructions for use, it appears that this product is to be used for a therapeutic effect. I would consider this product to be an NHP but will confirm with NHPD and get back to you ASAP.

Maggie - FYI. I will submit a PC request in the database now but as this product is being held at customs, please process asap.

Thanks,  
Jenny

**Ruby Yang/HC-  
SC/GC/CA**

2007-08-07 04:13 PM

To Christine Zaczynski/HC-SC/GC/CA@HWC  
cc Jenny McLaughlin/HC-SC/GC/CA@HWC  
Subject Salvia Divinorum  
ct

Hello

A shipment of Salvia Divinorum is being held by CBSA, the shipment contains 66 pkgs of Salvia Divinorum 10X and 69 pkgs of Salvia Divinorum 5X , label of the product attached for your reference.

I believe this is a repeated shipment, previous shipment contains same product addressed to the same individual with different address in the same city in January 2007.



Salvia\_Divinatorum.pdf

I checked NHP Work Book and noticed that you have put a request similar to my situation, however, this one

- contains Oaxacan Salvia Divinatorum Extract, and declared " For incense use only "
- The product is a consumer package not in bulk
- Please check the label, Directions,.....could we still consider the product a "NOT-NHP" ?

Would you please let me know if NHPD would support refusals of the shipment under the NHPR?

Thank you.

Ruby Yang  
Western Operational Centre

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(1) -

Notes:///85256C390068FEE8/AEDB0509386C9B9E85257218005109D3/8B5329BED325C46985  
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(2) -

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(3) -

Notes:///85256C9C005B5025/7FFF4AA8307F799985256FF60051AEAD/A3C476E1DAD190B38  
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(4) -

Notes:///8525719C004262B0/38D46BF5E8F08834852564B500129B2C/08D0F29E31F316A686  
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NOT CIRCULATED

# Issue Analysis Summary

DRAFT

## Scheduling *Salvia Divinorum* and/or *Salvinorin A* under the CDSA

Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Controlled Substances and Tobacco and Directorate

July 6, 2010 v. 1

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7. CONSIDERATIONS
8. RECOMMENDATION(S)
9. CONSULTATIONS
10. IMPLEMENTATION AND EVALUATION

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### 1. APPROVALS

This Issue Analysis Summary is approved.

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Diane Allan, Director  
Office of Controlled Substances  
Tobacco and Drugs Directorate

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[DD/MM/2010]

### 2. ISSUE

Health Canada has received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *S. divinorum*, and/or its main active ingredient, salvinorin A, ~~are~~ regulated under the *Controlled Drugs and Substances Act* (CDSA). These requests are further to reports from scientific and media sources suggesting that *S. divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has also noted an ongoing media

neither of which  
are currently

interest regarding the availability of *S. divinorum* in Canada.

### 3. PURPOSE

To assess *Salvia divinorum* and/or salvinorin A against the criteria for the addition of a substance to one of the Schedules to the CDSA, and determine whether one or both should be regulated as controlled substances in Canada.

### 4. CONTEXT

*Salvia divinorum* is a species of sage which belongs to the mint family, and which is found in the form of dried leaves, extract and plant cuttings. Also known as "diviner's sage", the plant is known to induce illusions and hallucinations when chewed or smoked. Salvinorin A, the psychoactive ingredient in *S. divinorum* (also referred to chemically as a neoclerodane diterpene) is found primarily in the leaves, and to a lesser extent in the stems.<sup>1</sup>

*S. divinorum* is widely touted as a "legal" <sup>hallucinogen</sup> alternative to street drugs on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs among adolescents and young adults.<sup>2</sup> While very little is known about how and where *S. divinorum* is sold in Canada, it is suspected that it is mainly purchased over the Internet and/or bought at head shops or alternative life style stores, etc.

The use of *S. divinorum* as a psychotropic agent first came to Health Canada's attention in 2002. In 2004, Health Canada received four adverse drug reaction (ADR) reports associated with the use of *S. divinorum* as a hallucinogen, with three being considered non-serious (requiring no medical attention) and the fourth being considered serious (medical intervention was required). The serious ADR report involved the concomitant use of alcohol in a person diagnosed with Attention Deficit Disorder.

Further to the receipt of the aforementioned ADRs, the Marketed Health Products Directorate (MHPD) and the Natural Health Products Directorate (NHPD) of the Health Products and Food Branch (HPFB) prepared an issue analysis summary (IAS), which recommended that *S. divinorum* and its active ingredient salvinorin A be regulated as controlled substances. This recommendation was maintained when the IAS was updated in November 2006.

Later, in December 2005, MHPD and NHPD prepared a Signal Assessment (SA) (updated in June 2007) that eventually led to the preparation of a Health Risk Assessment (HRA), which concluded that *S. divinorum* or salvinorin A-containing health products would constitute a Type II Health Risk according to the Health Hazard Classification of the Recall Policy of the Health

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<sup>1</sup> U.S. Department of Justice Drug Enforcement Administration. 2002. Drugs and Chemicals of Concern: Salvia Divinorum (salvinorin A, divinorin A) URL:

[http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm) Nov 2008

<sup>2</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.



Products and Food Branch Inspectorate (HBFBI). Such a risk is defined as “a situation in which the use of, or exposure to, a product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote”.

Further to an Assistant Deputy Minister (ADM) discussion in April 2007, the Drug Strategy and Controlled Substances Directorate (DSCSD) organized a meeting with MHPD, NHPD and HPFBI to discuss *S. divinorum*. HPFBI was to determine appropriate compliance activities regarding *S. divinorum* and consult with the Canada Border Services Agency (CBSA) regarding the movement of products containing *S. divinorum* into and out of Canada.

On September 13, 2007, a further meeting between DSCSD, MHDP, NHPD and HPFBI led to the conclusion that DSCSD would conduct a scheduling assessment of *S. divinorum* in order to explore the possibility of scheduling this substance under the CDSA.

In September 2008, the Director Generals of DSCSD, MHPD, TPD and the HPFBI agreed that media lines and an “It’s Your Health” article on *S. divinorum* would be prepared.

#### **4.1 Relevant Legislative Frameworks in Canada**

##### **4.1.1 Food and Drug Regulations (under the Food and Drugs Act)**

The *Food and Drug Regulations* (F&DR) serve to ensure the safety, efficacy, and quality of health products offered for sale in Canada, including drugs and medical devices. Prior to being given market authorization, a manufacturer must present substantive scientific evidence that a product is safe, efficacious and of high quality. For drugs, Health Canada reviews this information carefully and, if the review is satisfactory, a Notice of Compliance (NOC) is issued and appropriate Drug Identification Numbers (DINs) are assigned.

A “drug” is defined under the F&DR as any substance or mixture of substances manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
- (b) restoration, correction or modification of organic functions in human beings or animals, or
- (c) disinfection in premises in which food is manufactured, prepared or kept;

As no products containing *S. divinorum* or its extracts have been reviewed and approved by Health Canada as of July 2010, it is illegal to market *S. divinorum* when it is represented as a drug.

##### **↓ 4.1.2 Natural Health Product Regulations (under the Food and Drugs Act)**

The *Natural Health Products Regulations* (NHPR) aim to provide Canadians with ready access to natural health products (NHPs) that are safe, effective, and of high quality, while respecting freedom of choice and philosophical and cultural diversity. The NHPR require that all licensed products display a Natural Product Number (NPN), or, in the case of a homeopathic medicine, Drug Identification Number - Homeopathic Medicine (DIN-HM), on their labels. These numbers are issued once a product is authorized for sale in Canada further to a *natural health product monograph* or submission of other evidence of safety and efficacy. The NHPR also require that all manufacturers, packagers, labelers, and importers be licensed which in turn requires the presence of procedures respecting distribution records, product recalls, product handling, storage and delivery, and manufacturing practices.

The definition of an NHP under the NHPR has both a function and substance component. The function component refers to those substances that are manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
- (b) restoring or correcting organic functions in humans; or
- (c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

The substance component refers to whether the product or medicinal ingredient therein is safe for consideration as an over-the-counter product, can be available for self-care and self-selection, and does not require a prescription to be sold. To be considered a NHP, no direct health claims need to be made regarding the substance. In the case of *S. divinorum*, it is generally marketed for its hallucinogenic properties which are considered a modification of an organic function. Therefore products containing it meet the definition of a NHP.

As of July 2010, no products containing *S. divinorum* have been reviewed and approved by Health Canada and no NPNs or DIN-HMs have been issued. Therefore sales of *S. divinorum* are illegal under the NHPR if it is represented for use as a hallucinogen or if other health claims in regards to modifying organic functions are made.

#### **4.1.3 Controlled Drugs and Substances Act and its Regulations**

The CDSA provides a legislative framework for the control of substances that can alter mental processes and that may produce harm to the health of an individual or to society when diverted or misused. Except as authorized under its regulations, activities such as possession, possession for the purposes of trafficking, trafficking, importation, exportation, possession for the purposes of exportation and production of controlled substances are prohibited under the CDSA.

The substances regulated under the CDSA are grouped into eight Schedules, and each Schedule

is associated with particular offences and penalties as described in Part I of the CDSA.

In determining whether a substance should be regulated as a controlled substance, and into which Schedule of the CDSA it should be placed, Health Canada considers the following factors:

- International requirements and trends in the control and/or scheduling of the substance;
- Chemical and/or pharmacological similarity to substances listed in the Schedules to the CDSA;
- Legitimate use of the substance, including therapeutic, scientific, industrial or commercial uses;
- Potential for abuse and/or addiction liability of the substance;
- Evidence of extent of actual abuse of the substance in Canada and internationally; and
- Risk to personal and public health and safety.

## 4.2 Assessment of *Salvia Divinorum* for Scheduling Purposes

### 4.2.1 International Requirements and Trends in the Control and/or Scheduling of the Substance

At the present time, neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and therefore do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

#### *Australia*

In June 2002, Australia became the first country to prohibit the sale, supply, possession and use of *S. divinorum* and salvinorin A. Although both *S. divinorum* and salvinorin A are listed in Schedule 9 of Australia's Standard for the Uniform Scheduling of Drugs and Poisons on the basis of "high potential for abuse and risk to public health and safety", no substantiation of this risk was provided at the time of this scheduling decision.<sup>3</sup> Schedule 9 is Australia's most restrictive drug schedule, and includes "substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities."<sup>4</sup>

#### *Belgium*

A decree was passed in Belgium on October 22, 2006 which added *S. divinorum* to the list of controlled substances. This list includes substances such as psilocybin mushrooms, khat and peyote cactus.<sup>5</sup>

<sup>3</sup> <http://www.tga.gov.au/ndpsc/record/rr200111.pdf>

<sup>4</sup> [http://www.cognitiveliberty.org/news/salvia\\_australia.htm](http://www.cognitiveliberty.org/news/salvia_australia.htm)

<sup>5</sup>

<http://eldd.emcdda.europa.eu/html.cfm/index5176EN.html?pluginMethod=eldd.shownewsdetails&id=20/12/2006BE>

### **Denmark**

In 2003, Denmark added *S. divinorum* and salvinorin A to their list of "category B" controlled substances, a category which also includes psilocybin mushrooms, cocaine, amphetamine, and several others substances that are only legal for medicinal and scientific purposes. Illegal possession carries a penalty of up to two years in prison.

### **Germany**

*S. divinorum* (plant and plant parts) was added to Appendix I of the *Narcotics Act* in Germany on March 1, 2008, making it illegal to produce, traffic, or possess. The law does not specifically mention salvinorin A.

### **Italy**

On June 25, 2004, the Italian Ministry of Health issued an ordinance prohibiting the sale of *S. divinorum* and its active constituent salvinorin A. On January 11, 2005, the Ministry of Health made possession of *S. divinorum* and salvinorin A illegal by placing them in "Tabella 1" of the *Tabella Sostanze Stupefacenti o Psicotrope*.

### **Japan**

On November 9, 2006, the Japanese government added a group of thirty-three drugs to its list of controlled substances, including salvinorin A. The drugs are banned under a revised pharmaceutical law, under which persons involved in their illegal import, production, and sale, i.e. beyond medical treatment or research purposes, will be subject to up to five years imprisonment or a fine of up to five million yen.

### **Spain**

On January 28, 2004, <sup>↓</sup>the Spanish Ministry of Health and Consumption issued an order prohibiting the sale of *S. divinorum*. The regulation went into effect on May 6, 2004 and only prohibits activities related to commerce. Possession and/or use are not considered to be criminal offences.

### **Other Countries**

*Salvia divinorum* is illegal to possess or sell in Croatia, Latvia, Lithuania, Poland, Romania, South Korea and Sweden. In Russia it is illegal to grow or sell *S. divinorum*, but it is legal to possess it. In Estonia, Finland, Iceland and Norway, *S. divinorum* is treated as a medicinal herb and it is illegal to import it without a relevant prescription from a doctor.

## ***United States of America***

*S. divinorum* and salvinorin A are not included in the Schedules to the United States *Controlled Substances Act* although both *S. divinorum* and salvinorin A have been added to a list of chemicals "of concern" which has no legal implications. In addition, some individual states have implemented laws restricting its use, sale and/or distribution. As of July 2010, a number of states have enacted legislation placing regulatory controls on *S. divinorum* and/or salvinorin A including Delaware, Georgia, Florida, Hawaii, Illinois, Kansas, Kentucky, Maryland, Mississippi, Missouri, Nebraska, North Dakota, Ohio, Oklahoma, South Dakota, Wisconsin, Virginia, California, Louisiana, Maine, North Carolina, and Tennessee. More details regarding the regulation of *S. divinorum* in these last five states are provided below.

### ***California***

As of January 1, 2009, the sale or distribution of *S. divinorum* or salvinorin A, or any substance or material containing *S. divinorum* or salvinorin A, to any person under 18 years of age is a misdemeanor punishable by imprisonment in a county jail for not more than six months, by a fine of no more than \$1,000, or both.

### ***Louisiana***

In 2005, Louisiana passed a bill which prohibits the possession, production, manufacture and distribution of a material, compound, mixture, or preparation intended for human consumption and that contains a hallucinogenic plant. A "hallucinogenic plant" is defined as "any part or portion" of a plant on a list of forty plants, which includes *S. divinorum*.

### ***Maine***

In Maine, *S. divinorum* and salvinorin A are regulated in the same way as tobacco products; adults eighteen years of age or over can legally purchase and use the material, but selling or providing *S. divinorum* or salvinorin A to anyone under the age of eighteen is a criminal offence. Possession by a minor is a civil violation, punishable by a fine, community service, or both.

### ***North Carolina***

On December 1, 2009, the North Carolina State Legislature brought a new law into force which made *Salvia divinorum* and salvinorin A illegal. The only legal *S. divinorum* activities are the growing for aesthetic, landscaping, or decorative purposes or university-affiliated medical or pharmacological research.

## *Tennessee*

On July 1, 2006, Tennessee classified the deliberate production, manufacture, distribution, or possession of the active chemical ingredient in the hallucinogenic plant *S. divinorum* as a Class A misdemeanor. It is not, however, a criminal offence to possess, plant, cultivate, grow, or harvest *S. divinorum* for aesthetic, landscaping, or decorative purposes. The law also does not apply to any dosage that is legally obtainable from a retail establishment without a prescription when it is recognized by the Food and Drug Administration as a homeopathic drug.

### 4.2.2 Chemical and/or Pharmacological Similarity to Substances listed in the Schedules to the CDSA

The psychoactive ingredient in *Salvia divinorum* is salvinorin A. Other plants which contain psychotropic terpenoids are *Artemisia absinthium* (wormwood) and *Cannabis sativa*. Salvinorin A is considered by some as the most potent natural hallucinogen ever isolated.<sup>6</sup>

Unlike all other hallucinogens, salvinorin A is structurally distinct and does not interact with the serotonin-2A receptor or any other molecular target of classical hallucinogens. It thus affects the brain in a way that is quite unique.<sup>7</sup> Recent pharmacological screenings of receptors have found it to be a highly potent and selective  $\kappa$ -opioid receptor (KOR) agonist.<sup>8</sup>

The use of *S. divinorum* or salvinorin A can lead to a number of effects with variable onset and duration. These effects are generally accepted to be: sensation of becoming an object, visions of various two-dimensional surfaces, films and membranes, revisiting places of the past (particularly childhood), perceived loss of the body and/or identity, various sensations of motion (being pulled or twisted by a force of some kind), uncontrollable hysterical laughter, and overlapping realities (perceptions of being in more than one place).<sup>9</sup> Laughter, happiness, sense of well-being and dissociative effects were deemed the best aspects of *S. divinorum* by users, second only to the "trip" that the drug elicits.<sup>10</sup> Depersonalization, speaking gibberish, widening of consciousness and subjective illusions of rapid movement, flying or hovering have also been reported.<sup>11</sup>

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<sup>6</sup> Ott J. Ethnopharmacognosy and human pharmacology of *Salvia divinorum* and salvinorin A. *Curare*. 1995 18: 103-129. Unofficial transcription available online. URL <http://www.sagewisdom.org/ott2.html>

<sup>7</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>8</sup> Roth BL, Baner K, Westkaemper R, Siebert D, Rice KC, Steinberg S, Ernsberger P, Rothman RB. Salvinorin A: a potent naturally occurring nonnitrogenous kappa opioid selective agonist. *Proc Natl Acad Sci U S A*. 2002 Sep 3;99(18):11934-9.

<sup>9</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>10</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>11</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage).

The psychomimetic effects of *S. divinorum* closely resemble schizophrenia symptoms induced by lysergic acid diethylamide (LSD) or phencyclidine (PCP).<sup>14</sup> Yet, it is said to have only weak influence on the prevailing mood of the user which differentiates it from other hallucinogens such as LSD and psilocybin.<sup>15</sup> Its strong dissociative effects are often compared to those of ketamine. Users have reported that the psychedelic effects of *S. divinorum* were most similar to those caused by psilocybin mushrooms.<sup>16</sup> However, users familiar with the effects of other hallucinogens agree that despite certain similarities to classical hallucinogens, the visions and overall experience is quite unique.<sup>17</sup>

In addition, the psychedelic effects of *S. divinorum* are similar to those of classical psychedelics regarding changes in perception and somatic sensations. *S. divinorum* causes an unusually high degree of sedation, weakness and fatigue, while the increased de-realization is not commonly reported for classical psychedelics.<sup>18</sup> The combination of these effects seems to correlate with that of other KOR agonists such as pentazocine.<sup>19</sup>

#### 4.2.3 Legitimate Use of the Substance, including Therapeutic, Scientific, Industrial or Commercial Uses

*Salvia divinorum* has traditionally been used for spiritual and medicinal purposes by the Mazatec Indians in Oaxaca, Mexico,<sup>20</sup> where an infusion of the leaves or the leaves themselves are ingested to treat gastrointestinal problems, headaches, rheumatism, anemia and swelling of the

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Pharmacopsychiatry. 2005 Jan;38(1):1-5 and Siebert DJ. Salvia divinorum and salvinin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>14</sup> Bücheler R, Gleiter CH, Schworer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5.

<sup>15</sup> Siebert DJ. Salvia divinorum and salvinin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>16</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>17</sup> Siebert DJ. Salvia divinorum and salvinin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6 and González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>18</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>19</sup> Arasteh K, Poudevida S, Farre M, Roset PN, Cami J. Response patterns of the Spanish version of the 49-item short form of the Addiction Research Center Inventory after the use of sedatives, stimulants, and opioids. Drug Alcohol Depend. 1999 Jun 1;55(1-2):117-25.

<sup>20</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

stomach.<sup>21</sup> Its main use today is, however, for its psychoactive properties in the aid of producing “mystical” or hallucinogenic experiences as part of spiritual rituals.<sup>22</sup>

Although selective kappa receptor agonists have been shown to produce analgesic effects, adverse effects such as psychotomimesis, dysphoria and diuresis have been observed in studies investigating their therapeutic use.<sup>23</sup> In addition, while it has been speculated that KOR agonists may prove to be useful in the treatment of certain psychiatric disorders including Alzheimer’s disease, schizophrenia, dementia and bipolar disorder,<sup>24</sup> much more research is needed in order to substantiate these hypotheses. Similarly, another study has suggested that chemical analogues of salvinorin A may be a useful treatment for those suffering from addiction to other substances.<sup>25</sup> That said, there are presently no legitimate medical uses for *S. divinorum* in Canada.

Similarly, there are no known industrial uses for *S. divinorum* in Canada. The plant is a semi-tropical perennial that can only grow outdoors in a humid climate where it will not encounter frost. Most websites offering *S. divinorum* cuttings and seeds for sale appear to do so in the context of growing the plant for its psychoactive properties, rather than out of horticultural interest or for its esthetic appeal. *in order to experience*

#### 4.2.4 Potential for Abuse and/or Addiction Liability of the Substance

Salvinorin A is a potent, selective agonist of the  $\kappa$ -opioid receptor (KOR), and in contrast to the euphoria produced by  $\mu$ -opioid receptor (MOR) agonists, KOR agonists are negatively reinforcing and aversive.<sup>26</sup> In addition, KOR agonists have analgesic properties but are not associated with respiratory depression like MOR agonists. Finally, while MOR agonists increase

<sup>21</sup> Munro, T. The Chemistry of Salvia divinorum. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

<sup>22</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage Salvia divinorum. Life Sci. 2005 Dec 22;78(5):527-31.

<sup>23</sup> Barker RL, Fawcett J, Barkin SJ. 2002. Chronic pain management with a focus on the role of newer antidepressants and centrally acting agents. In: Pain Management: A Practical Guide for Clinicians, 6th edition, Weiner RS ed. CRC Press, Boca Raton, FL. pp. 415-34 and Tidgewell et al., 2004. A facile method for the preparation of deuterium labelled salvinorin A: Biorganic & Medicinal Chemistry Letters, 14: 5099-5102.

<sup>24</sup> Sheffler DJ & Roth BL. Salvinorin A: the ‘magic mint’ hallucinogen finds a molecular target in the kappa opioid receptor. Trends Pharmacol Sci. 2003 Mar;24(3):107-109.

<sup>25</sup> Prisinzano TE. Natural products as tools for neuroscience: discovery and development of novel agents to treat drug abuse. J Nat Prod. 2009 Mar 27;72(3):581-7.

<sup>26</sup> Gustein HB & Akil H. Opioid Analgesics. In: Goodman and Gilman’s The Pharmacological Basis of Therapeutics 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590, Cooper S. Interactions between endogenous opioids and dopamine: Implications for reward and aversion. In: The Mesolimbic Dopamine System: From Motivation to Action. Willner P and Scheel-Kruger J (editors) Wiley, Chester, England, 1991, pp. 331-366, and Shippenberg TS, Herz A, Spanagel R, Bals-Kubik R, Stein C. Conditioning of opioid reinforcement: neuroanatomical and neurochemical substrates. Ann N Y Acad Sci. 1992 Jun 28;654:347-56.

<sup>28</sup> Gustein HB & Akil H. Opioid Analgesics. In: Goodman and Gilman’s The Pharmacological Basis of Therapeutics 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.



the release of dopamine, the activation of KOR decreases dopamine release in the nucleus accumbens.<sup>28</sup>

The onset and intensity of the effects of *Salvia divinorum* appear to be related to the route of administration.

Traditional uses generally produce mild effects because the leaves are rolled and chewed or crushed and prepared as a foamy infusion whereby the salvinorin A is degraded in the gastrointestinal system before being absorbed into the bloodstream. Hence, the level of effect relates quite closely to the length of time the material spends in the mouth, with the onset of effect generally taking 5-10 minutes. The effects build over the next hour and last for another hour before they begin to subside.<sup>29</sup>

Routes of administration that avoid the hepatic first-pass effect (i.e. intravenous, intramuscular, inhalation and sublingual use) are the quickest and most intense.<sup>30</sup> Salvinorin A can be isolated from the plant to make a powder which can be vaporized and inhaled. The onset of effects felt from vaporizing salvinorin A powder occurs in about 30 seconds and effects last for about 5-10 minutes and then subside over the next 30 minutes.<sup>31</sup>

Smoking is by far the most popular method of administration<sup>32</sup> and this is accomplished by smoking the dried leaves or a concentrated extract using a pipe or bong. Dried leaves may also be fortified with a concentrated extract of salvinorin A. A concentrated extract can also be used sublingually. Neither *S. divinorum* nor salvinorin A can be injected because the powder is insoluble in water.<sup>33</sup>

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<sup>29</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>30</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.

<sup>31</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>32</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62 and Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>33</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs.* 1994 Jul-Sep;26(3):277-83.

The aversive effects of previously studied KOR agonists predict that the risk of addiction to *S. divinorum* is negligible. However, very few controlled scientific studies of the physical and psychotropic effects of *Salvia divinorum* on humans have been carried out. Therefore, it is difficult to predict its potential for addiction and abuse. In studies that have been conducted, there is conflicting information around the addiction liability of *S. divinorum* in both animals and humans. Some users have noted that they require increasing doses of salvinorin A in order to achieve the desired effect and the stimulated cerebral KOR may act as a mechanism of tolerance.<sup>37</sup> Further studies in this area and on the mediated decrease of dopamine as well as the impact of dose on the rewarding and aversive effects are also required.

While the concerns for the potential of abuse were once minimal because 1 kg of dried leaves yields only 3 to 6 human doses of salvinorin A, it was discovered that vaporizing and inhaling 200-500 micrograms had profound hallucinogenic effects.<sup>38</sup> The extraction of salvinorin A from the plant is very easy and with care, approximately 1.5 grams of pure salvinorin A per kilogram of dried leaves (8kg of fresh leaves) can be isolated, which is enough substance to provide for 2000 human doses.<sup>39</sup>

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<sup>37</sup> Bucheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>38</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>39</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs*. 1994 Jul-Sep;26(3):277-83.

<sup>44</sup> Turner DM. *Salvinorin - The Psychedelic Essence of Salvia Divinorum*. Panther Press, San Francisco, CA 1996.

#### 4.2.5 Evidence of Extent of Actual Abuse of the Substance in Canada and Internationally

In Canada, the extent of actual abuse of *Salvia divinorum* and salvinorin A is relatively unknown.

There is, however, some data regarding the use of *Salvia divinorum* in Canada. Questions about the use of *S. divinorum* were included in the 2008-2009 Youth Smoking Survey, the 2009 Canadian Alcohol and Drug Use Monitoring Survey and the 2009 Ontario Student Drug Use and Health Survey.

As there are no established legitimate uses for this plant it can be assumed that all use is illegitimate in nature

The results from the 2009 Ontario Student Drug Use and Health Survey were published on November 18, 2009 and indicate that:

- Among all responding students in Ontario, 4.4% reported using *Salvia divinorum* at least once in the past year. In comparison, 58.2% indicated they had used alcohol, 25.6% indicated they had used cannabis and 5.0% indicated they had used hallucinogens other than LSD and PCP in the past year;
- Males (6.2%) were significantly more likely than females (2.3%) to report using *Salvia divinorum*;
- There is significant grade variation, with *Salvia divinorum* use most likely among 11<sup>th</sup> graders (8.6%) and 12<sup>th</sup> graders (8.4%); and
- There are significant regional variations, with students in Northern Ontario (9.2%) most likely to use *Salvia divinorum*.

The results of the 2008-2009 Youth Smoking Survey were published on May 31, 2010 and indicate that:

- 4.9% of students stated that they had used *S. divinorum* in the last twelve months. In comparison, 53.0% indicated they had used alcohol, 27.3% indicated they had used cannabis and 6.9% indicated they had used other hallucinogens in the last twelve months;
- 2.6% of students in Grades 7-9 and 7.0% of students in Grades 10-12 had used *S. divinorum* in the last twelve months; and
- Males (6.6%) were more likely to have used *S. divinorum* in the past twelve months compared to females (3.2%).

The scope of the previously mentioned studies did not provide for any explanations regarding differences in usage between ages, genders and regions. In this regard, it is difficult to speculate on the causality of such differences.

The Canadian Alcohol and Drug Use Monitoring Survey specifically examined Salvia for the first time in 2009. An estimated 1.6% of Canadians, aged 15 years and older, reported that they had used salvia in their lifetime, and 0.2% reported using it in the past-year. In comparison, the prevalence of past-year cannabis use among Canadians 15 years of age and older was 10.6%. 1.2% of respondents reported using cocaine or crack in the past 12 months, 0.9% had used ecstasy and 0.7% used illicit hallucinogens.

Health Canada's Drug Analysis Services (DAS) has identified salvinorin A in a number of

samples seized by law enforcement, as shown in the following table.

**NUMBER OF SAMPLES FOUND TO CONTAIN SALVINORIN A**

Year	Count
2006	9
2007	8
2008	4
2009	20
2010 (as of May 7)	8

The National Forensic Laboratory Information System (NFLIS) and the System to Retrieve Information from Drug Evidence (STRIDE) in the United States ~~is a~~ <sup>are</sup> Drug Enforcement Agency (DEA) databases that collect scientifically verified data on analyzed samples in state and local forensic labs as well as samples from DEA labs. The following table shows the quantity of *S. divinorum* products that were seized from 2000 through to 2009.

**ANALYZED SALVIA DIVINORUM or SALVINORIN A SEIZURES**

(Number of items/Exhibits)

Source	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009*
NFLIS-State/Local <sup>1</sup>	0	0	0	0	1	8	12	12	70	34
STRIDE <sup>2</sup>	0	0	1	1	1	0	0	0	N/A	N/A
<b>TOTAL</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>1</b>	<b>2</b>	<b>8</b>	<b>12</b>	<b>12</b>	<b>70</b>	<b>34</b>

Data Source: NFLIS & STRIDE, 2008 data queried 11/24/08, updated 06/10/2010

<sup>1</sup> NFLIS reported seizures of *Salvia divinorum* and/or salvinorin A

<sup>2</sup> STRIDE reported items of *Salvia divinorum*.

\* Includes only January – May data in 2009.

It is difficult to determine the extent of actual abuse of *S. divinorum* in Canada or elsewhere as there appear to be inconsistencies in the literature regarding risk aversion. For example, one author states: "Many who have used salvinorin A find the experience extremely unnerving, frightening and overly intense and most have no desire to repeat the experience."<sup>44</sup> However, another study suggested that this is not the experience of all recreational users of *S. divinorum*.<sup>45</sup> Over eighty percent of users surveyed on a web-based questionnaire about their *S. divinorum* use said that they would probably or definitely use *S. divinorum* again.<sup>46</sup> Users have reported the negative effects of *S. divinorum* as: the short duration of action, lack of control over the

<sup>45</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62, Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry.* 2005 Jan;38(1):1-5, and Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs.* 1994 Jul-Sep;26(3):277-83.

<sup>46</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

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experience, persisting negative effects (most often anxiety),<sup>47</sup> sweating, chills, increased diuresis, impaired vigilance,<sup>48</sup> and negative after-effects including tiredness, feeling head heavy, dizziness, physical exhaustion, and some degree of malaise or 'hangover' as they 'comedown' from the drug.<sup>49</sup>

#### 4.2.6 Risk to Personal and Public Health and Safety

The increase in both the number of enquiries from various municipalities and members of the public and in the amount of media interest regarding the availability of *Salvia divinorum* in Canada may be an indication that the recreational use of *S. divinorum* as a hallucinogen is on the rise in Canada. However, there are no available statistics that indicate there has been a significant increase in *S. divinorum* use in the Canadian population and, in comparison to the use of other drugs such as alcohol and cannabis, the actual use of *S. divinorum* is quite low.

The potential for harm to the user and/or other individuals is primarily related to the hallucinogenic properties of the substance. Users may get up and walk around without apparent awareness of their movements, behaviour or surroundings, and distinction between self and surroundings is often lost. At doses greater than 1mg of salvinorin A, out of body experiences are frequent and loss of consciousness has been reported.<sup>50</sup> There is little information regarding the social behaviours of persons under the influence of *S. divinorum* products, and what risks their activities, such as operating a motorized vehicle, may pose to the general public. There is also very little data regarding the toxicity, teratogenicity or other long-term effects of *S. divinorum* use.<sup>51</sup>

As far as law enforcement is concerned, the Department has only received a limited number of communications indicating concern with respect to *S. divinorum* and none of these have advised that the use of *S. divinorum* poses any threat to public safety. The Royal Canadian Mounted Police (RCMP) has stated that while *S. divinorum* is readily available, it has not become a popular drug in Canada, probably due to its aversive effects such as anxiety and introversion.

A handful of case reports regarding the use of *S. divinorum* have been published in the academic literature. One report was an international case report in which a young man (19 years of age) described his perceptions after inhaling smoke from *S. divinorum*. The peak psychotropic effects, including prickling of the skin, fever-like hot flashes, muscular tremor, and depersonalization, were reached in less than five minutes after inhalation of an unknown amount of smoke from burning dried leaves.<sup>52</sup> Another report involved a 15-year-old male who presented

<sup>47</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>48</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>49</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>50</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>51</sup> Grundmann O, Phipps SM, Zadezensky I, Butterweck V. *Salvia divinorum* and Salvinorin A: An Update on Pharmacology and Analytical Methodology. *Planta Med* 2007 Jun;73:1039-1046.

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to psychiatric emergency services with acute onset of paranoia, déjà vu, blunted affect, difficulties in thought processing and slowed speech after smoking *Salvia divinorum* over an unknown period of time. During his hospitalization all symptoms improved significantly except the feeling of déjà vu. Based on this case presentation, the author suggested that the feelings of déjà vu may be a long-term effect of *S. divinorum* use.<sup>53</sup> However, given that this is the only case report in which déjà vu was associated with the use of *S. divinorum*, more reports are needed to substantiate this finding.

In addition to the above-mentioned reports, in 2006, a case was reported in the U.S. in which a 17-year-old boy committed suicide after smoking *S. divinorum* for an unknown period of time.<sup>54</sup> It should be noted that alcohol and general depression were the main confounders in this case. After this case was reported, the state of Delaware passed a law which classified *S. divinorum* as a Schedule I controlled substance along with other hallucinogenic substances.

Like many drugs of abuse, users are often unaware of the potency and adulterants in the product they purchase. A study by Wolowich *et al.* (2006)<sup>55</sup>, showed that the salvinorin A content in five out of five *S. divinorum* products was falsely indicated on the label and 4 out of 5 products contained unidentified adulterants (i.e. vitamin E, caffeine).

Health Canada has only anecdotal information about the use and abuse of *S. divinorum* in Canada as well as the threat *S. divinorum* may pose to the health and safety of Canadians. Although reports of domestic adverse reactions related to the use of *S. divinorum* as a hallucinogen have been received through the Canada Vigilance database, it is important to note that the number of reports and the nature of reactions reported are not adequate to characterize the risk to the general population.

## 5. ASSESSMENT OF RISKS AND BENEFITS

<sup>53</sup> Singh S. (2007) Adolescent salvia substance abuse. *Addiction*. 102, 823-824.

<sup>54</sup> <http://www.kvbc.com/Global/story.asp?S=4893692>

<sup>55</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

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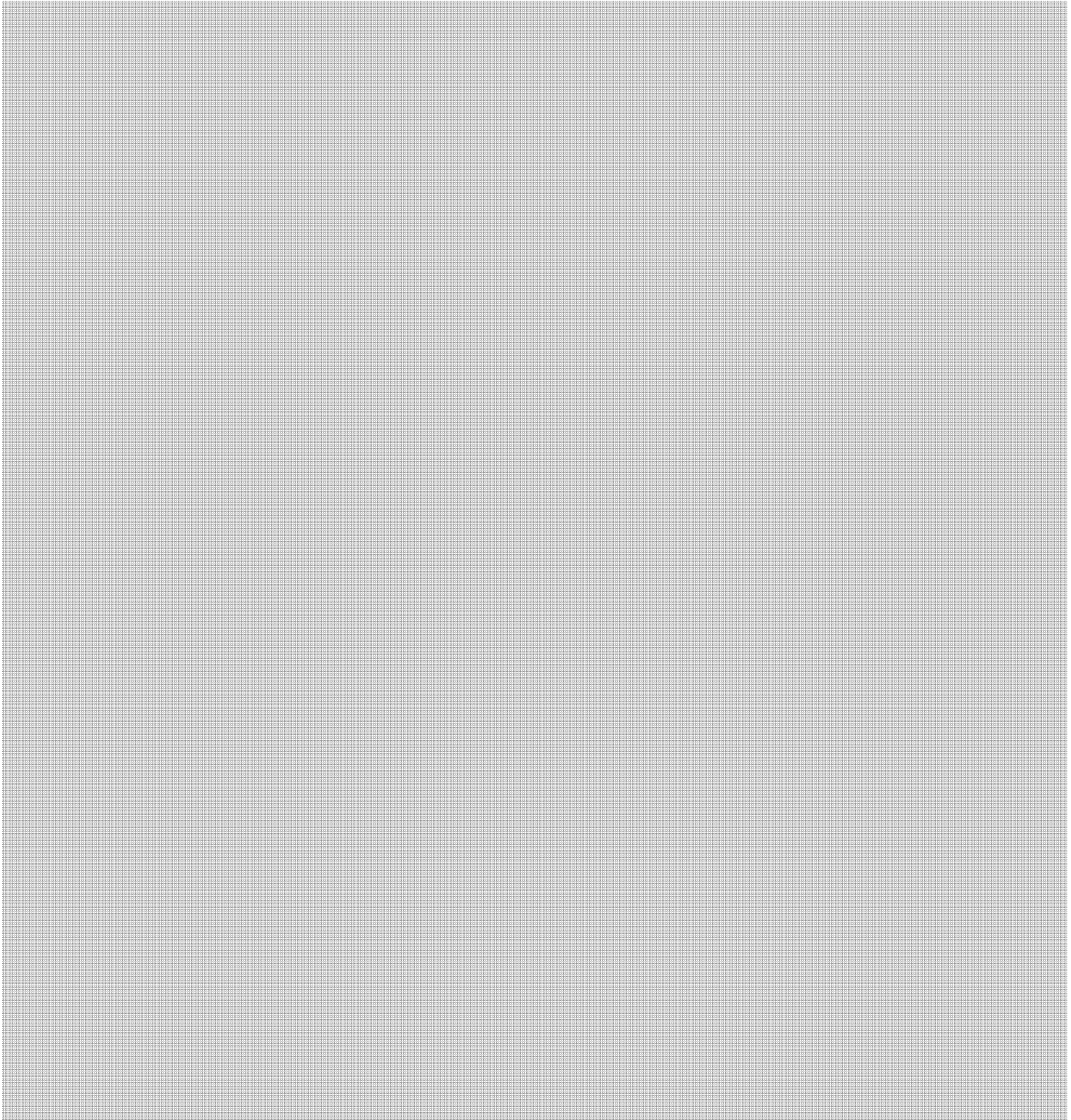
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**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**

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s.21(1)(b)



## 7. CONSIDERATIONS

The KOR-mediated aversive and dysphoric effects of *Salvia divinorum* do not appear to be hampering its use as young adults have begun smoking the leaves and leaf extract recreationally.<sup>56</sup> It can be purchased through online botanical companies and other ~~drug promotional~~ sites and is often

<sup>56</sup> Hazelden Foundation, 2004. Drug Abuse Trends. June 2004. URL: [www.reserach.hazelden.org](http://www.reserach.hazelden.org).



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touted as a legal alternative to substances such as cannabis and mescaline.<sup>57</sup> Interestingly, after being widely available for over a decade, the drug does not appear to have had the same social impact as LSD or ecstasy.<sup>58</sup>

While there has been an increase over the past few years in the number of enquiries from various municipalities and members of the public regarding the availability of *Salvia divinorum* as a hallucinogen, the reported use of *S. divinorum* by young Canadians is much lower than that of alcohol or cannabis, according to available statistics.

The NHPR are limited in their capacity to control the availability of *S. divinorum* in that *S. divinorum* products are often declared as incense and therefore cannot be considered unapproved natural health products. In addition, compliance and enforcement actions, such as voluntary stop-sales, forfeiture, destruction, and administrative seizure, cannot be implemented unless the labeling of the product indicates that it is to be used for consumption and/or pharmacological effects.

The previous HPFB recommendation to schedule *S. divinorum* under the CDSA was likely based on a misunderstanding of the previously-described criteria upon which scheduling is based. In particular, it did not consider a number of factors, including potential for abuse and risk to public health and safety. The Office of Controlled Substances (OCS) was also not consulted by HPFB at the time this recommendation was made. In addition, among countries who have decided to control *S. divinorum* in some way, very little or no substantiation of the risks of *S. divinorum* upon which the decision was based are available.

Neither *Salvia divinorum* nor salvinorin A meet the criteria for scheduling a substance under the CDSA. Despite being regulated in some jurisdictions, neither the plant nor salvinorin A are scheduled under any of the UN Drug Control Conventions. *S. divinorum* and salvinorin A are not structurally or pharmacologically similar to other substances included in the schedules to the CDSA. There are currently no legitimate therapeutic or industrial uses for *S. divinorum*. The abuse liability and potential for dependence of *S. divinorum* is not known as very few controlled scientific studies of its physical and psychotropic effects have been carried out on humans. The extent of actual abuse of *S. divinorum* is also largely unknown. Evidence of a risk to public health and safety is anecdotal in nature and not quantified in any way as there is a lack of information regarding <sup>usage</sup> in Canada. Therefore, it would not be appropriate to include *S. divinorum* and/or salvinorin A under any of the Schedules to the CDSA at this time.

## 8. RECOMMENDATIONS

<sup>57</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

<sup>58</sup> Munro, T. The Chemistry of *Salvia divinorum*. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

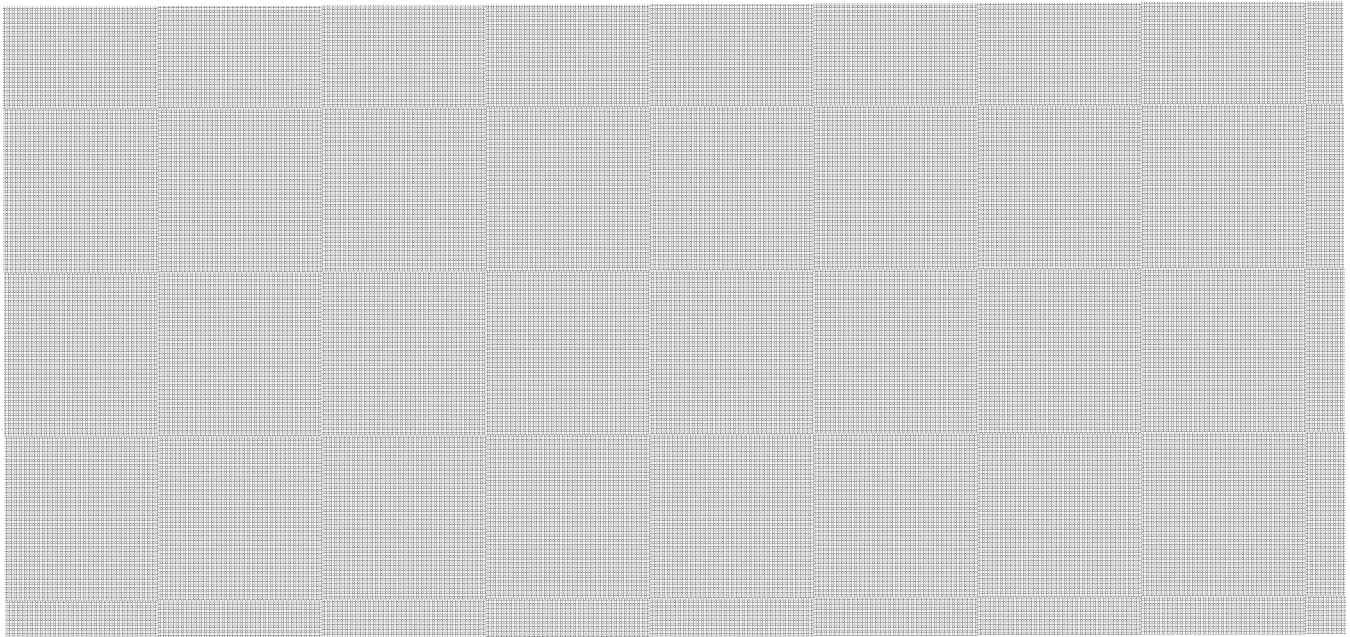
## 9. CONSULTATIONS

The Drug Analysis Services (DAS) was contacted in order to provide any data available regarding the identification of salvinorin A in samples submitted by law enforcement.

The Royal Canadian Mounted Police (RCMP) was contacted in order to establish their views with respect to *S. divinorum* use in Canada. The RCMP advised that though *S. divinorum* is readily available, it does not appear to pose a threat to public safety.

OCS has received a number of correspondences from Canada Border Service Agency (CBSA) officers concerning a lack of information regarding the status of *S. divinorum* and how the plant should be treated at the border. CBSA officers have also expressed concern regarding the plant's hallucinogenic properties. At present, only shipments of *S. divinorum* that are represented as health products/ hallucinogens can be refused for import under the NHPR.

## 10. IMPLEMENTATION AND EVALUATION



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# Issue Analysis Summary

DRAFT

## Scheduling *Salvia Divinorum* and/or Salvinorin A under the CDSA

Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Controlled Substances and Tobacco and Directorate

July 6, 2010

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### 1. APPROVALS

This Issue Analysis Summary is approved.

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Diane Allan, Director  
Office of Controlled Substances  
Tobacco and Drugs Directorate

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[DD/MM/2010]

### 2. ISSUE

Health Canada has received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *S. divinorum*, and/or its main active ingredient, salvinorin A, neither of which are currently regulated under the *Controlled Drugs and Substances Act* (CDSA). These requests are further to reports from scientific and media sources suggesting that *S. divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has

also noted an ongoing media interest regarding the availability of *S. divinorum* in Canada.

### 3. PURPOSE

To assess *Salvia divinorum* and/or salvinorin A against the criteria for the addition of a substance to one of the Schedules to the CDSA, and determine whether one or both should be regulated as controlled substances in Canada.

### 4. CONTEXT

*Salvia divinorum* is a species of sage which belongs to the mint family, and which is found in the form of dried leaves, extract and plant cuttings. Also known as "diviner's sage", the plant is known to induce illusions and hallucinations when chewed or smoked. Salvinorin A, the psychoactive ingredient in *S. divinorum* (also referred to chemically as a neoclerodane diterpene) is found primarily in the leaves, and to a lesser extent in the stems.<sup>1</sup>

*S. divinorum* is widely touted as a "legal" hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs among adolescents and young adults.<sup>2</sup> While very little is known about how and where *S. divinorum* is sold in Canada, it is suspected that it is mainly purchased over the Internet and/or bought at head shops or alternative life style stores, etc.

The use of *S. divinorum* as a psychotropic agent first came to Health Canada's attention in 2002. In 2004, Health Canada received four adverse drug reaction (ADR) reports associated with the use of *S. divinorum* as a hallucinogen, with three being considered non-serious (requiring no medical attention) and the fourth being considered serious (medical intervention was required). The serious ADR report involved the concomitant use of alcohol in a person diagnosed with Attention Deficit Disorder.

Further to the receipt of the aforementioned ADRs, the Marketed Health Products Directorate (MHPD) and the Natural Health Products Directorate (NHPD) of the Health Products and Food Branch (HPFB) prepared an issue analysis summary (IAS), which recommended that *S. divinorum* and its active ingredient salvinorin A be regulated as controlled substances. This recommendation was maintained when the IAS was updated in November 2006.

Later, in December 2005, MHPD and NHPD prepared a Signal Assessment (SA) (updated in June 2007) that eventually led to the preparation of a Health Risk Assessment (HRA), which concluded that *S. divinorum* or salvinorin A-containing health products would constitute a Type II Health Risk according to the Health Hazard Classification of the Recall Policy of the Health

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<sup>1</sup> U.S. Department of Justice Drug Enforcement Administration. 2002. Drugs and Chemicals of Concern: *Salvia Divinorum* (salvinorin A, divinorin A) URL:

[http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm) Nov 2008

<sup>2</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.

Products and Food Branch Inspectorate (HBFBI). Such a risk is defined as “a situation in which the use of, or exposure to, a product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote”.

Further to an Assistant Deputy Minister (ADM) discussion in April 2007, the Drug Strategy and Controlled Substances Directorate (DSCSD) organized a meeting with MHPD, NHPD and HPFBI to discuss *S. divinorum*. HPFBI was to determine appropriate compliance activities regarding *S. divinorum* and consult with the Canada Border Services Agency (CBSA) regarding the movement of products containing *S. divinorum* into and out of Canada.

On September 13, 2007, a further meeting between DSCSD, MHPD, NHPD and HPFBI led to the conclusion that DSCSD would conduct a scheduling assessment of *S. divinorum* in order to explore the possibility of scheduling this substance under the CDSA.

In September 2008, the Director Generals of DSCSD, MHPD, TPD and the HPFBI agreed that media lines and an “It’s Your Health” article on *S. divinorum* would be prepared.

#### **4.1 Relevant Legislative Frameworks in Canada**

##### **4.1.1 Food and Drug Regulations (under the Food and Drugs Act)**

The *Food and Drug Regulations* (F&DR) serve to ensure the safety, efficacy, and quality of health products offered for sale in Canada, including drugs and medical devices. Prior to being given market authorization, a manufacturer must present substantive scientific evidence that a product is safe, efficacious and of high quality. For drugs, Health Canada reviews this information carefully and, if the review is satisfactory, a Notice of Compliance (NOC) is issued and appropriate Drug Identification Numbers (DINs) are assigned.

A “drug” is defined under the F&DR as any substance or mixture of substances manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
- (b) restoration, correction or modification of organic functions in human beings or animals, or
- (c) disinfection in premises in which food is manufactured, prepared or kept;

As no products containing *S. divinorum* or its extracts have been reviewed and approved by Health Canada as of July 2010, it is illegal to market *S. divinorum* when it is represented as a drug.

#### **4.1.2 Natural Health Product Regulations (under the Food and Drugs Act)**

The *Natural Health Products Regulations* (NHPR) aim to provide Canadians with ready access to natural health products (NHPs) that are safe, effective, and of high quality, while respecting freedom of choice and philosophical and cultural diversity. The NHPR require that all licensed products display a Natural Product Number (NPN), or, in the case of a homeopathic medicine, Drug Identification Number - Homeopathic Medicine (DIN-HM), on their labels. These numbers are issued once a product is authorized for sale in Canada further to a *natural health product monograph* or submission of other evidence of safety and efficacy. The NHPR also require that all manufacturers, packagers, labelers, and importers be licensed which in turn requires the presence of procedures respecting distribution records, product recalls, product handling, storage and delivery, and manufacturing practices.

The definition of an NHP under the NHPR has both a function and substance component. The function component refers to those substances that are manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
- (b) restoring or correcting organic functions in humans; or
- (c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

The substance component refers to whether the product or medicinal ingredient therein is safe for consideration as an over-the-counter product, can be available for self-care and self-selection, and does not require a prescription to be sold. To be considered a NHP, no direct health claims need to be made regarding the substance. In the case of *S. divinorum*, it is generally marketed for its hallucinogenic properties which are considered a modification of an organic function. Therefore products containing it meet the definition of a NHP.

As of July 2010, no products containing *S. divinorum* have been reviewed and approved by Health Canada and no NPNs or DIN-HMs have been issued. Therefore sales of *S. divinorum* are illegal under the NHPR if it is represented for use as a hallucinogen or if other health claims in regards to modifying organic functions are made.

#### **4.1.3 Controlled Drugs and Substances Act and its Regulations**

The CDSA provides a legislative framework for the control of substances that can alter mental processes and that may produce harm to the health of an individual or to society when diverted or misused. Except as authorized under its regulations, activities such as possession, possession for the purposes of trafficking, trafficking, importation, exportation, possession for the purposes of exportation and production of controlled substances are prohibited under the CDSA.

The substances regulated under the CDSA are grouped into eight Schedules, and each Schedule is associated with particular offences and penalties as described in Part I of the CDSA.

In determining whether a substance should be regulated as a controlled substance, and into which Schedule of the CDSA it should be placed, Health Canada considers the following factors:

- International requirements and trends in the control and/or scheduling of the substance;
- Chemical and/or pharmacological similarity to substances listed in the Schedules to the CDSA;
- Legitimate use of the substance, including therapeutic, scientific, industrial or commercial uses;
- Potential for abuse and/or addiction liability of the substance;
- Evidence of extent of actual abuse of the substance in Canada and internationally; and
- Risk to personal and public health and safety.

## 4.2 Assessment of *Salvia Divinorum* for Scheduling Purposes

### 4.2.1 International Requirements and Trends in the Control and/or Scheduling of the Substance

At the present time, neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and therefore do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

#### *Australia*

In June 2002, Australia became the first country to prohibit the sale, supply, possession and use of *S. divinorum* and salvinorin A. Although both *S. divinorum* and salvinorin A are listed in Schedule 9 of Australia's Standard for the Uniform Scheduling of Drugs and Poisons on the basis of "high potential for abuse and risk to public health and safety", no substantiation of this risk was provided at the time of this scheduling decision.<sup>3</sup> Schedule 9 is Australia's most restrictive drug schedule, and includes "substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities."<sup>4</sup>

#### *Belgium*

A decree was passed in Belgium on October 22, 2006 which added *S. divinorum* to the list of controlled substances. This list includes substances such as psilocybin mushrooms, khat and

<sup>3</sup> <http://www.tga.gov.au/ndpsc/record/rr200111.pdf>

<sup>4</sup> [http://www.cognitiveliberty.org/news/salvia\\_australia.htm](http://www.cognitiveliberty.org/news/salvia_australia.htm)

peyote cactus.<sup>5</sup>

### **Denmark**

In 2003, Denmark added *S. divinorum* and salvinorin A to their list of “category B” controlled substances, a category which also includes psilocybin mushrooms, cocaine, amphetamine, and several others substances that are only legal for medicinal and scientific purposes. Illegal possession carries a penalty of up to two years in prison.

### **Germany**

*S. divinorum* (plant and plant parts) was added to Appendix I of the *Narcotics Act* in Germany on March 1, 2008, making it illegal to produce, traffic, or possess. The law does not specifically mention salvinorin A.

### **Italy**

On June 25, 2004, the Italian Ministry of Health issued an ordinance prohibiting the sale of *S. divinorum* and its active constituent salvinorin A. On January 11, 2005, the Ministry of Health made possession of *S. divinorum* and salvinorin A illegal by placing them in “*Tabella I*” of the *Tabella Sostanze Stupefacenti o Psicotrope*.

### **Japan**

On November 9, 2006, the Japanese government added a group of thirty-three drugs to its list of controlled substances, including salvinorin A. The drugs are banned under a revised pharmaceutical law, under which persons involved in their illegal import, production, and sale, i.e. beyond medical treatment or research purposes, will be subject to up to five years imprisonment or a fine of up to five million yen.

### **Spain**

On January 28, 2004, the Spanish Ministry of Health and Consumption issued an order prohibiting the sale of *S. divinorum*. The regulation went into effect on May 6, 2004 and only prohibits activities related to commerce. Possession and/or use are not considered to be criminal offences.

### **Other Countries**

*Salvia divinorum* is illegal to possess or sell in Croatia, Latvia, Lithuania, Poland, Romania, South Korea and Sweden. In Russia it is illegal to grow or sell *S. divinorum*, but it is legal to

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<http://eldd.emcdda.europa.eu/html.cfm/index5176EN.html?pluginMethod=eldd.shownewsdetails&id=20/12/2006BELGIUM:%20New%20substances%20controlled%20include%20mCPP%20and%20khat>



possess it. In Estonia, Finland, Iceland and Norway, *S. divinorum* is treated as a medicinal herb and it is illegal to import it without a relevant prescription from a doctor.

### ***United States of America***

*S. divinorum* and salvinorin A are not included in the Schedules to the United States *Controlled Substances Act* although both *S. divinorum* and salvinorin A have been added to a list of chemicals "of concern" which has no legal implications. In addition, some individual states have implemented laws restricting its use, sale and/or distribution. As of July 2010, a number of states have enacted legislation placing regulatory controls on *S. divinorum* and/or salvinorin A including Delaware, Georgia, Florida, Hawaii, Illinois, Kansas, Kentucky, Maryland, Mississippi, Missouri, Nebraska, North Dakota, Ohio, Oklahoma, South Dakota, Wisconsin, Virginia, California, Louisiana, Maine, North Carolina, and Tennessee. More details regarding the regulation of *S. divinorum* in these last five states are provided below.

#### ***California***

As of January 1, 2009, the sale or distribution of *S. divinorum* or salvinorin A, or any substance or material containing *S. divinorum* or salvinorin A, to any person under 18 years of age is a misdemeanor punishable by imprisonment in a county jail for not more than six months, a fine of no more than \$1,000, or both.

#### ***Louisiana***

In 2005, Louisiana passed a bill which prohibits the possession, production, manufacture and distribution of a material, compound, mixture, or preparation intended for human consumption and that contains a hallucinogenic plant. A "hallucinogenic plant" is defined as "any part or portion" of a plant on a list of forty plants, which includes *S. divinorum*.

#### ***Maine***

In Maine, *S. divinorum* and salvinorin A are regulated in the same way as tobacco products; adults eighteen years of age or over can legally purchase and use the material, but selling or providing *S. divinorum* or salvinorin A to anyone under the age of eighteen is a criminal offence. Possession by a minor is a civil violation, punishable by a fine, community service, or both.

#### ***North Carolina***

On December 1, 2009, the North Carolina State Legislature brought a new law into force which made *Salvia divinorum* and salvinorin A illegal. The only legal *S. divinorum* activities are the growing for aesthetic, landscaping, or decorative purposes or university-affiliated medical or pharmacological research.

## *Tennessee*

On July 1, 2006, Tennessee classified the deliberate production, manufacture, distribution, or possession of the active chemical ingredient in the hallucinogenic plant *S. divinorum* as a Class A misdemeanor. It is not, however, a criminal offence to possess, plant, cultivate, grow, or harvest *S. divinorum* for aesthetic, landscaping, or decorative purposes. The law also does not apply to any dosage that is legally obtainable from a retail establishment without a prescription when it is recognized by the Food and Drug Administration as a homeopathic drug.

### 4.2.2 Chemical and/or Pharmacological Similarity to Substances listed in the Schedules to the CDSA

The psychoactive ingredient in *Salvia divinorum* is salvinorin A. Other plants which contain psychotropic terpenoids are *Artemisia absinthium* (wormwood) and *Cannabis sativa*. Salvinorin A is considered by some as the most potent natural hallucinogen ever isolated.<sup>6</sup>

Unlike all other hallucinogens, salvinorin A is structurally distinct and does not interact with the serotonin-2A receptor or any other molecular target of classical hallucinogens. It thus affects the brain in a way that is quite unique.<sup>7</sup> Recent pharmacological screenings of receptors have found it to be a highly potent and selective  $\kappa$ -opioid receptor (KOR) agonist.<sup>8</sup>

The use of *S. divinorum* or salvinorin A can lead to a number of effects with variable onset and duration. These effects are generally accepted to be: sensation of becoming an object, visions of various two-dimensional surfaces, films and membranes, revisiting places of the past (particularly childhood), perceived loss of the body and/or identity, various sensations of motion (being pulled or twisted by a force of some kind), uncontrollable hysterical laughter, and overlapping realities (perceptions of being in more than one place).<sup>9</sup> Laughter, happiness, sense of well-being and dissociative effects were deemed the best aspects of *S. divinorum* by users, second only to the "trip" that the drug elicits.<sup>10</sup> Depersonalization, speaking gibberish, widening of consciousness and subjective illusions of rapid movement, flying or hovering have also been

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<sup>6</sup> Ott J. Ethnopharmacognosy and human pharmacology of *Salvia divinorum* and salvinorin A. *Curare*. 1995 18: 103-129. Unofficial transcription available online. URL <http://www.sagewisdom.org/ott2.html>

<sup>7</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>8</sup> Roth BL, Baner K, Westkaemper R, Siebert D, Rice KC, Steinberg S, Ernsberger P, Rothman RB. Salvinorin A: a potent naturally occurring nonnitrogenous kappa opioid selective agonist. *Proc Natl Acad Sci U S A*. 2002 Sep 3;99(18):11934-9.

<sup>9</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>10</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

reported.<sup>11</sup>

The psychomimetic effects of *S. divinorum* closely resemble schizophrenia symptoms induced by lysergic acid diethylamide (LSD) or phencyclidine (PCP).<sup>14</sup> Yet, it is said to have only weak influence on the prevailing mood of the user which differentiates it from other hallucinogens such as LSD and psilocybin.<sup>15</sup> Its strong dissociative effects are often compared to those of ketamine. Users have reported that the psychedelic effects of *S. divinorum* were most similar to those caused by psilocybin mushrooms.<sup>16</sup> However, users familiar with the effects of other hallucinogens agree that despite certain similarities to classical hallucinogens, the visions and overall experience is quite unique.<sup>17</sup>

In addition, the psychedelic effects of *S. divinorum* are similar to those of classical psychedelics regarding changes in perception and somatic sensations. *S. divinorum* causes an unusually high degree of sedation, weakness and fatigue, while the increased de-realization is not commonly reported for classical psychedelics.<sup>18</sup> The combination of these effects seems to correlate with that of other KOR agonists such as pentazocine.<sup>19</sup>

#### 4.2.3 Legitimate Use of the Substance, including Therapeutic, Scientific, Industrial or Commercial Uses

*Salvia divinorum* has traditionally been used for spiritual and medicinal purposes by the Mazatec

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<sup>11</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5 and Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>14</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>15</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>16</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>17</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6 and González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>18</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>19</sup> Arasteh K, Poudevida S, Farre M, Roset PN, Cami J. Response patterns of the Spanish version of the 49-item short form of the Addiction Research Center Inventory after the use of sedatives, stimulants, and opioids. *Drug Alcohol Depend*. 1999 Jun 1;55(1-2):117-25.

Indians in Oaxaca, Mexico,<sup>20</sup> where an infusion of the leaves or the leaves themselves are ingested to treat gastrointestinal problems, headaches, rheumatism, anemia and swelling of the stomach.<sup>21</sup> Its main use today is, however, for its psychoactive properties in the aid of producing “mystical” or hallucinogenic experiences as part of spiritual rituals.<sup>22</sup>

Although selective kappa receptor agonists have been shown to produce analgesic effects, adverse effects such as psychotomimesis, dysphoria and diuresis have been observed in studies investigating their therapeutic use.<sup>23</sup> In addition, while it has been speculated that KOR agonists may prove to be useful in the treatment of certain psychiatric disorders including Alzheimer's disease, schizophrenia, dementia and bipolar disorder,<sup>24</sup> much more research is needed in order to substantiate these hypotheses. Similarly, another study has suggested that chemical analogues of salvinorin A may be a useful treatment for those suffering from addiction to other substances.<sup>25</sup> That said, there are presently no legitimate medical uses for *S. divinorum* in Canada.

Similarly, there are no known industrial uses for *S. divinorum* in Canada. The plant is a semi-tropical perennial that can only grow outdoors in a humid climate where it will not encounter frost. Most websites offering *S. divinorum* cuttings and seeds for sale appear to do so in the context of growing the plant in order to utilize its psychoactive properties, rather than out of horticultural interest or for its esthetic appeal.

#### 4.2.4 Potential for Abuse and/or Addiction Liability of the Substance

Salvinorin A is a potent, selective agonist of the  $\kappa$ -opioid receptor (KOR), and in contrast to the euphoria produced by  $\mu$ -opioid receptor (MOR) agonists, KOR agonists are negatively reinforcing and aversive.<sup>26</sup> In addition, KOR agonists have analgesic properties but are not

<sup>20</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>21</sup> Munro, T. *The Chemistry of Salvia divinorum*. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

<sup>22</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage *Salvia divinorum*. *Life Sci.* 2005 Dec 22;78(5):527-31.

<sup>23</sup> Barker RL, Fawcett J, Barkin SJ. 2002. Chronic pain management with a focus on the role of newer antidepressants and centrally acting agents. In: *Pain Management: A Practical Guide for Clinicians*, 6th edition, Weiner RS ed. CRC Press, Boca Raton, FL. pp. 415-34 and Tidgewell et al., 2004. A facile method for the preparation of deuterium labelled salvinorin A: *Biorganic & Medicinal Chemistry Letters*, 14: 5099-5102.

<sup>24</sup> Sheffler DJ & Roth BL. Salvinorin A: the ‘magic mint’ hallucinogen finds a molecular target in the kappa opioid receptor. *Trends Pharmacol Sci.* 2003 Mar;24(3):107-109.

<sup>25</sup> Prisinzano TE. Natural products as tools for neuroscience: discovery and development of novel agents to treat drug abuse. *J Nat Prod.* 2009 Mar 27;72(3):581-7.

<sup>26</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590, Cooper S. Interactions between endogenous opioids and dopamine: Implications for reward and aversion. In: *The Mesolimbic Dopamine System: From Motivation to Action*. Willner P and Scheel-Kruger J (editors) Wiley, Chester, England, 1991, pp. 331-366, and Shippenberg TS, Herz A, Spanagel R, Bals-Kubik R, Stein C. Conditioning of opioid reinforcement: neuroanatomical and neurochemical substrates. *Ann N Y Acad Sci.* 1992 Jun 28;654:347-56.

associated with respiratory depression like MOR agonists. Finally, while MOR agonists increase the release of dopamine, the activation of KOR decreases dopamine release in the nucleus accumbens.<sup>28</sup>

The onset and intensity of the effects of *Salvia divinorum* appear to be related to the route of administration.

Traditional uses generally produce mild effects because the leaves are rolled and chewed or crushed and prepared as a foamy infusion whereby the salvinorin A is degraded in the gastrointestinal system before being absorbed into the bloodstream. Hence, the level of effect relates quite closely to the length of time the material spends in the mouth, with the onset of effect generally taking 5-10 minutes. The effects build over the next hour and last for another hour before they begin to subside.<sup>29</sup>

Routes of administration that avoid the hepatic first-pass effect (i.e. intravenous, intramuscular, inhalation and sublingual use) are the quickest and most intense.<sup>30</sup> Salvinorin A can be isolated from the plant to make a powder which can be vaporized and inhaled. The onset of effects felt from vaporizing salvinorin A powder occurs in about 30 seconds and effects last for about 5-10 minutes and then subside over the next 30 minutes.<sup>31</sup>

Smoking is by far the most popular method of administration<sup>32</sup> and this is accomplished by smoking the dried leaves or a concentrated extract using a pipe or bong. Dried leaves may also be fortified with a concentrated extract of salvinorin A. A concentrated extract can also be used sublingually. Neither *S. divinorum* nor salvinorin A can be injected because the powder is insoluble in water.<sup>33</sup>

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<sup>28</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.

<sup>29</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>30</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.

<sup>31</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>32</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62 and Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>33</sup> Valdés LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs.* 1994 Jul-Sep;26(3):277-83.

The aversive effects of previously studied KOR agonists predict that the risk of addiction to *S. divinorum* is negligible. However, very few controlled scientific studies of the physical and psychotropic effects of *S. divinorum* on humans have been carried out. Therefore, it is difficult to predict its potential for addiction and abuse. In studies that have been conducted, there is conflicting information around the addiction liability of *S. divinorum* in both animals and humans. Some users have noted that they require increasing doses of salvinorin A in order to achieve the desired effect and the stimulated cerebral KOR may act as a mechanism of tolerance.<sup>37</sup> Further studies in this area and on the mediated decrease of dopamine as well as the impact of dose on the rewarding and aversive effects are also required.

While concerns for the potential of abuse were once minimal because 1 kg of dried leaves yields only 3 to 6 human doses of salvinorin A, it was discovered that vaporizing and inhaling 200-500 micrograms had profound hallucinogenic effects.<sup>38</sup> The extraction of salvinorin A from the plant is very easy and with care, approximately 1.5 grams of pure salvinorin A per kilogram of dried leaves (8kg of fresh leaves) can be isolated, which is enough substance to provide for 2000 human doses.<sup>39</sup>

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<sup>37</sup> Bucheler R, Gleiter CH, Schworer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>38</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>39</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs*. 1994 Jul-Sep;26(3):277-83.

<sup>44</sup> Turner DM. *Salvinorin - The Psychedelic Essence of Salvia Divinorum*. Panther Press, San Francisco, CA 1996.

#### 4.2.5 Evidence of Extent of Actual Abuse of the Substance in Canada and Internationally

In Canada, the extent of actual abuse of *Salvia divinorum* and salvinorin A is relatively unknown.

There is, however, some data regarding the use of *Salvia divinorum* in Canada. As there are no approved uses for this plant, any use (i.e. for consumption) is illegitimate in nature. Questions about the use of *S. divinorum* were included in the 2008-2009 Youth Smoking Survey, the 2009 Canadian Alcohol and Drug Use Monitoring Survey and the 2009 Ontario Student Drug Use and Health Survey.

The results from the 2009 Ontario Student Drug Use and Health Survey were published on November 18, 2009 and indicate that:

- Among all responding students in Ontario, 4.4% reported using *Salvia divinorum* at least once in the past year. In comparison, 58.2% indicated they had used alcohol, 25.6% indicated they had used cannabis and 5.0% indicated they had used hallucinogens other than LSD and PCP in the past year;
- Males (6.2%) were significantly more likely than females (2.3%) to report using *Salvia divinorum*;
- There is significant grade variation, with *Salvia divinorum* use most likely among 11<sup>th</sup> graders (8.6%) and 12<sup>th</sup> graders (8.4%); and
- There are significant regional variations, with students in Northern Ontario (9.2%) most likely to use *Salvia divinorum*.

The results of the 2008-2009 Youth Smoking Survey were published on May 31, 2010 and indicate that:

- 4.9% of students stated that they had used *S. divinorum* in the last twelve months. In comparison, 53.0% indicated they had used alcohol, 27.3% indicated they had used cannabis and 6.9% indicated they had used other hallucinogens in the last twelve months;
- 2.6% of students in Grades 7-9 and 7.0% of students in Grades 10-12 had used *S. divinorum* in the last twelve months; and
- Males (6.6%) were more likely to have used *S. divinorum* in the past twelve months compared to females (3.2%).

The scope of the previously mentioned studies did not provide for any explanations regarding differences in usage between ages, genders and regions. In this regard, it is difficult to speculate on the causality of such differences.

The Canadian Alcohol and Drug Use Monitoring Survey specifically examined *Salvia* for the first time in 2009. An estimated 1.6% of Canadians, aged 15 years and older, reported that they had used *salvia* in their lifetime, and 0.2% reported using it in the past-year. In comparison, the prevalence of past-year cannabis use among Canadians 15 years of age and older was 10.6%. 1.2% of respondents reported using cocaine or crack in the past 12 months, 0.9% had used ecstasy and 0.7% used illicit hallucinogens.

Health Canada's Drug Analysis Services (DAS) has identified salvinorin A in a number of samples seized by law enforcement, as shown in the following table.

**NUMBER OF SAMPLES FOUND TO CONTAIN SALVINORIN A**

Year	Count
2006	9
2007	8
2008	4
2009	20
2010 (as of May 7)	8

The National Forensic Laboratory Information System (NFLIS) and the System to Retrieve Information from Drug Evidence (STRIDE) in the United States are Drug Enforcement Agency (DEA) databases that collect scientifically verified data on analyzed samples in state and local forensic labs as well as samples from DEA labs. The following table shows the quantity of *S. divinorum* products that were seized from 2000 through to 2009.

**ANALYZED SALVIA DIVINORUM or SALVINORIN A SEIZURES**

(Number of items/Exhibits)

Source	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009*
NFLIS-State/Local <sup>1</sup>	0	0	0	0	1	8	12	12	70	34
STRIDE <sup>2</sup>	0	0	1	1	1	0	0	0	N/A	N/A
<b>TOTAL</b>	0	0	1	1	2	8	12	12	70	34

Data Source: NFLIS & STRIDE, 2008 data queried 11/24/08, updated 06/10/2010

<sup>1</sup> NFLIS reported seizures of *Salvia divinorum* and/or salvinorin A

<sup>2</sup> STRIDE reported items of *Salvia divinorum*.

\* Includes only January – May data in 2009.

It is difficult to determine the extent of actual abuse of *S. divinorum* in Canada or elsewhere as there appear to be inconsistencies in the literature regarding risk aversion. For example, one author states: "Many who have used salvinorin A find the experience extremely unnerving, frightening and overly intense and most have no desire to repeat the experience."<sup>44</sup> However, another study suggested that this is not the experience of all recreational users of *S. divinorum*.<sup>45</sup> Over eighty percent of users surveyed on a web-based questionnaire about their *S. divinorum* use said that they would probably or definitely use *S. divinorum* again.<sup>46</sup> Users have reported the negative effects of *S. divinorum* as: the short duration of action, lack of control over the

<sup>45</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62, Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry.* 2005 Jan;38(1):1-5, and Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs.* 1994 Jul-Sep;26(3):277-83.

<sup>46</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.



experience, persisting negative effects (most often anxiety),<sup>47</sup> sweating, chills, increased diuresis, impaired vigilance,<sup>48</sup> and negative after-effects including tiredness, feeling head heavy, dizziness, physical exhaustion, and some degree of malaise or 'hangover' as they 'comedown' from the drug.<sup>49</sup>

#### 4.2.6 Risk to Personal and Public Health and Safety

The increase in both the number of enquiries from various municipalities and members of the public and in the amount of media interest regarding the availability of *Salvia divinorum* in Canada may be an indication that the recreational use of *S. divinorum* as a hallucinogen is on the rise. However, there are no available statistics that indicate there has been a significant increase in *S. divinorum* use in the Canadian population and, in comparison to the use of other drugs such as alcohol and cannabis, the actual use of *S. divinorum* is quite low.

The potential for harm to the user and/or other individuals is primarily related to the hallucinogenic properties of the substance. Users may get up and walk around without apparent awareness of their movements, behaviour or surroundings, and distinction between self and surroundings is often lost. At doses greater than 1mg of salvinorin A, out of body experiences are frequent and loss of consciousness has been reported.<sup>50</sup> There is little information regarding the social behaviours of persons under the influence of *S. divinorum* products, and what risks their activities such as operating a motorized vehicle may pose to the general public. There is also very little data regarding the toxicity, teratogenicity or other long-term effects of *S. divinorum* use.<sup>51</sup>

As far as law enforcement is concerned, the Department has only received a limited number of communications indicating concern with respect to *S. divinorum* and none of these have advised that the use of *S. divinorum* poses any threat to public safety. The Royal Canadian Mounted Police (RCMP) has stated that while *S. divinorum* is readily available, it has not become a popular drug in Canada, probably due to its aversive effects such as anxiety and introversion.

A handful of case reports regarding the use of *S. divinorum* have been published in the academic literature. One report was an international case report in which a young man (19 years of age) described his perceptions after inhaling smoke from *S. divinorum*. The peak psychotropic effects, including prickling of the skin, fever-like hot flashes, muscular tremor, and depersonalization, were reached in less than five minutes after inhalation of an unknown amount of smoke from burning dried leaves.<sup>52</sup> Another report involved a 15-year-old male who presented

<sup>47</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>48</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>49</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>50</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>51</sup> Grundmann O, Phipps SM, Zadezensky I, Butterweck V. *Salvia divinorum* and Salvinorin A: An Update on Pharmacology and Analytical Methodology. *Planta Med* 2007 Jun;73:1039-1046.

to psychiatric emergency services with acute onset of paranoia, déjà vu, blunted affect, difficulties in thought processing and slowed speech after smoking *Salvia divinorum* over an unknown period of time. During his hospitalization all symptoms improved significantly except the feeling of déjà vu. Based on this case presentation, the author suggested that the feelings of déjà vu may be a long-term effect of *S. divinorum* use.<sup>53</sup> However, given that this is the only case report in which déjà vu was associated with the use of *S. divinorum*, more reports are needed to substantiate this finding.

In addition to the above-mentioned reports, in 2006, a case was reported in the U.S. in which a 17-year-old boy committed suicide after smoking *S. divinorum* for an unknown period of time.<sup>54</sup> It should be noted that alcohol and general depression were the main confounders in this case. After this case was reported, the state of Delaware passed a law which classified *S. divinorum* as a Schedule I controlled substance along with other hallucinogenic substances.

Like many drugs of abuse, users are often unaware of the potency and adulterants in the product they purchase. A study by Wolowich *et al.* (2006)<sup>55</sup>, showed that the salvinorin A content in five out of five *S. divinorum* products was falsely indicated on the label and 4 out of 5 products contained unidentified adulterants (i.e. vitamin E, caffeine).

Health Canada has only anecdotal information about the use and abuse of *S. divinorum* in Canada as well as the threat *S. divinorum* may pose to the health and safety of Canadians. Although reports of domestic adverse reactions related to the use of *S. divinorum* as a hallucinogen have  
s.21(1)(a) been received through the Canada Vigilance database, it is important to note that the number of  
s.21(1)(b) reports and the nature of reactions reported are not adequate to characterize the risk to the general population.

## 5. ASSESSMENT OF RISKS AND BENEFITS

<sup>53</sup> Singh S. (2007) Adolescent salvia substance abuse. *Addiction*. 102, 823-824.

<sup>54</sup> <http://www.kybc.com/Global/story.asp?S=4893692>

<sup>55</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

**Page(s) 000962 to\à 000962**

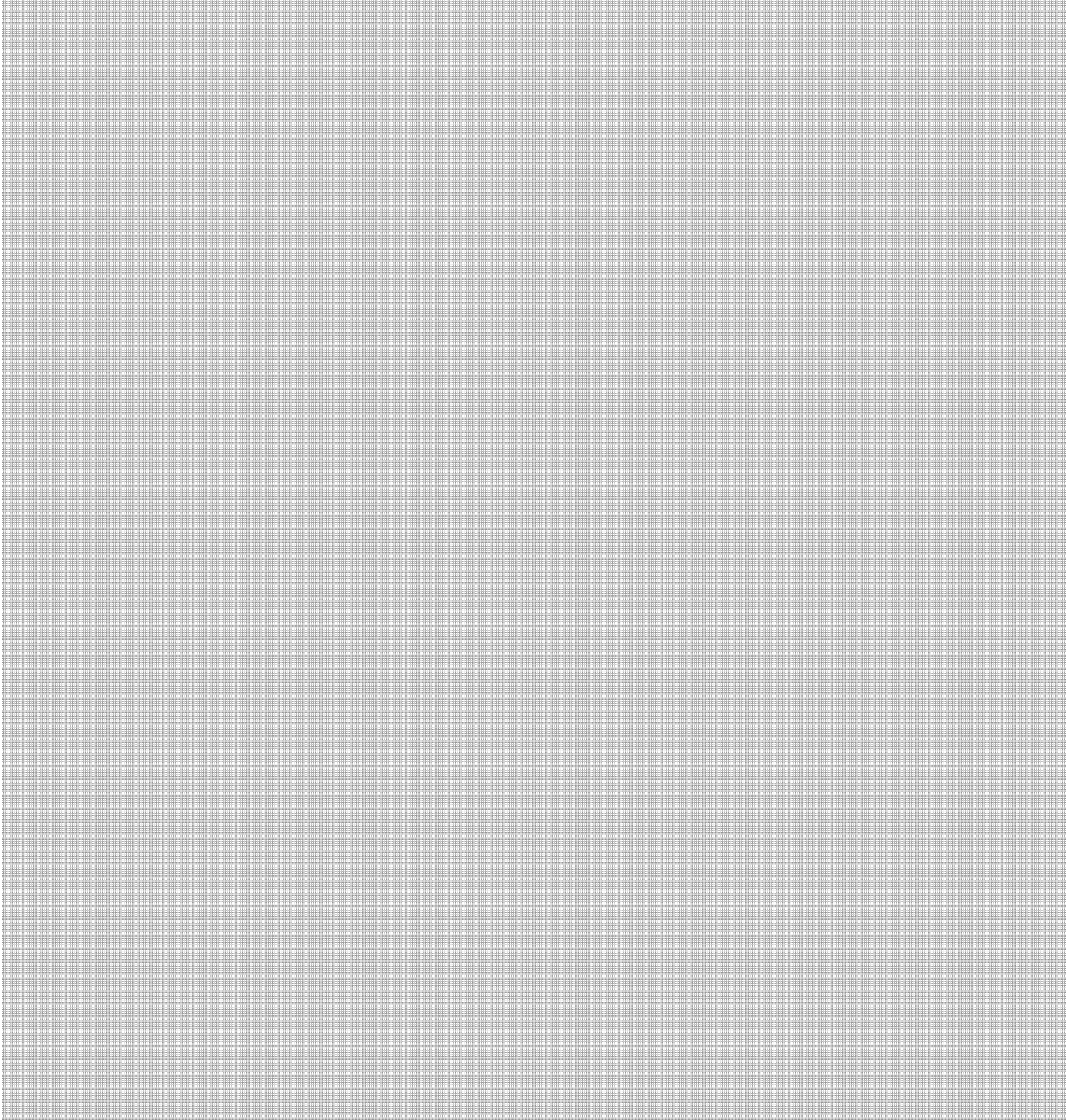
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est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**

s.21(1)(a)

s.21(1)(b)



## 7. CONSIDERATIONS

The KOR-mediated aversive and dysphoric effects of *Salvia divinorum* do not appear to be hampering its use as young adults have begun smoking the leaves and leaf extract recreationally.<sup>56</sup> It can be purchased through online botanical companies and other drug promotion sites and is often

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<sup>56</sup> Hazelden Foundation, 2004. Drug Abuse Trends. June 2004. URL: [www.research.hazelden.org](http://www.research.hazelden.org).

s.21(1)(a)

s.21(1)(b)

touted as a legal alternative to substances such as cannabis and mescaline.<sup>57</sup> Interestingly, after being widely available for over a decade, the drug does not appear to have had the same social impact as LSD or ecstasy.<sup>58</sup>

While there has been an increase over the past few years in the number of enquiries from various municipalities and members of the public regarding the availability of *Salvia divinorum* as a hallucinogen, the reported use of *S. divinorum* by young Canadians is much lower than that of alcohol or cannabis, according to available statistics.

The NHPR are limited in their capacity to control the availability of *S. divinorum* in that *S. divinorum* products are often declared as incense and therefore cannot be considered unapproved natural health products. In addition, compliance and enforcement actions, such as voluntary stop-sales, forfeiture, destruction, and administrative seizure, cannot be implemented unless the labeling of the product indicates that it is to be used for consumption and/or its pharmacological effects.

The previous HPFB recommendation to schedule *S. divinorum* under the CDSA was likely based on a misunderstanding of the previously-described criteria upon which scheduling is based. In particular, it did not consider a number of factors, including potential for abuse and risk to public health and safety. The Office of Controlled Substances (OCS) was also not consulted by HPFB at the time this recommendation was made. In addition, among countries who have decided to control *S. divinorum* in some way, very little or no substantiation of the risks of *S. divinorum* upon which the decision was based are available.

Neither *Salvia divinorum* nor salvinorin A meet the criteria for scheduling a substance under the CDSA. Despite being regulated in some jurisdictions, neither the plant nor salvinorin A are scheduled under any of the UN Drug Control Conventions. *S. divinorum* and salvinorin A are not structurally or pharmacologically similar to other substances included in the schedules to the CDSA. There are currently no legitimate therapeutic or industrial uses for *S. divinorum*. The abuse liability and potential for dependence of *S. divinorum* is not known as very few controlled scientific studies of its physical and psychotropic effects have been carried out on humans. The extent of actual abuse of *S. divinorum* is also largely unknown. Evidence of a risk to public health and safety is anecdotal in nature and not quantified in any way as there is a lack of information regarding abuse in Canada. Therefore, it would not be appropriate to include *S. divinorum* and/or salvinorin A under any of the Schedules to the CDSA at this time.

## 8. RECOMMENDATIONS

<sup>57</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

<sup>58</sup> Munro, T. The Chemistry of *Salvia divinorum*. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

s.21(1)(a)

s.21(1)(b)

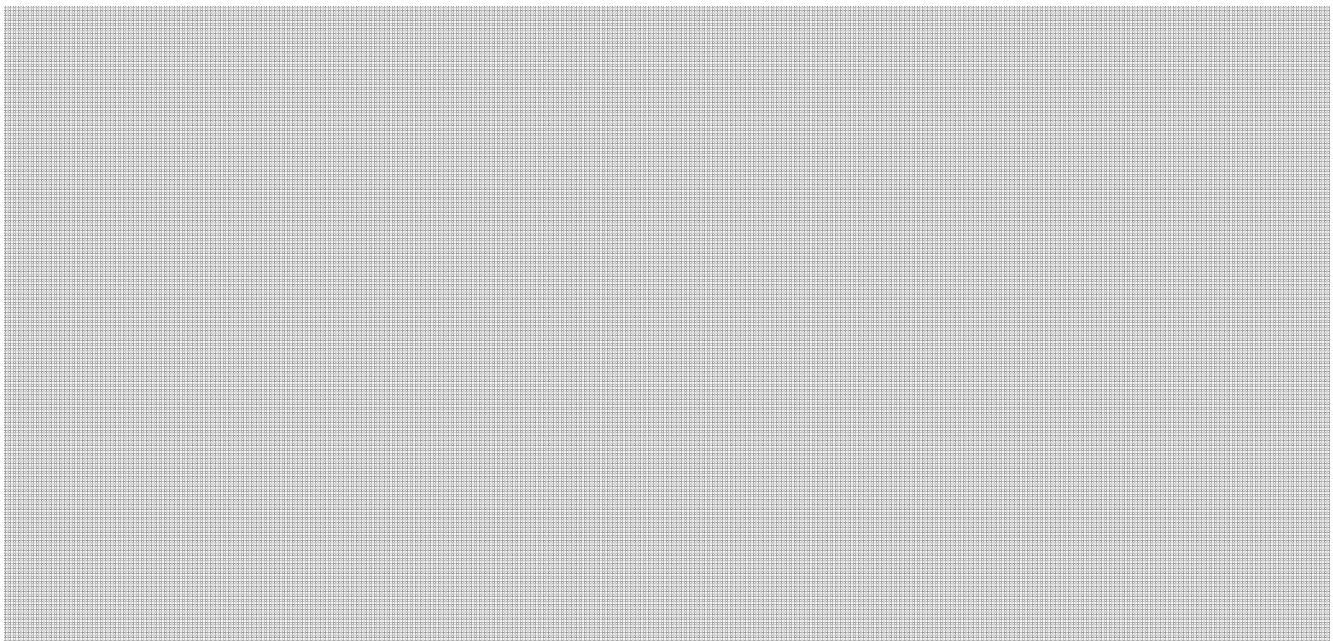
## 9. CONSULTATIONS

The Drug Analysis Services (DAS) was contacted in order to provide any data available regarding the identification of salvinorin A in samples submitted by law enforcement.

The Royal Canadian Mounted Police (RCMP) was contacted in order to establish their views with respect to *S. divinorum* use in Canada. The RCMP advised that though *S. divinorum* is readily available, it does not appear to pose a threat to public safety.

OCS has received a number of correspondences from Canada Border Service Agency (CBSA) officers concerning a lack of information regarding the status of *S. divinorum* and how the plant should be treated at the border. CBSA officers have also expressed concern regarding the plant's hallucinogenic properties. At present, only shipments of *S. divinorum* that are represented as health products/ hallucinogens can be refused for import under the NHPR.

## 10. IMPLEMENTATION AND EVALUATION



Not circulated

# Issue Analysis Summary

DRAFT

## Scheduling *Salvia Divinorum* and/or Salvinorin A under the CDSA

Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Controlled Substances and Tobacco and Directorate

July 7, 2010

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### 1. APPROVALS

This Issue Analysis Summary is approved.

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Diane Allan, Director  
Office of Controlled Substances  
Tobacco and Drugs Directorate

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[DD/MM/2010]

### 2. ISSUE

Health Canada has received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *S. divinorum* and/or its main active ingredient/salvinorin A, neither of which are currently regulated under the *Controlled Drugs and Substances Act* (CDSA). These requests are further to reports from scientific and media sources suggesting that *S. divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has

also noted an ongoing media interest regarding the availability of *S. divinorum* in Canada.

### 3. PURPOSE

To assess *Salvia divinorum* and/or salvinorin A against the criteria for the addition of a substance to one of the Schedules to the CDSA, and determine whether one or both should be regulated as controlled substances in Canada.

### 4. CONTEXT

*Salvia divinorum* is a species of sage which belongs to the mint family, and which is found in the form of dried leaves, extract and plant cuttings. Also known as "diviner's sage", the plant is known to induce illusions and hallucinations when chewed or smoked. Salvinorin A, the psychoactive ingredient in *S. divinorum* (also referred to chemically as a neoclerodane diterpene) is found primarily in the leaves, and to a lesser extent in the stems.<sup>1</sup>

*S. divinorum* is widely touted as a "legal" hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs among adolescents and young adults.<sup>2</sup> While very little is known about how and where *S. divinorum* is sold in Canada, it is suspected that it is mainly purchased over the Internet and/or bought at head shops or alternative life style stores, etc.

The use of *S. divinorum* as a psychotropic agent first came to Health Canada's attention in 2002. In 2004, Health Canada received four adverse drug reaction (ADR) reports associated with the use of *S. divinorum* as a hallucinogen, with three being considered non-serious (requiring no medical attention) and the fourth being considered serious (medical intervention was required). The serious ADR report involved the concomitant use of alcohol in a person diagnosed with Attention Deficit Disorder.

Further to the receipt of the aforementioned ADRs, the Marketed Health Products Directorate (MHPD) and the Natural Health Products Directorate (NHPD) of the Health Products and Food Branch (HPFB) prepared an issue analysis summary (IAS), which recommended that *S. divinorum* and its active ingredient salvinorin A be regulated as controlled substances. This recommendation was maintained when the IAS was updated in November 2006.

Later, in December 2005, MHPD and NHPD prepared a Signal Assessment (SA) (updated in June 2007) that eventually led to the preparation of a Health Risk Assessment (HRA), which concluded that *S. divinorum* or salvinorin A-containing health products would constitute a Type II Health Risk according to the Health Hazard Classification of the Recall Policy of the Health

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<sup>1</sup> U.S. Department of Justice Drug Enforcement Administration. 2002. Drugs and Chemicals of Concern: Salvia Divinorum (salvinorin A, divinorin A) URL:

[http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm) Nov 2008

<sup>2</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.



Products and Food Branch Inspectorate (HBFBI). Such a risk is defined as “a situation in which the use of, or exposure to, a product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote”.

Further to an Assistant Deputy Minister (ADM) discussion in April 2007, the Drug Strategy and Controlled Substances Directorate (DSCSD) organized a meeting with MHPD, NHPD and HPFBI to discuss *S. divinorum*. HPFBI was to determine appropriate compliance activities regarding *S. divinorum* and consult with the Canada Border Services Agency (CBSA) regarding the movement of products containing *S. divinorum* into and out of Canada.

On September 13, 2007, a further meeting between DSCSD, <sup>MHPD</sup> (MHPD), NHPD and HPFBI led to the conclusion that DSCSD would conduct a scheduling assessment of *S. divinorum* in order to explore the possibility of scheduling this substance under the CDSA.

In September 2008, the Director Generals of DSCSD, MHPD, TPD and the HPFBI agreed that media lines and an “It’s Your Health” article on *S. divinorum* would be prepared.

#### **4.1 Relevant Legislative Frameworks in Canada**

##### **4.1.1 Food and Drug Regulations (under the Food and Drugs Act)**

The *Food and Drug Regulations* (F&DR) serve to ensure the safety, efficacy, and quality of health products offered for sale in Canada, including drugs and medical devices. Prior to being given market authorization, a manufacturer must present substantive scientific evidence that a product is safe, efficacious and of high quality. For drugs, Health Canada reviews this information carefully and, if the review is satisfactory, a Notice of Compliance (NOC) is issued and appropriate Drug Identification Numbers (DINs) are assigned.

A “drug” is defined under the F&DR as any substance or mixture of substances manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
- (b) restoration, correction or modification of organic functions in human beings or animals, or
- (c) disinfection in premises in which food is manufactured, prepared or kept;

As no products containing *S. divinorum* or its extracts have been reviewed and approved by Health Canada as of July 2010, it is illegal to market *S. divinorum* when it is represented as a drug.

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#### 4.1.2 Natural Health Products Regulations (under the Food and Drugs Act)

The *Natural Health Products Regulations* (NHPR) aim to provide Canadians with ready access to natural health products (NHPs) that are safe, effective, and of high quality, while respecting freedom of choice and philosophical and cultural diversity. The NHPR require that all licensed products display a Natural Product Number (NPN), or, in the case of a homeopathic medicine, Drug Identification Number - Homeopathic Medicine (DIN-HM), on their labels. These numbers are issued once a product is authorized for sale in Canada further to a *natural health product monograph* or submission of other evidence of safety and efficacy. The NHPR also require that all manufacturers, packagers, labelers, and importers be licensed which in turn requires the presence of procedures respecting distribution records, product recalls, product handling, storage and delivery, and manufacturing practices.

The definition of an NHP under the NHPR has both a function and substance component. The function component refers to those substances that are manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
- (b) restoring or correcting organic functions in humans; or
- (c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

The substance component refers to whether the product or medicinal ingredient therein is safe for consideration as an over-the-counter product, can be available for self-care and self-selection, and does not require a prescription to be sold. To be considered a NHP, no direct health claims need to be made regarding the substance. In the case of *S. divinorum*, it is generally marketed for its hallucinogenic properties which are considered a modification of an organic function. Therefore products containing it meet the definition of a NHP.

As of July 2010, no products containing *S. divinorum* have been reviewed and approved by Health Canada and no NPNs or DIN-HMs have been issued. Therefore sales of *S. divinorum* are illegal under the NHPR if it is represented for use as a hallucinogen or if other health claims in regards to modifying organic functions are made.

#### 4.1.3 Controlled Drugs and Substances Act and its Regulations

The CDSA provides a legislative framework for the control of substances that can alter mental processes and that may produce harm to the health of an individual or to society when diverted or misused. Except as authorized under its regulations, activities such as possession, possession for the purposes of trafficking, trafficking, importation, exportation, possession for the purposes of exportation and production of controlled substances are prohibited under the CDSA.

The substances regulated under the CDSA are grouped into eight Schedules, and each Schedule is associated with particular offences and penalties as described in Part I of the CDSA.

In determining whether a substance should be regulated as a controlled substance, and into which Schedule of the CDSA it should be placed, Health Canada considers the following factors:

- International requirements and trends in the control and/or scheduling of the substance;
- Chemical and/or pharmacological similarity to substances listed in the Schedules to the CDSA;
- Legitimate use of the substance, including therapeutic, scientific, industrial or commercial uses;
- Potential for abuse and/or addiction liability of the substance;
- Evidence of extent of actual abuse of the substance in Canada and internationally; and
- Risk to personal and public health and safety.

## **4.2 Assessment of *Salvia Divinorum* for Scheduling Purposes**

### **4.2.1 International Requirements and Trends in the Control and/or Scheduling of the Substance**

At the present time, neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and therefore do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

#### ***Australia***

In June 2002, Australia became the first country to prohibit the sale, supply, possession and use of *S. divinorum* and salvinorin A. Although both *S. divinorum* and salvinorin A are listed in Schedule 9 of Australia's Standard for the Uniform Scheduling of Drugs and Poisons on the basis of "high potential for abuse and risk to public health and safety", no substantiation of this risk was provided at the time of this scheduling decision.<sup>3</sup> Schedule 9 is Australia's most restrictive drug schedule, and includes "substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities."<sup>4</sup>

#### ***Belgium***

A decree was passed in Belgium on October 22, 2006 which added *S. divinorum* to the list of controlled substances. This list includes substances such as psilocybin mushrooms, khat and

<sup>3</sup> <http://www.tga.gov.au/ndpsc/record/rr200111.pdf>

<sup>4</sup> [http://www.cognitiveliberty.org/news/salvia\\_australia.htm](http://www.cognitiveliberty.org/news/salvia_australia.htm)

peyote cactus.<sup>5</sup>

### **Denmark**

In 2003, Denmark added *S. divinorum* and salvinorin A to their list of “category B” controlled substances, a category which also includes psilocybin mushrooms, cocaine, amphetamine, and several others substances that are only legal for medicinal and scientific purposes. Illegal possession carries a penalty of up to two years in prison.

### **Germany**

*S. divinorum* (plant and plant parts) was added to Appendix I of the *Narcotics Act* in Germany on March 1, 2008, making it illegal to produce, traffic, or possess. The law does not specifically mention salvinorin A.

### **Italy**

On June 25, 2004, the Italian Ministry of Health issued an ordinance prohibiting the sale of *S. divinorum* and its active constituent salvinorin A. On January 11, 2005, the Ministry of Health made possession of *S. divinorum* and salvinorin A illegal by placing them in “*Tabella I*” of the *Tabelle Sostanze Stupefacenti o Psicotrope*.

### **Japan**

On November 9, 2006, the Japanese government added a group of thirty-three drugs to its list of controlled substances, including salvinorin A. The drugs are banned under a revised pharmaceutical law, under which persons involved in their illegal import, production, and sale, i.e. beyond medical treatment or research purposes, will be subject to up to five years imprisonment or a fine of up to five million yen.

### **Spain**

On January 28, 2004, the Spanish Ministry of Health and Consumption issued an order prohibiting the sale of *S. divinorum*. The regulation went into effect on May 6, 2004 and only prohibits activities related to commerce. Possession and/or use are not considered to be criminal offences.

### **Other Countries**

*Salvia divinorum* is illegal to possess or sell in Croatia, Latvia, Lithuania, Poland, Romania, South Korea and Sweden. In Russia it is illegal to grow or sell *S. divinorum*, but it is legal to

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<sup>5</sup>

<http://eldd.emcdda.europa.eu/html.cfm/index5176EN.html?pluginMethod=eldd.shownewsdetails&id=20/12/2006BELGIUM:%20New%20substances%20controlled%20include%20mCPP%20and%20khat>

possess it. In Estonia, Finland, Iceland and Norway, *S. divinorum* is treated as a medicinal herb and it is illegal to import it without a relevant prescription from a doctor.

### ***United States of America***

*S. divinorum* and salvinorin A are not included in the Schedules to the United States *Controlled Substances Act* although both *S. divinorum* and salvinorin A have been added to a list of chemicals "of concern" which has no legal implications. In addition, some individual states have implemented laws restricting its use, sale and/or distribution. As of July 2010, a number of states have enacted legislation placing regulatory controls on *S. divinorum* and/or salvinorin A including Delaware, Georgia, Florida, Hawaii, Illinois, Kansas, Kentucky, Maryland, Mississippi, Missouri, Nebraska, North Dakota, Ohio, Oklahoma, South Dakota, Wisconsin, Virginia, California, Louisiana, Maine, North Carolina, and Tennessee. More details regarding the regulation of *S. divinorum* in these last five states are provided below.

#### ***California***

As of January 1, 2009, the sale or distribution of *S. divinorum* or salvinorin A, or any substance or material containing *S. divinorum* or salvinorin A, to any person under 18 years of age is a misdemeanor punishable by imprisonment in a county jail for not more than six months, a fine of no more than \$1,000, or both.

#### ***Louisiana***

In 2005, Louisiana passed a bill which prohibits the possession, production, manufacture and distribution of a material, compound, mixture, or preparation intended for human consumption and that contains a hallucinogenic plant. A "hallucinogenic plant" is defined as "any part or portion" of a plant on a list of forty plants, which includes *S. divinorum*.

#### ***Maine***

In Maine, *S. divinorum* and salvinorin A are regulated in the same way as tobacco products; adults eighteen years of age or over can legally purchase and use the material, but selling or providing *S. divinorum* or salvinorin A to anyone under the age of eighteen is a criminal offence. Possession by a minor is a civil violation, punishable by a fine, community service, or both.

#### ***North Carolina***

On December 1, 2009, the North Carolina State Legislature brought a new law into force which made *Salvia divinorum* and salvinorin A illegal. The only legal *S. divinorum* activities are the growing for aesthetic, landscaping, or decorative purposes or university-affiliated medical or pharmacological research.

## *Tennessee*

On July 1, 2006, Tennessee classified the deliberate production, manufacture, distribution, or possession of the active chemical ingredient in the hallucinogenic plant *S. divinorum* as a Class A misdemeanor. It is not, however, a criminal offence to possess, plant, cultivate, grow, or harvest *S. divinorum* for aesthetic, landscaping, or decorative purposes. The law also does not apply to any dosage that is legally obtainable from a retail establishment without a prescription when it is recognized by the Food and Drug Administration as a homeopathic drug. <sup>and if</sup>

### 4.2.2 Chemical and/or Pharmacological Similarity to Substances listed in the Schedules to the CDSA

The psychoactive ingredient in *Salvia divinorum* is salvinorin A. Other plants which contain psychotropic terpenoids are *Artemisia absinthium* (wormwood) and *Cannabis sativa*. Salvinorin A is considered by some as the most potent natural hallucinogen ever isolated.<sup>6</sup>

Unlike all other hallucinogens, salvinorin A is structurally distinct and does not interact with the serotonin-2A receptor or any other molecular target of classical hallucinogens. It thus affects the brain in a way that is quite unique.<sup>7</sup> Recent pharmacological screenings of receptors have found it to be a highly potent and selective  $\kappa$ -opioid receptor (KOR) agonist.<sup>8</sup>

The use of *S. divinorum* or salvinorin A can lead to a number of effects with variable onset and duration. These effects are generally accepted to be: sensation of becoming an object, visions of various two-dimensional surfaces, films and membranes, revisiting places of the past (particularly childhood), perceived loss of the body and/or identity, various sensations of motion (being pulled or twisted by a force of some kind), uncontrollable hysterical laughter, and overlapping realities (perceptions of being in more than one place).<sup>9</sup> Laughter, happiness, sense of well-being and dissociative effects were deemed the best aspects of *S. divinorum* by users, second only to the "trip" that the drug elicits.<sup>10</sup> Depersonalization, speaking gibberish, widening of consciousness and subjective illusions of rapid movement, flying or hovering have also been

<sup>6</sup> Ott J. Ethnopharmacognosy and human pharmacology of *Salvia divinorum* and salvinorin A. *Curare*. 1995 18: 103-129. Unofficial transcription available online. URL <http://www.sagewisdom.org/ott2.html>

<sup>7</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>8</sup> Roth BL, Baner K, Westkaemper R, Siebert D, Rice KC, Steinberg S, Ernsberger P, Rothman RB. Salvinorin A: a potent naturally occurring nonnitrogenous kappa opioid selective agonist. *Proc Natl Acad Sci U S A*. 2002 Sep 3;99(18):11934-9.

<sup>9</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>10</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

reported.<sup>11</sup>

The psychomimetic effects of *S. divinorum* closely resemble schizophrenia symptoms induced by lysergic acid diethylamide (LSD) or phencyclidine (PCP).<sup>14</sup> Yet, it is said to have only weak influence on the prevailing mood of the user which differentiates it from other hallucinogens such as LSD and psilocybin.<sup>15</sup> Its strong dissociative effects are often compared to those of ketamine. Users have reported that the psychedelic effects of *S. divinorum* were most similar to those caused by psilocybin mushrooms.<sup>16</sup> However, users familiar with the effects of other hallucinogens agree that despite certain similarities to classical hallucinogens, the visions and overall experience ~~is~~ quite unique.<sup>17</sup>  
*are*

In addition, the psychedelic effects of *S. divinorum* are similar to those of classical psychedelics regarding changes in perception and somatic sensations. *S. divinorum* causes an unusually high degree of sedation, weakness and fatigue, while the increased de-realization is not commonly reported for classical psychedelics.<sup>18</sup> The combination of these effects seems to correlate with that of other KOR agonists such as pentazocine.<sup>19</sup>

#### 4.2.3 Legitimate Use of the Substance, including Therapeutic, Scientific, Industrial or Commercial Uses

*Salvia divinorum* has traditionally been used for spiritual and medicinal purposes by the Mazatec

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<sup>11</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5 and Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>14</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>15</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>16</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>17</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6 and González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>18</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>19</sup> Arasteh K, Poudevida S, Farre M, Roset PN, Cami J. Response patterns of the Spanish version of the 49-item short form of the Addiction Research Center Inventory after the use of sedatives, stimulants, and opioids. *Drug Alcohol Depend*. 1999 Jun 1;55(1-2):117-25.

Indians in Oaxaca, Mexico,<sup>20</sup> where an infusion of the leaves or the leaves themselves are ingested to treat gastrointestinal problems, headaches, rheumatism, anemia and swelling of the stomach.<sup>21</sup> Its main use today is, however, for its psychoactive properties in the aid of producing “mystical” or hallucinogenic experiences as part of spiritual rituals.<sup>22</sup>

Although selective kappa receptor agonists have been shown to produce analgesic effects, adverse effects such as psychotomimesis, dysphoria and diuresis have been observed in studies investigating their therapeutic use.<sup>23</sup> In addition, while it has been speculated that KOR agonists may prove to be useful in the treatment of certain psychiatric disorders including Alzheimer’s disease, schizophrenia, dementia and bipolar disorder,<sup>24</sup> much more research is needed in order to substantiate these hypotheses. Similarly, another study has suggested that chemical analogues of salvinorin A may be a useful treatment for those suffering from addiction to other substances.<sup>25</sup> That said, there are presently no legitimate medical uses for *S. divinorum* in Canada.

Commercial

Similarly, there are no known industrial uses for *S. divinorum* in Canada. The plant is a semi-tropical perennial that can only grow outdoors in a humid climate where it will not encounter frost. Most websites offering *S. divinorum* cuttings and seeds for sale appear to do so in the context of growing the plant in order to utilize its psychoactive properties, rather than out of horticultural interest or for its esthetic appeal.

#### 4.2.4 Potential for Abuse and/or Addiction Liability of the Substance

Salvinorin A is a potent, selective agonist of the  $\kappa$ -opioid receptor (KOR), and in contrast to the euphoria produced by  $\mu$ -opioid receptor (MOR) agonists, KOR agonists are negatively reinforcing and aversive.<sup>26</sup> In addition, KOR agonists have analgesic properties but are not

<sup>20</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>21</sup> Munro, T. The Chemistry of *Salvia divinorum*. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

<sup>22</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage *Salvia divinorum*. *Life Sci.* 2005 Dec 22;78(5):527-31.

<sup>23</sup> Barker RL, Fawcett J, Barkin SJ. 2002. Chronic pain management with a focus on the role of newer antidepressants and centrally acting agents. In: *Pain Management: A Practical Guide for Clinicians*, 6th edition, Weiner RS ed. CRC Press, Boca Raton, FL. pp. 415-34 and Tidgewell et al., 2004. A facile method for the preparation of deuterium labelled salvinorin A: *Biorganic & Medicinal Chemistry Letters*, 14: 5099-5102.

<sup>24</sup> Sheffler DJ & Roth BL. Salvinorin A: the ‘magic mint’ hallucinogen finds a molecular target in the kappa opioid receptor. *Trends Pharmacol Sci.* 2003 Mar;24(3):107-109.

<sup>25</sup> Prisinzano TE. Natural products as tools for neuroscience: discovery and development of novel agents to treat drug abuse. *J Nat Prod.* 2009 Mar 27;72(3):581-7.

<sup>26</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590, Cooper S. Interactions between endogenous opioids and dopamine: Implications for reward and aversion. In: *The Mesolimbic Dopamine System: From Motivation to Action*. Willner P and Scheel-Kruger J (editors) Wiley, Chester, England, 1991, pp. 331-366, and Shippenberg TS, Herz A, Spanagel R, Bals-Kubik R, Stein C. Conditioning of opioid reinforcement: neuroanatomical and neurochemical substrates. *Ann N Y Acad Sci.* 1992 Jun 28;654:347-56.



associated with respiratory depression like MOR agonists. Finally, while MOR agonists increase the release of dopamine, the activation of KOR decreases dopamine release in the nucleus accumbens.<sup>28</sup>

The onset and intensity of the effects of *Salvia divinorum* appear to be related to the route of administration.

Traditional uses generally produce mild effects because the leaves are rolled and chewed or crushed and prepared as a foamy infusion whereby the salvinorin A is degraded in the gastrointestinal system before being absorbed into the bloodstream. Hence, the level of effect relates quite closely to the length of time the material spends in the mouth, with the onset of effect generally taking 5-10 minutes. The effects build over the next hour and last for another hour before they begin to subside.<sup>29</sup>

Routes of administration that avoid the hepatic first-pass effect (i.e. <sup>inhalation route</sup> intravenous, intramuscular, ~~inhalation~~ and sublingual use) are the quickest and most intense.<sup>30</sup> Salvinorin A can be isolated from the plant to make a powder which can be vaporized and inhaled. The onset of effects felt from vaporizing salvinorin A powder occurs in about 30 seconds and effects last for about 5-10 minutes and then subside over the next 30 minutes.<sup>31</sup>

Smoking is by far the most popular method of administration<sup>32</sup> and this is accomplished by smoking the dried leaves or a concentrated extract using a pipe or bong. Dried leaves may also be fortified with a concentrated extract of salvinorin A. A concentrated extract can also be used sublingually. Neither *S. divinorum* nor salvinorin A can be injected because the powder is insoluble in water.<sup>33</sup>

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<sup>28</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.

<sup>29</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>30</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.

<sup>31</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>32</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62 and Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>33</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs.* 1994 Jul-Sep;26(3):277-83.

The aversive effects of previously studied KOR agonists predict that the risk of addiction to *S. divinorum* is negligible. However, very few controlled scientific studies of the physical and psychotropic effects of *S. divinorum* on humans have been carried out. Therefore, it is difficult to predict its potential for addiction and abuse. In studies that have been conducted, there is conflicting information around the addiction liability of *S. divinorum* in both animals and humans. Some users have noted that they require increasing doses of salvinorin A in order to achieve the desired effect and the stimulated cerebral KOR may act as a mechanism of tolerance.<sup>37</sup> Further studies in this area and on the mediated decrease of dopamine <sup>and</sup> as well as the impact of dose on ~~the rewarding and aversive~~ effects are also required.

While concerns for the potential of abuse were once minimal because 1 kg of dried leaves yields only 3 to 6 human doses of salvinorin A, it was discovered that vaporizing and inhaling 200-500 micrograms had profound hallucinogenic effects.<sup>38</sup> The extraction of salvinorin A from the plant is very easy and with care, approximately 1.5 grams of pure salvinorin A per kilogram of dried leaves (8kg of fresh leaves) can be isolated, <sup>grams</sup> which is enough substance to provide for 2000 human doses.<sup>39</sup>

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<sup>37</sup> Bucheler R, Gleiter CH, Schworer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>38</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>39</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs*. 1994 Jul-Sep;26(3):277-83.

<sup>44</sup> Turner DM. *Salvinorin - The Psychedelic Essence of Salvia Divinorum*. Panther Press, San Francisco, CA 1996.

#### 4.2.5 Evidence of Extent of Actual Abuse of the Substance in Canada and Internationally

In Canada, the extent of actual abuse of *Salvia divinorum* and <sup>10<sup>r</sup></sup>salvinorin A is relatively unknown. There is, however, some data regarding the use of *Salvia divinorum* in Canada. ~~As there are no approved uses for this plant, any use (i.e. for consumption) is illegitimate in nature.~~ Questions about the use of *S. divinorum* were included in the 2008-2009 Youth Smoking Survey, the 2009 Canadian Alcohol and Drug Use Monitoring Survey and the 2009 Ontario Student Drug Use and Health Survey.

despite the lack of legitimate uses for this plant

The results from the 2009 Ontario Student Drug Use and Health Survey were published on November 18, 2009 and indicate that:

- Among all responding students in Ontario, 4.4% reported using *Salvia divinorum* at least once in the past year. In comparison, 58.2% indicated they had used alcohol, 25.6% indicated they had used cannabis and 5.0% indicated they had used hallucinogens other than LSD and PCP in the past year;
- Males (6.2%) were significantly more likely than females (2.3%) to report using *Salvia divinorum*;
- There is significant grade variation, with *Salvia divinorum* use most likely among 11<sup>th</sup> graders (8.6%) and 12<sup>th</sup> graders (8.4%); and
- There are significant regional variations, with students in Northern Ontario (9.2%) most likely to use *Salvia divinorum*.

The results of the 2008-2009 Youth Smoking Survey were published on May 31, 2010 and indicate that:

- 4.9% of students stated that they had used *S. divinorum* in the last twelve months. In comparison, 53.0% indicated they had used alcohol, 27.3% indicated they had used cannabis and 6.9% indicated they had used other hallucinogens in the last twelve months;
- 2.6% of students in Grades 7-9 and 7.0% of students in Grades 10-12 had used *S. divinorum* in the last twelve months; and
- Males (6.6%) were more likely to have used *S. divinorum* in the past twelve months compared to females (3.2%).

The scope of the previously mentioned studies did not provide for any explanations regarding differences in usage between ages, genders and regions. In this regard, it is difficult to speculate on the causality of such differences.

The Canadian Alcohol and Drug Use Monitoring Survey specifically examined Salvia for the first time in 2009. An estimated 1.6% of Canadians, aged 15 years and older, reported that they had used salvia in their lifetime, and 0.2% reported using it in the past-year. In comparison, the prevalence of past-year cannabis use among Canadians 15 years of age and older was 10.6%. 1.2% of respondents reported using cocaine or crack in the past 12 months, 0.9% had used ecstasy and 0.7% used illicit hallucinogens.

Health Canada's Drug Analysis Services (DAS) has identified salvinorin A in a number of samples seized by law enforcement, as shown in the following table.

**NUMBER OF SAMPLES FOUND TO CONTAIN SALVINORIN A**

Year	Count
2006	9
2007	8
2008	4
2009	20
2010 (as of May 7)	8

The National Forensic Laboratory Information System (NFLIS) and the System to Retrieve Information from Drug Evidence (STRIDE) in the United States are Drug Enforcement Agency (DEA) databases that collect scientifically verified data on analyzed samples in state and local forensic labs as well as samples from DEA labs. The following table shows the quantity of *S. divinorum* products that were seized from 2000 through to 2009.

**ANALYZED SALVIA DIVINORUM or SALVINORIN A SEIZURES**

(Number of Items/Exhibits)

Source	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009*
NFLIS-State/Local <sup>1</sup>	0	0	0	0	1	8	12	12	70	34
STRIDE <sup>2</sup>	0	0	1	1	1	0	0	0	N/A	N/A
<b>TOTAL</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>1</b>	<b>2</b>	<b>8</b>	<b>12</b>	<b>12</b>	<b>70</b>	<b>34</b>

Data Source: NFLIS & STRIDE, 2008 data queried 11/24/08, updated 06/10/2010

<sup>1</sup> NFLIS reported seizures of *Salvia divinorum* and/or salvinorin A

<sup>2</sup> STRIDE reported items of *Salvia divinorum*.

\* Includes only January – May data in 2009.

It is difficult to determine the extent of actual abuse of *S. divinorum* in Canada or elsewhere as there appear to be inconsistencies in the literature regarding risk aversion. For example, one author states: "Many who have used salvinorin A find the experience extremely unnerving, frightening and overly intense and most have no desire to repeat the experience."<sup>44</sup> However, another study suggested that this is not the experience of all recreational users of *S. divinorum*.<sup>45</sup> Over eighty percent of users surveyed on a web-based questionnaire about their *S. divinorum* use said that they would probably or definitely use *S. divinorum* again.<sup>46</sup> Users have reported the negative effects of *S. divinorum* as: the short duration of action, lack of control over the

<sup>45</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62, Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry.* 2005 Jan;38(1):1-5, and Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs.* 1994 Jul-Sep;26(3):277-83.

<sup>46</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

experience, persisting negative effects (most often anxiety),<sup>47</sup> sweating, chills, increased diuresis, impaired vigilance,<sup>48</sup> and negative after-effects including tiredness, feeling head heavy, dizziness, physical exhaustion, and some degree of malaise or 'hangover' as they 'comedown' from the drug.<sup>49</sup>

#### 4.2.6 Risk to Personal and Public Health and Safety

The increase in both the number of enquiries from various municipalities and members of the public and the amount of media interest regarding the availability of *Salvia divinorum* in Canada may be an indication that the recreational use of *S. divinorum* as a hallucinogen is on the rise. However, there are no available statistics that indicate there has been a significant increase in *S. divinorum* use in the Canadian population and, in comparison to the use of other drugs such as alcohol and cannabis, the actual use of *S. divinorum* is quite low.

The potential for harm to the user and/or other individuals is primarily related to the hallucinogenic properties of the substance. Users may get up and walk around without apparent awareness of their movements, behaviour or surroundings, and distinction between self and surroundings is often lost. At doses greater than 1mg of salvinorin A, out of body experiences are frequent and loss of consciousness has been reported.<sup>50</sup> There is little information regarding the social behaviours of persons under the influence of *S. divinorum* products, and what risks their activities such as operating a motorized vehicle may pose to the general public. There is also very little data regarding the toxicity, teratogenicity or other long-term effects of *S. divinorum* use.<sup>51</sup>

As far as law enforcement is concerned, the Department has only received a limited number of communications indicating concern with respect to *S. divinorum* and none of these have advised that the use of *S. divinorum* poses any threat to public safety. The Royal Canadian Mounted Police (RCMP) has stated that while *S. divinorum* is readily available, it has not become a popular drug in Canada, probably due to its aversive effects such as anxiety and introversion.

A handful of case reports regarding the use of *S. divinorum* have been published in the academic literature. One report was an international case report in which a young man (19 years of age) described his perceptions after inhaling smoke from *S. divinorum*. The peak psychotropic effects, including prickling of the skin, fever-like hot flashes, muscular tremor, and depersonalization, were reached in less than five minutes after inhalation of an unknown amount of smoke from burning dried leaves.<sup>52</sup> Another report involved a 15-year-old male who presented

<sup>47</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>48</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>49</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>50</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>51</sup> Grundmann O, Phipps SM, Zadezensky I, Butterweck V. *Salvia divinorum* and Salvinorin A: An Update on Pharmacology and Analytical Methodology. *Planta Med* 2007 Jun;73:1039-1046.

s.21(1)(a)

s.21(1)(b)

to psychiatric emergency services with acute onset of paranoia, déjà vu, blunted affect, difficulties in thought processing and slowed speech after smoking *Salvia divinorum* over an unknown period of time. During his hospitalization all symptoms improved significantly except the feeling of déjà vu. Based on this case presentation, the author suggested that the feelings of déjà vu may be a long-term effect of *S. divinorum* use.<sup>53</sup> However, given that this is the only case report in which déjà vu was associated with the use of *S. divinorum*, more reports are needed to substantiate this finding.

In addition to the above-mentioned reports, in 2006, a case was reported in the U.S. in which a 17-year-old boy committed suicide after smoking *S. divinorum* for an unknown period of time.<sup>54</sup> It should be noted that alcohol and general depression were the main confounders in this case. After this case was reported, the state of Delaware passed a law which classified *S. divinorum* as a Schedule I controlled substance along with other hallucinogenic substances.

Like many drugs of abuse, users are often unaware of the potency and adulterants in the product they purchase. A study by Wolowich *et al.* (2006)<sup>55</sup>, showed that the salvinorin A content in five out of five *S. divinorum* products was falsely indicated on the label and 4 out of 5 products contained unidentified adulterants (i.e. vitamin E, caffeine).

Health Canada has only anecdotal information about the use and abuse of *S. divinorum* in Canada as well as the threat *S. divinorum* may pose to the health and safety of Canadians. Although reports of domestic adverse reactions related to the use of *S. divinorum* as a hallucinogen have been received through the Canada Vigilance database, it is important to note that the number of reports and the nature of reactions reported are not adequate to characterize the risk to the general population.

## 5. ASSESSMENT OF RISKS AND BENEFITS

<sup>53</sup> Singh S. (2007) Adolescent salvia substance abuse. *Addiction*. 102, 823-824.

<sup>54</sup> <http://www.kvbc.com/Global/story.asp?S=4893692>

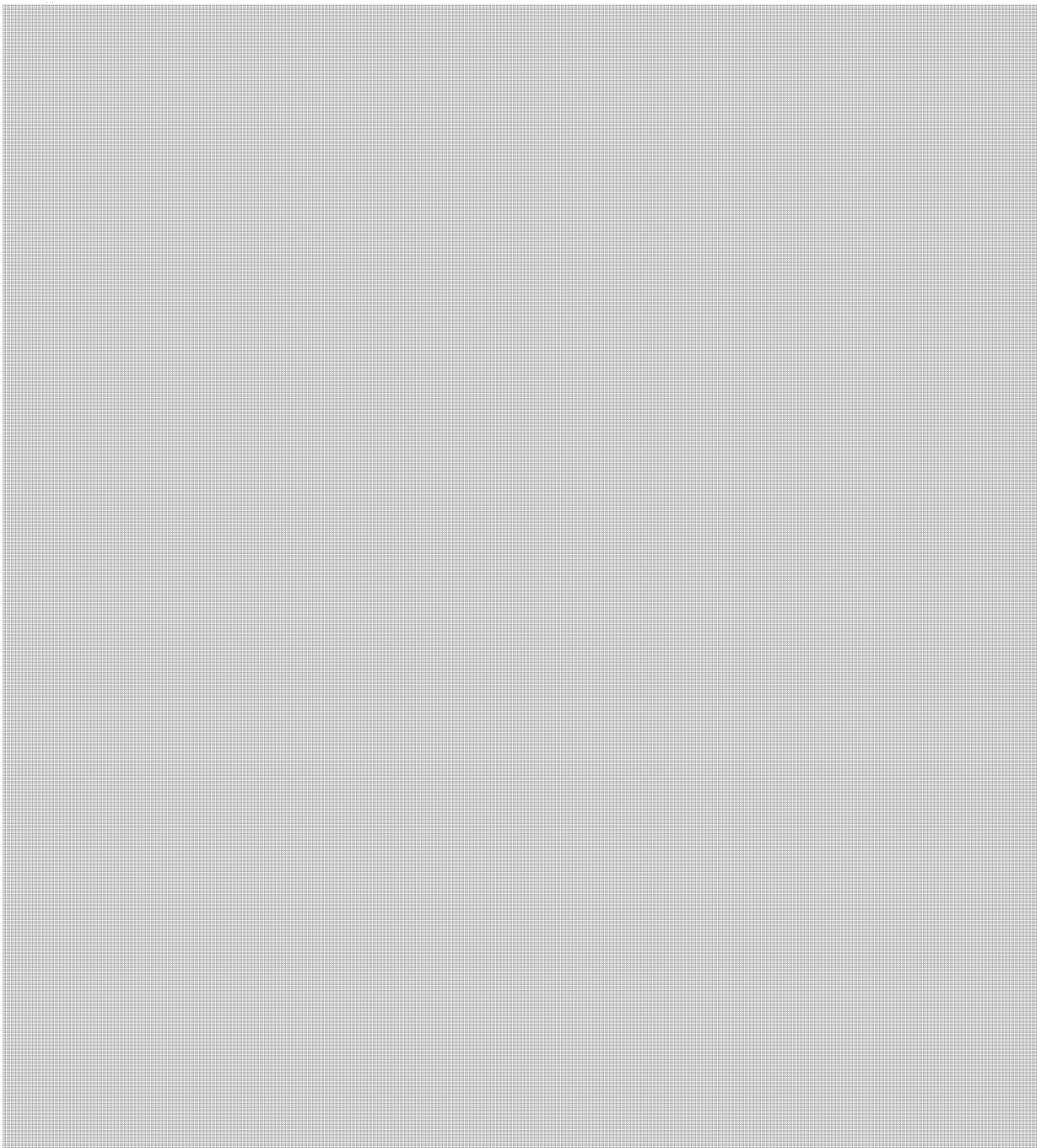
<sup>55</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

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**Is(Are) exempted pursuant to section(s)  
est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**



## 7. CONSIDERATIONS

The KOR-mediated aversive and dysphoric effects of *Salvia divinorum* do not appear to be hampering its use as young adults have begun smoking the leaves and leaf extract recreationally.<sup>56</sup> It can be purchased through online botanical companies and other drug promotion sites and is often

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<sup>56</sup> Hazelden Foundation, 2004. Drug Abuse Trends. June 2004. URL: [www.research.haz000983](http://www.research.haz000983)



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touted as a legal alternative to substances such as cannabis and mescaline.<sup>57</sup> Interestingly, after being widely available for over a decade, the drug does not appear to have had the same social impact as LSD or ecstasy.<sup>58</sup>

While there has been an increase over the past few years in the number of enquiries from various municipalities and members of the public regarding the availability of *Salvia divinorum* as a hallucinogen, the reported use of *S. divinorum* by young Canadians is much lower than that of alcohol or cannabis, according to available statistics.

The NHPR are limited in their capacity to control the availability of *S. divinorum* in that *S. divinorum* products are often declared as incense and therefore cannot be considered unapproved natural health products. In addition, compliance and enforcement actions, such as voluntary stop-sales, forfeiture, destruction, and administrative seizure, cannot be implemented unless the labeling of the product indicates that it is to be used for consumption and/or its pharmacological effects.

The previous HPFB recommendation to schedule *S. divinorum* under the CDSA was likely based on a misunderstanding of the previously-described criteria upon which scheduling is based. In particular, it did not consider a number of factors, including potential for abuse and risk to public health and safety. The Office of Controlled Substances (OCS) was also not consulted by HPFB at the time<sup>HPFB</sup> this recommendation was made. In addition, among countries who have decided to control *S. divinorum* in some way, very little or no substantiation of the risks of *S. divinorum* upon which the decision was based are available.

Neither *Salvia divinorum* nor salvinorin A meet the criteria for scheduling a substance under the CDSA. Despite being regulated in some jurisdictions, neither the plant nor salvinorin A are scheduled under any of the UN Drug Control Conventions. *S. divinorum* and salvinorin A are not structurally or pharmacologically similar to other substances included in the schedules to the CDSA. There are currently no legitimate therapeutic or industrial uses for *S. divinorum*. The abuse liability and potential for dependence of *S. divinorum* is not known as very few controlled scientific studies of its physical and psychotropic effects have been carried out on humans. The extent of actual abuse of *S. divinorum* is also largely unknown. Evidence of a risk to public health and safety is anecdotal in nature and not quantified in any way as there is a lack of information regarding abuse in Canada. Therefore, it would not be appropriate to include *S. divinorum* and/or salvinorin A under any of the Schedules to the CDSA at this time.

## **8. RECOMMENDATIONS**

<sup>57</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

<sup>58</sup> Munro, T. The Chemistry of *Salvia divinorum*. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

s.21(1)(a)

s.21(1)(b)

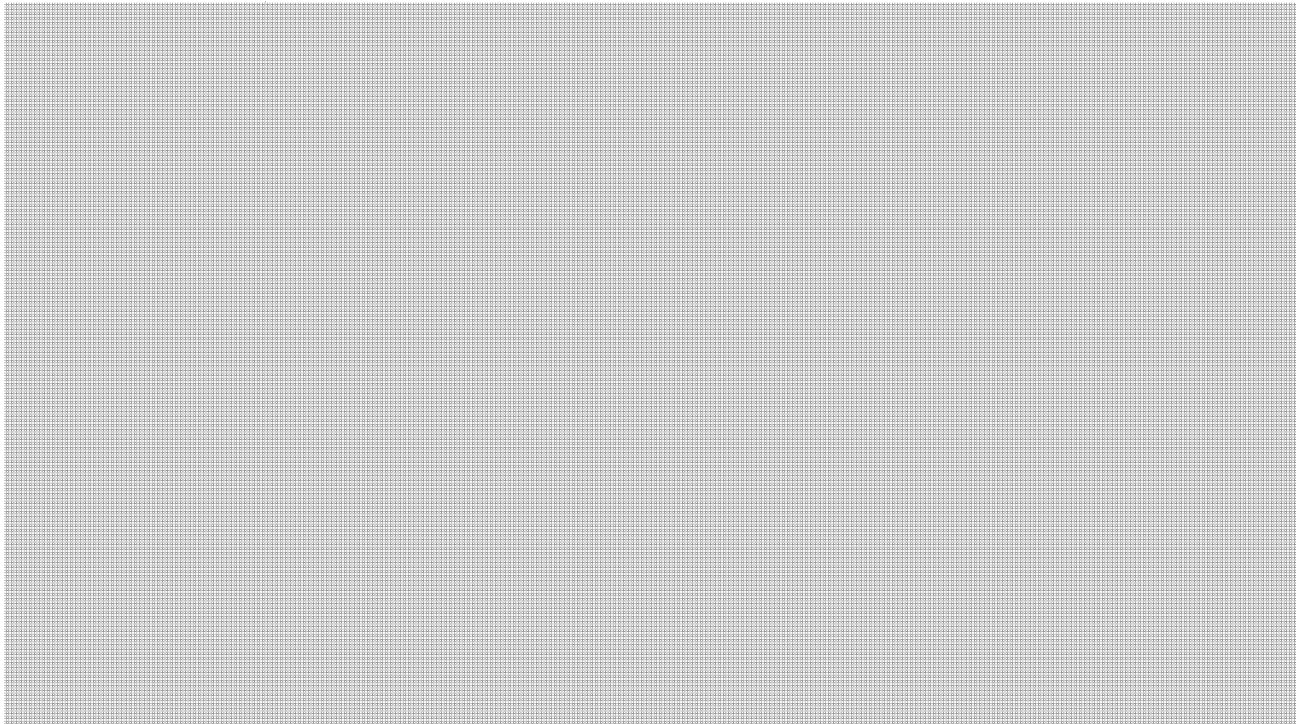
## 9. CONSULTATIONS

The Drug Analysis Services (DAS) was contacted in order to provide any data available regarding the identification of salvinorin A in samples submitted by law enforcement.

The Royal Canadian Mounted Police (RCMP) was contacted in order to establish their views with respect to *S. divinorum* use in Canada. The RCMP advised that though *S. divinorum* is readily available, it does not appear to pose a threat to public safety.

OCS has received a number of correspondences from Canada Border Service Agency (CBSA) officers concerning a lack of information regarding the status of *S. divinorum* and how the plant should be treated at the border. CBSA officers have also expressed concern regarding the plant's hallucinogenic properties. At present, only shipments of *S. divinorum* that are represented as health products/ hallucinogens can be refused for import under the NHPR.

## 10. IMPLEMENTATION AND EVALUATION



# Issue Analysis Summary

DRAFT

## Scheduling *Salvia Divinorum* and/or Salvinorin A under the CDSA

Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Controlled Substances and Tobacco and Directorate

July 8, 2010

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#### 1. APPROVALS

This Issue Analysis Summary is approved.

\_\_\_\_\_  
Diane Allan, Director  
Office of Controlled Substances  
Tobacco and Drugs Directorate

\_\_\_\_\_  
[DD/MM/2010]

#### 2. ISSUE

Health Canada has received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *S. divinorum* and/or its main active ingredient salvinorin A, neither of which are currently regulated under the *Controlled Drugs and Substances Act* (CDSA). These requests are further to reports from scientific and media sources suggesting that *S. divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has also noted an

Good work Stephanie!  
Few minor changes  
then pass back to  
me via email.  
Will then send to  
CSS WLT.  
JK.

ongoing media interest regarding the availability of *S. divinorum* in Canada.

### 3. PURPOSE

To assess *Salvia divinorum* and/or salvinorin A against the criteria for the addition of a substance to one of the Schedules to the CDSA, and determine whether one or both should be regulated as controlled substances in Canada.

### 4. CONTEXT

*Salvia divinorum* is a species of sage which belongs to the mint family, and which is found in the form of dried leaves, extract and plant cuttings. Also known as "diviner's sage", the plant is known to induce illusions and hallucinations when chewed or smoked. Salvinorin A, the psychoactive ingredient in *S. divinorum* (also referred to chemically as a neoclerodane diterpene) is found primarily in the leaves, and to a lesser extent in the stems.<sup>1</sup>

*S. divinorum* is widely touted as a "legal" hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs among adolescents and young adults.<sup>2</sup> While very little is known about how and where *S. divinorum* is sold in Canada, it is suspected that it is mainly purchased over the Internet and/or bought at head shops or alternative life style stores, etc.

The use of *S. divinorum* as a psychotropic agent first came to Health Canada's attention in 2002. In 2004, Health Canada received four adverse drug reaction (ADR) reports associated with the use of *S. divinorum* as a hallucinogen, with three being considered non-serious (requiring no medical attention) and the fourth being considered serious (medical intervention was required). The serious ADR report involved the concomitant use of alcohol in a person diagnosed with Attention Deficit Disorder.

Further to the receipt of the aforementioned ADRs, the Marketed Health Products Directorate (MHPD) and the Natural Health Products Directorate (NHPD) of the Health Products and Food Branch (HPFB) prepared an issue analysis summary (IAS), which recommended that *S. divinorum* and its active ingredient salvinorin A be regulated as controlled substances. This recommendation was maintained when the IAS was updated in November 2006.

Later, in December 2005, MHPD and NHPD prepared a Signal Assessment (SA) (updated in June 2007) that eventually led to the preparation of a Health Risk Assessment (HRA), which concluded that *S. divinorum* or salvinorin A-containing health products would constitute a Type II Health Risk according to the Health Hazard Classification of the Recall Policy of the Health

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<sup>1</sup> U.S. Department of Justice Drug Enforcement Administration. 2002. Drugs and Chemicals of Concern: Salvia Divinorum (salvinorin A, divinorin A) URL:

[http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm) Nov 2008

<sup>2</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.

Products and Food Branch Inspectorate (HBFBI). Such a risk is defined as “a situation in which the use of, or exposure to, a product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote”.

Further to an Assistant Deputy Minister (ADM) discussion in April 2007, the Drug Strategy and Controlled Substances Directorate (DSCSD) organized a meeting with MHPD, NHPD and HPFBI to discuss *S. divinorum*. HPFBI was to determine appropriate compliance activities regarding *S. divinorum* and consult with the Canada Border Services Agency (CBSA) regarding the movement of products containing *S. divinorum* into and out of Canada.

On September 13, 2007, a further meeting between DSCSD, MHPD, NHPD and HPFBI led to the conclusion that DSCSD would conduct a scheduling assessment of *S. divinorum* in order to explore the possibility of scheduling this substance under the CDSA.

In September 2008, the Director Generals of DSCSD, MHPD, TPD and the HPFBI agreed that media lines and an “It’s Your Health” article on *S. divinorum* would be prepared.

#### **4.1 Relevant Legislative Frameworks in Canada**

##### **4.1.1 Food and Drug Regulations (under the Food and Drugs Act)**

The *Food and Drug Regulations* (F&DR) serve to ensure the safety, efficacy, and quality of health products offered for sale in Canada, including drugs and medical devices. Prior to being given market authorization, a manufacturer must present substantive scientific evidence that a product is safe, efficacious and of high quality. For drugs, Health Canada reviews this information carefully and, if the review is satisfactory, a Notice of Compliance (NOC) is issued and appropriate Drug Identification Numbers (DINs) are assigned.

A “drug” is defined under the F&DR as any substance or mixture of substances manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
- (b) restoration, correction or modification of organic functions in human beings or animals, or
- (c) disinfection in premises in which food is manufactured, prepared or kept;

As no products containing *S. divinorum* or its extracts have been reviewed and approved by Health Canada as of July 2010, it is illegal to market *S. divinorum* when it is represented as a drug.

#### 4.1.2 Natural Health Products Regulations (under the Food and Drugs Act)

The *Natural Health Products Regulations* (NHPR) aim to provide Canadians with ready access to natural health products (NHPs) that are safe, effective, and of high quality, while respecting freedom of choice and philosophical and cultural diversity. The NHPR require that all licensed products display a Natural Product Number (NPN), or, in the case of a homeopathic medicine, Drug Identification Number - Homeopathic Medicine (DIN-HM), on their labels. These numbers are issued once a product is authorized for sale in Canada further to a *natural health product monograph* or submission of other evidence of safety and efficacy. The NHPR also require that all manufacturers, packagers, labelers, and importers be licensed which in turn requires the presence of procedures respecting distribution records, product recalls, product handling, storage and delivery, and manufacturing practices.

The definition of an NHP under the NHPR has both a function and substance component. The function component refers to those substances that are manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
- (b) restoring or correcting organic functions in humans; or
- (c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

The substance component refers to whether the product or medicinal ingredient therein is safe for consideration as an over-the-counter product, can be available for self-care and self-selection, and does not require a prescription to be sold. To be considered a NHP, no direct health claims need to be made regarding the substance. In the case of *S. divinorum*, it is generally marketed for its hallucinogenic properties which are considered a modification of an organic function. Therefore products containing it meet the definition of a NHP.

As of July 2010, no products containing *S. divinorum* have been reviewed and approved by Health Canada and no NPNs or DIN-HMs have been issued. Therefore sales of *S. divinorum* are illegal under the NHPR if it is represented for use as a hallucinogen or if other health claims in regards to modifying organic functions are made.

#### 4.1.3 Controlled Drugs and Substances Act and its Regulations

The CDSA provides a legislative framework for the control of substances that can alter mental processes and that may produce harm to the health of an individual or to society when diverted or misused. Except as authorized under its regulations, activities such as possession, possession for the purposes of trafficking, trafficking, importation, exportation, possession for the purposes of exportation and production of controlled substances are prohibited under the CDSA.

The substances regulated under the CDSA are grouped into eight Schedules, and each Schedule is associated with particular offences and penalties as described in Part I of the CDSA.

In determining whether a substance should be regulated as a controlled substance, and into which Schedule of the CDSA it should be placed, Health Canada considers the following factors:

- International requirements and trends in the control and/or scheduling of the substance;
- Chemical and/or pharmacological similarity to substances listed in the Schedules to the CDSA;
- Legitimate use of the substance, including therapeutic, scientific, industrial or commercial uses;
- Potential for abuse and/or addiction liability of the substance;
- Evidence of extent of actual abuse of the substance in Canada and internationally; and
- Risk to personal and public health and safety.

## **4.2 Assessment of *Salvia Divinorum* for Scheduling Purposes**

### **4.2.1 International Requirements and Trends in the Control and/or Scheduling of the Substance**

At the present time, neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and therefore do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

#### ***Australia***

In June 2002, Australia became the first country to prohibit the sale, supply, possession and use of *S. divinorum* and salvinorin A. Although both *S. divinorum* and salvinorin A are listed in Schedule 9 of Australia's Standard for the Uniform Scheduling of Drugs and Poisons on the basis of "high potential for abuse and risk to public health and safety", no substantiation of this risk was provided at the time of this scheduling decision.<sup>3</sup> Schedule 9 is Australia's most restrictive drug schedule, and includes "substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities."<sup>4</sup>

#### ***Belgium***

A decree was passed in Belgium on October 22, 2006 which added *S. divinorum* to the list of controlled substances. This list includes substances such as psilocybin mushrooms, khat and

<sup>3</sup> <http://www.tga.gov.au/ndpsc/record/tr200111.pdf>

<sup>4</sup> [http://www.cognitiveliberty.org/news/salvia\\_australia.htm](http://www.cognitiveliberty.org/news/salvia_australia.htm)

peyote cactus.<sup>5</sup>

### **Denmark**

In 2003, Denmark added *S. divinorum* and salvinorin A to their list of “category B” controlled substances, a category which also includes psilocybin mushrooms, cocaine, amphetamine, and several others substances that are only legal for medicinal and scientific purposes. Illegal possession carries a penalty of up to two years in prison.

### **Germany**

*S. divinorum* (plant and plant parts) was added to Appendix I of the *Narcotics Act* in Germany on March 1, 2008, making it illegal to produce, traffic, or possess. The law does not specifically mention salvinorin A.

### **Italy**

On June 25, 2004, the Italian Ministry of Health issued an ordinance prohibiting the sale of *S. divinorum* and its active constituent salvinorin A. On January 11, 2005, the Ministry of Health made possession of *S. divinorum* and salvinorin A illegal by placing them in “*Tabella I*” of the *Tabella Sostanze Stupefacenti o Psicotrope*.

### **Japan**

On November 9, 2006, the Japanese government added a group of thirty-three drugs to its list of controlled substances, including salvinorin A. The drugs are banned under a revised pharmaceutical law, under which persons involved in their illegal import, production, and sale, i.e. beyond medical treatment or research purposes, will be subject to up to five years imprisonment or a fine of up to five million yen.

### **Spain**

On January 28, 2004, the Spanish Ministry of Health and Consumption issued an order prohibiting the sale of *S. divinorum*. The regulation went into effect on May 6, 2004 and only prohibits activities related to commerce. Possession and/or use are not considered to be criminal offences.

### **Other Countries**

*Salvia divinorum* is illegal to possess or sell in Croatia, Latvia, Lithuania, Poland, Romania, South Korea and Sweden. In Russia it is illegal to grow or sell *S. divinorum*, but it is legal to

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<http://eldd.emcdda.europa.eu/html.cfm/index5176EN.html?pluginMethod=eldd.shownewsdetails&id=20/12/2006BELGIUM:%20New%20substances%20controlled%20include%20mCPP%20and%20khat>



possess it. In Estonia, Finland, Iceland and Norway, *S. divinorum* is treated as a medicinal herb and it is illegal to import it without a relevant prescription from a doctor.

### ***United States of America***

*S. divinorum* and salvinorin A are not included in the Schedules to the United States *Controlled Substances Act* although both *S. divinorum* and salvinorin A have been added to a list of chemicals "of concern" which has no legal implications. In addition, some individual states have implemented laws restricting its use, sale and/or distribution. As of July 2010, a number of states have enacted legislation placing regulatory controls on *S. divinorum* and/or salvinorin A including Delaware, Georgia, Florida, Hawaii, Illinois, Kansas, Kentucky, Maryland, Mississippi, Missouri, Nebraska, North Dakota, Ohio, Oklahoma, South Dakota, Wisconsin, Virginia, California, Louisiana, Maine, North Carolina, and Tennessee. More details regarding the regulation of *S. divinorum* in these last five states are provided below.

#### ***California***

As of January 1, 2009, the sale or distribution of *S. divinorum* or salvinorin A, or any substance or material containing *S. divinorum* or salvinorin A, to any person under 18 years of age is a misdemeanor punishable by imprisonment in a county jail for not more than six months, a fine of no more than \$1,000, or both.

#### ***Louisiana***

In 2005, Louisiana passed a bill which prohibits the possession, production, manufacture and distribution of a material, compound, mixture, or preparation intended for human consumption and that contains a hallucinogenic plant. A "hallucinogenic plant" is defined as "any part or portion" of a plant on a list of forty plants, which includes *S. divinorum*.

#### ***Maine***

In Maine, *S. divinorum* and salvinorin A are regulated in the same way as tobacco products; adults eighteen years of age or over can legally purchase and use the material, but selling or providing *S. divinorum* or salvinorin A to anyone under the age of eighteen is a criminal offence. Possession by a minor is a civil violation, punishable by a fine, community service, or both.

#### ***North Carolina***

On December 1, 2009, the North Carolina State Legislature brought a new law into force which made *Salvia divinorum* and salvinorin A illegal. The only legal *S. divinorum* activities are the growing for aesthetic, landscaping, or decorative purposes or university-affiliated medical or pharmacological research.

## *Tennessee*

On July 1, 2006, Tennessee classified the deliberate production, manufacture, distribution, or possession of the active chemical ingredient in the hallucinogenic plant *S. divinorum* as a Class A misdemeanor. It is not, however, a criminal offence to possess, plant, cultivate, grow, or harvest *S. divinorum* for aesthetic, landscaping, or decorative purposes. The law also does not apply to any dosage that is legally obtainable from a retail establishment without a prescription when (and if) it is recognized by the Food and Drug Administration as a homeopathic drug.

### 4.2.2 Chemical and/or Pharmacological Similarity to Substances listed in the Schedules to the CDSA

The psychoactive ingredient in *Salvia divinorum* is salvinorin A. Other plants which contain psychotropic terpenoids are *Artemisia absinthium* (wormwood) and *Cannabis sativa*. Salvinorin A is considered by some as the most potent natural hallucinogen ever isolated.<sup>6</sup>

Unlike all other hallucinogens, salvinorin A is structurally distinct and does not interact with the serotonin-2A receptor or any other molecular target of classical hallucinogens. It thus affects the brain in a way that is quite unique.<sup>7</sup> Recent pharmacological screenings of receptors have found it to be a highly potent and selective  $\kappa$ -opioid receptor (KOR) agonist.<sup>8</sup>

The use of *S. divinorum* or salvinorin A can lead to a number of effects with variable onset and duration. These effects are generally accepted to be: sensation of becoming an object, visions of various two-dimensional surfaces, films and membranes, revisiting places of the past (particularly childhood), perceived loss of the body and/or identity, various sensations of motion (being pulled or twisted by a force of some kind), uncontrollable hysterical laughter, and overlapping realities (perceptions of being in more than one place).<sup>9</sup> Laughter, happiness, sense of well-being and dissociative effects were deemed the best aspects of *S. divinorum* by users, second only to the "trip" that the drug elicits.<sup>10</sup> Depersonalization, speaking gibberish, widening of consciousness and subjective illusions of rapid movement, flying or hovering have also been

<sup>6</sup> Ott J. Ethnopharmacognosy and human pharmacology of *Salvia divinorum* and salvinorin A. *Curare*. 1995 18: 103-129. Unofficial transcription available online. URL <http://www.sagewisdom.org/ott2.html>

<sup>7</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>8</sup> Roth BL, Baner K, Westkaemper R, Siebert D, Rice KC, Steinberg S, Ernsberger P, Rothman RB. Salvinorin A: a potent naturally occurring nonnitrogenous kappa opioid selective agonist. *Proc Natl Acad Sci U S A*. 2002 Sep 3;99(18):11934-9.

<sup>9</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>10</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

reported.<sup>11</sup>

The psychomimetic effects of *S. divinorum* closely resemble schizophrenia symptoms induced by lysergic acid diethylamide (LSD) or phencyclidine (PCP).<sup>14</sup> Yet, it is said to have only weak influence on the prevailing mood of the user which differentiates it from other hallucinogens such as LSD and psilocybin.<sup>15</sup> Its strong dissociative effects are often compared to those of ketamine. Users have reported that the psychedelic effects of *S. divinorum* were most similar to those caused by psilocybin mushrooms.<sup>16</sup> However, users familiar with the effects of other hallucinogens agree that despite certain similarities to classical hallucinogens, the visions and overall experience are quite unique.<sup>17</sup>

In addition, the psychedelic effects of *S. divinorum* are similar to those of classical psychedelics regarding changes in perception and somatic sensations. *S. divinorum* causes an unusually high degree of sedation, weakness and fatigue, while the increased de-realization is not commonly reported for classical psychedelics.<sup>18</sup> The combination of these effects seems to correlate with that of other KOR agonists such as pentazocine.<sup>19</sup>

#### 4.2.3 Legitimate Use of the Substance, including Therapeutic, Scientific, Industrial or Commercial Uses

*Salvia divinorum* has traditionally been used for spiritual and medicinal purposes by the Mazatec

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<sup>11</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5 and Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>14</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>15</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>16</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>17</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6 and González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>18</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>19</sup> Arasteh K, Poudevida S, Farre M, Roset PN, Cami J. Response patterns of the Spanish version of the 49-item short form of the Addiction Research Center Inventory after the use of sedatives, stimulants, and opioids. *Drug Alcohol Depend*. 1999 Jun 1;55(1-2):117-25.

Indians in Oaxaca, Mexico,<sup>20</sup> where an infusion of the leaves or the leaves themselves are ingested to treat gastrointestinal problems, headaches, rheumatism, anemia and swelling of the stomach.<sup>21</sup> Its main use today is, however, for its psychoactive properties in the aid of producing “mystical” or hallucinogenic experiences as part of spiritual rituals.<sup>22</sup>

Although selective kappa receptor agonists have been shown to produce analgesic effects, adverse effects such as psychotomimesis, dysphoria and diuresis have been observed in studies investigating their therapeutic use.<sup>23</sup> In addition, while it has been speculated that KOR agonists may prove to be useful in the treatment of certain psychiatric disorders including Alzheimer's disease, schizophrenia, dementia and bipolar disorder,<sup>24</sup> much more research is needed in order to substantiate these hypotheses. Similarly, another study has suggested that chemical analogues of salvinorin A may be a useful treatment for those suffering from addiction to other substances.<sup>25</sup> That said, there are presently no legitimate medical uses for *S. divinorum* in Canada.

Similarly, there are no known industrial or commercial uses for *S. divinorum* in Canada. The plant is a semi-tropical perennial that can only grow outdoors in a humid climate where it will not encounter frost. Most websites offering *S. divinorum* cuttings and seeds for sale appear to do so in the context of growing the plant in order to utilize its psychoactive properties, rather than out of horticultural interest or for its esthetic appeal.

#### 4.2.4 Potential for Abuse and/or Addiction Liability of the Substance

Salvinorin A is a potent, selective agonist of the  $\kappa$ -opioid receptor (KOR), and in contrast to the euphoria produced by  $\mu$ -opioid receptor (MOR) agonists, KOR agonists are negatively reinforcing and aversive.<sup>26</sup> In addition, KOR agonists have analgesic properties but are not

<sup>20</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>21</sup> Munro, T. The Chemistry of Salvia divinorum. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

<sup>22</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage Salvia divinorum. *Life Sci.* 2005 Dec 22;78(5):527-31.

<sup>23</sup> Barker RL, Fawcett J, Barkin SJ. 2002. Chronic pain management with a focus on the role of newer antidepressants and centrally acting agents. In: *Pain Management: A Practical Guide for Clinicians*, 6th edition, Weiner RS ed. CRC Press, Boca Raton, FL. pp. 415-34 and Tidgewell et al., 2004. A facile method for the preparation of deuterium labelled salvinorin A: *Biorganic & Medicinal Chemistry Letters*, 14: 5099-5102.

<sup>24</sup> Sheffler DJ & Roth BL. Salvinorin A: the ‘magic mint’ hallucinogen finds a molecular target in the kappa opioid receptor. *Trends Pharmacol Sci.* 2003 Mar;24(3):107-109.

<sup>25</sup> Prisinzano TE. Natural products as tools for neuroscience: discovery and development of novel agents to treat drug abuse. *J Nat Prod.* 2009 Mar 27;72(3):581-7.

<sup>26</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590, Cooper S. Interactions between endogenous opioids and dopamine: Implications for reward and aversion. In: *The Mesolimbic Dopamine System: From Motivation to Action*. Willner P and Scheel-Kruger J (editors) Wiley, Chester, England, 1991, pp. 331-366, and Shippenberg TS, Herz A, Spanagel R, Bals-Kubik R, Stein C. Conditioning of opioid reinforcement: neuroanatomical and neurochemical substrates. *Ann N Y Acad Sci.* 1992 Jun 28;654:347-56.

associated with respiratory depression like MOR agonists. Finally, while MOR agonists increase the release of dopamine, the activation of KOR decreases dopamine release in the nucleus accumbens.<sup>28</sup>

The onset and intensity of the effects of *Salvia divinorum* appear to be related to the route of administration.

Traditional uses generally produce mild effects because the leaves are rolled and chewed or crushed and prepared as a foamy infusion whereby the salvinorin A is degraded in the gastrointestinal system before being absorbed into the bloodstream. Hence, the level of effect relates quite closely to the length of time the material spends in the mouth, with the onset of effect generally taking 5-10 minutes. The effects build over the next hour and last for another hour before they begin to subside.<sup>29</sup>

Routes of administration that avoid the hepatic first-pass effect (i.e. inhalation, intravenous, intramuscular and sublingual use) are the quickest and most intense.<sup>30</sup> Salvinorin A can be isolated from the plant to make a powder which can be vaporized and inhaled. The onset of effects felt from vaporizing salvinorin A powder occurs in about 30 seconds and effects last for about 5-10 minutes and then subside over the next 30 minutes.<sup>31</sup>

Smoking is by far the most popular method of administration<sup>32</sup> and this is accomplished by smoking the dried leaves or a concentrated extract using a pipe or bong. Dried leaves may also be fortified with a concentrated extract of salvinorin A. A concentrated extract can also be used sublingually. Neither *S. divinorum* nor salvinorin A can be injected because the powder is insoluble in water.<sup>33</sup>

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<sup>28</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.

<sup>29</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>30</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.

<sup>31</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>32</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62 and Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>33</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs.* 1994 Jul-Sep;26(3):277-83.

The aversive effects of previously studied KOR agonists predict that the risk of addiction to *S. divinorum* is negligible. However, very few controlled scientific studies of the physical and psychotropic effects of *S. divinorum* on humans have been carried out. Therefore, it is difficult to predict its potential for addiction and abuse. In studies that have been conducted, there is conflicting information around the addiction liability of *S. divinorum* in both animals and humans. Some users have noted that they require increasing doses of salvinorin A in order to achieve the desired effect and the stimulated cerebral KOR may act as a mechanism of tolerance.<sup>37</sup> Further studies in this area and on the mediated decrease of dopamine as well as the impact of dose on effects are also required.

While concerns for the potential of abuse were once minimal because 1 kg of dried leaves yields only 3 to 6 human doses of salvinorin A, it was discovered that vaporizing and inhaling 200-500 micrograms had profound hallucinogenic effects.<sup>38</sup> The extraction of salvinorin A from the plant is very easy, and with care, approximately 1.5 grams of pure salvinorin A per kilogram of dried leaves (8kg of fresh leaves) can be isolated. This is enough substance to provide for 2000 human doses.<sup>39</sup>

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<sup>37</sup> Bucheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>38</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>39</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs*. 1994 Jul-Sep;26(3):277-83.

<sup>44</sup> Turner DM. *Salvinorin - The Psychedelic Essence of Salvia Divinorum*. Panther Press, San Francisco, CA 1996.

#### 4.2.5 Evidence of Extent of Actual Abuse of the Substance in Canada and Internationally

In Canada, the extent of actual abuse of *Salvia divinorum* and/or salvinorin A is relatively unknown. There is, however, some data regarding the use of *Salvia divinorum* in Canada, despite the lack of legitimate uses for this plant. Questions about the use of *S. divinorum* were included in the 2008-2009 Youth Smoking Survey, the 2009 Canadian Alcohol and Drug Use Monitoring Survey and the 2009 Ontario Student Drug Use and Health Survey.

The results from the 2009 Ontario Student Drug Use and Health Survey were published on November 18, 2009 and indicate that:

- Among all responding students in Ontario, 4.4% reported using *Salvia divinorum* at least once in the past year. In comparison, 58.2% indicated they had used alcohol, 25.6% indicated they had used cannabis and 5.0% indicated they had used hallucinogens other than LSD and PCP in the past year;
- Males (6.2%) were significantly more likely than females (2.3%) to report using *Salvia divinorum*;
- There is significant grade variation, with *Salvia divinorum* use most likely among 11<sup>th</sup> graders (8.6%) and 12<sup>th</sup> graders (8.4%); and
- There are significant regional variations, with students in Northern Ontario (9.2%) most likely to use *Salvia divinorum*.

The results of the 2008-2009 Youth Smoking Survey were published on May 31, 2010 and indicate that:

- 4.9% of students stated that they had used *S. divinorum* in the last twelve months. In comparison, 53.0% indicated they had used alcohol, 27.3% indicated they had used cannabis and 6.9% indicated they had used other hallucinogens in the last twelve months;
- 2.6% of students in Grades 7-9 and 7.0% of students in Grades 10-12 had used *S. divinorum* in the last twelve months; and
- Males (6.6%) were more likely to have used *S. divinorum* in the past twelve months compared to females (3.2%).

The scope of the previously mentioned studies did not provide for any explanations regarding differences in usage between ages, genders and regions. In this regard, it is difficult to speculate on the causality of such differences.

The Canadian Alcohol and Drug Use Monitoring Survey specifically examined *Salvia* for the first time in 2009. An estimated 1.6% of Canadians, aged 15 years and older, reported that they had used *salvia* in their lifetime, and 0.2% reported using it in the past-year. In comparison, the prevalence of past-year cannabis use among Canadians 15 years of age and older was 10.6%. 1.2% of respondents reported using cocaine or crack in the past 12 months, 0.9% had used ecstasy and 0.7% used illicit hallucinogens.

Health Canada's Drug Analysis Services (DAS) has identified salvinorin A in a number of

samples seized by law enforcement, as shown in the following table.

**NUMBER OF SAMPLES FOUND TO CONTAIN SALVINORIN A**

Year	Count
2006	9
2007	8
2008	4
2009	20
2010 (as of May 7)	8

The National Forensic Laboratory Information System (NFLIS) and the System to Retrieve Information from Drug Evidence (STRIDE) in the United States are Drug Enforcement Agency (DEA) databases that collect scientifically verified data on analyzed samples in state and local forensic labs as well as samples from DEA labs. The following table shows the quantity of *S. divinorum* products that were seized from 2000 through to 2009.

**ANALYZED SALVIA DIVINORUM or SALVINORIN A SEIZURES**

(Number of Items/Exhibits)

Source	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009*
NFLIS-State/Local <sup>1</sup>	0	0	0	0	1	8	12	12	70	34
STRIDE <sup>2</sup>	0	0	1	1	1	0	0	0	N/A	N/A
<b>TOTAL</b>	0	0	1	1	2	8	12	12	70	34

Data Source: NFLIS & STRIDE, 2008 data queried 11/24/08, updated 06/10/2010

<sup>1</sup> NFLIS reported seizures of *Salvia divinorum* and/or salvinorin A

<sup>2</sup> STRIDE reported items of *Salvia divinorum*.

\* Includes only January – May data in 2009.

It is difficult to determine the extent of actual abuse of *S. divinorum* in Canada or elsewhere as there appear to be inconsistencies in the literature regarding risk aversion. For example, one author states: "Many who have used salvinorin A find the experience extremely unnerving, frightening and overly intense and most have no desire to repeat the experience."<sup>44</sup> However, another study suggested that this is not the experience of all recreational users of *S. divinorum*.<sup>45</sup> Over eighty percent of users surveyed on a web-based questionnaire about their *S. divinorum* use said that they would probably or definitely use *S. divinorum* again.<sup>46</sup> Users have reported the negative effects of *S. divinorum* as: the short duration of action, lack of control over the

<sup>45</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62, Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry.* 2005 Jan;38(1):1-5, and Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs.* 1994 Jul-Sep;26(3):277-83.

<sup>46</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.



experience, persisting negative effects (most often anxiety),<sup>47</sup> sweating, chills, increased diuresis, impaired vigilance,<sup>48</sup> and negative after-effects including tiredness, feeling head heavy, dizziness, physical exhaustion, and some degree of malaise or 'hangover' as they 'comedown' from the drug.<sup>49</sup>

#### 4.2.6 Risk to Personal and Public Health and Safety

The increase in both the number of enquiries from various municipalities and members of the public and the amount of media interest regarding the availability of *Salvia divinorum* in Canada may be an indication that the recreational use of *S. divinorum* as a hallucinogen is on the rise. However, there are no available statistics that indicate there has been a significant increase in *S. divinorum* use in the Canadian population and, in comparison to the use of other drugs such as alcohol and cannabis, the actual use of *S. divinorum* is quite low.

The potential for harm to the user and/or other individuals is primarily related to the hallucinogenic properties of the substance. Users may get up and walk around without apparent awareness of their movements, behaviour or surroundings, and distinction between self and surroundings is often lost. At doses greater than 1mg of salvinorin A, out of body experiences are frequent and loss of consciousness has been reported.<sup>50</sup> There is little information regarding the social behaviours of persons under the influence of *S. divinorum* products, and what risks their activities such as operating a motorized vehicle may pose to the general public. There is also very little data regarding the toxicity, teratogenicity or other long-term effects of *S. divinorum* use.<sup>51</sup>

As far as law enforcement is concerned, the Department has only received a limited number of communications indicating concern with respect to *S. divinorum* and none of these have advised that the use of *S. divinorum* poses any threat to public safety. The Royal Canadian Mounted Police (RCMP) has stated that while *S. divinorum* is readily available, it has not become a popular drug in Canada, probably due to its aversive effects such as anxiety and introversion.

A handful of case reports regarding the use of *S. divinorum* have been published in the academic literature. One report was an international case report in which a young man (19 years of age) described his perceptions after inhaling smoke from *S. divinorum*. The peak psychotropic effects, including prickling of the skin, fever-like hot flashes, muscular tremor, and depersonalization, were reached in less than five minutes after inhalation of an unknown amount of smoke from burning dried leaves.<sup>52</sup> Another report involved a 15-year-old male who presented

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<sup>47</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>48</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>49</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>50</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>51</sup> Grundmann O, Phipps SM, Zadezensky I, Butterweck V. *Salvia divinorum* and Salvinorin A: An Update on Pharmacology and Analytical Methodology. *Planta Med* 2007 Jun;73:1039-1046.

**s.21(1)(a)**

**s.21(1)(b)**

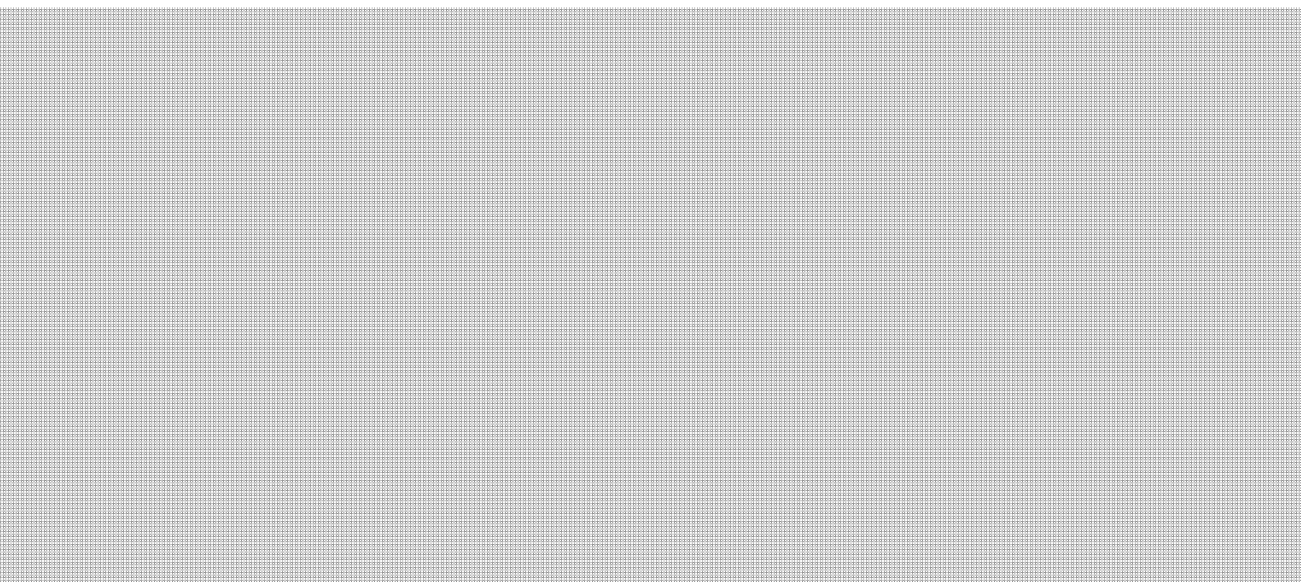
to psychiatric emergency services with acute onset of paranoia, déjà vu, blunted affect, difficulties in thought processing and slowed speech after smoking *Salvia divinorum* over an unknown period of time. During his hospitalization all symptoms improved significantly except the feeling of déjà vu. Based on this case presentation, the author suggested that the feelings of déjà vu may be a long-term effect of *S. divinorum* use.<sup>53</sup> However, given that this is the only case report in which déjà vu was associated with the use of *S. divinorum*, more reports are needed to substantiate this finding.

In addition to the above-mentioned reports, in 2006, a case was reported in the U.S. in which a 17-year-old boy committed suicide after smoking *S. divinorum* for an unknown period of time.<sup>54</sup> It should be noted that alcohol and general depression were the main confounders in this case. After this case was reported, the state of Delaware passed a law which classified *S. divinorum* as a Schedule I controlled substance along with other hallucinogenic substances.

Like many drugs of abuse, users are often unaware of the potency and adulterants in the product they purchase. A study by Wolowich *et al.* (2006)<sup>55</sup>, showed that the salvinorin A content in five out of five *S. divinorum* products was falsely indicated on the label and 4 out of 5 products contained unidentified adulterants (i.e. vitamin E, caffeine).

Health Canada has only anecdotal information about the use and abuse of *S. divinorum* in Canada as well as the threat *S. divinorum* may pose to the health and safety of Canadians. Although reports of domestic adverse reactions related to the use of *S. divinorum* as a hallucinogen have been received through the Canada Vigilance database, it is important to note that the number of reports and the nature of reactions reported are not adequate to characterize the risk to the general population.

## **5. ASSESSMENT OF RISKS AND BENEFITS**



<sup>53</sup> Singh S. (2007) Adolescent salvia substance abuse. *Addiction*. 102, 823-824.

<sup>54</sup> <http://www.kvbc.com/Global/story.asp?S=4893692>

<sup>55</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

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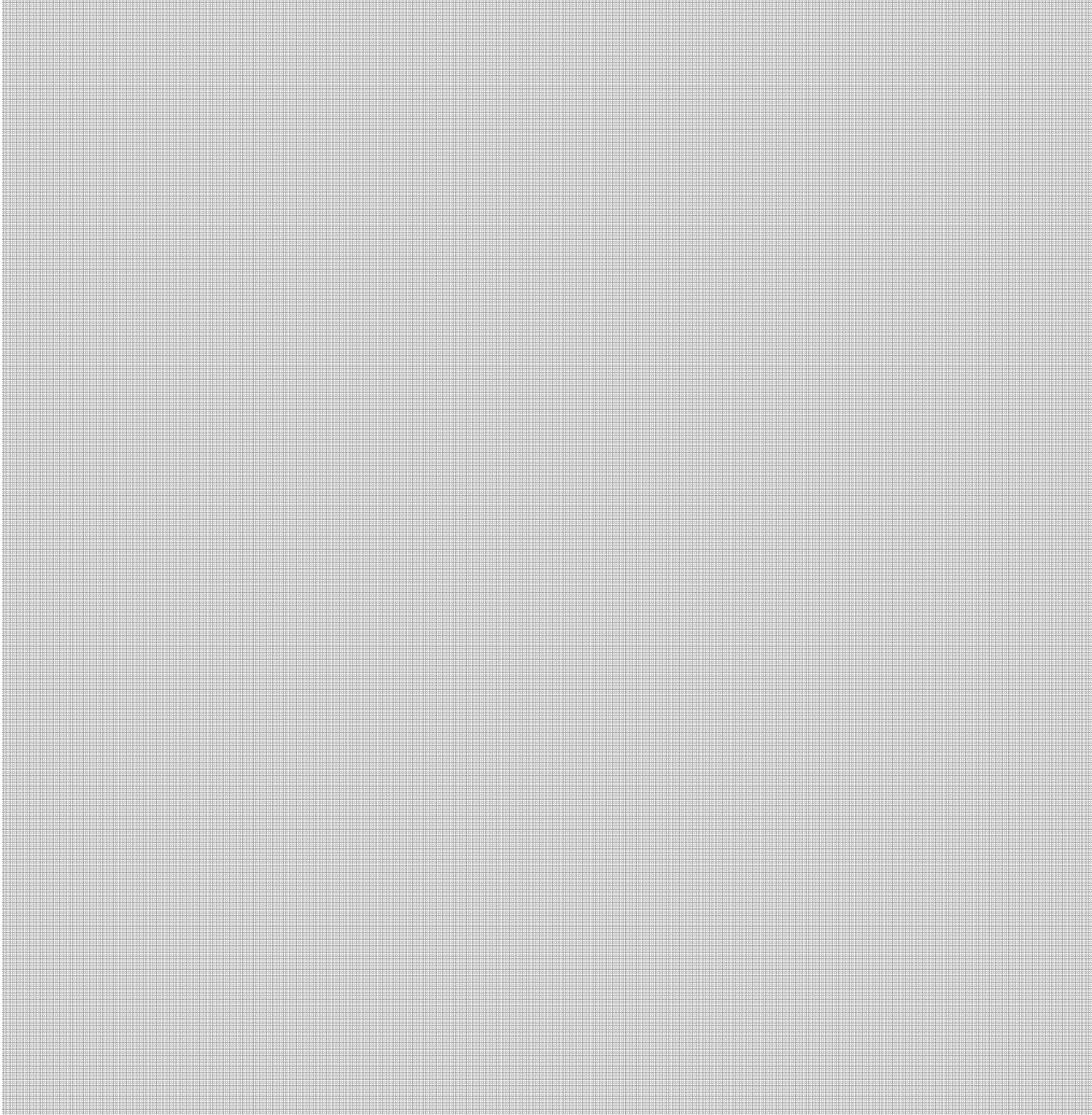
**Is(Are) exempted pursuant to section(s)  
est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**

s.21(1)(a)

s.21(1)(b)



## 7. CONSIDERATIONS

The KOR-mediated aversive and dysphoric effects of *Salvia divinorum* do not appear to be hampering its use as young adults have begun smoking the leaves and leaf extract recreationally.<sup>56</sup> It can be purchased through online botanical companies and other drug promotion sites and is often

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<sup>56</sup> Hazelden Foundation, 2004. Drug Abuse Trends. June 2004. URL: [www.research.hazelden.org](http://www.research.hazelden.org).

s.21(1)(a)

s.21(1)(b)

touted as a legal alternative to substances such as cannabis and mescaline.<sup>57</sup> Interestingly, after being widely available for over a decade, the drug does not appear to have had the same social impact as LSD or ecstasy.<sup>58</sup>

While there has been an increase over the past few years in the number of enquiries from various municipalities and members of the public regarding the availability of *Salvia divinorum* as a hallucinogen, the reported use of *S. divinorum* by young Canadians is much lower than that of alcohol or cannabis, according to available statistics.

The NHPR are limited in their capacity to control the availability of *S. divinorum* in that *S. divinorum* products are often declared as incense and therefore cannot be considered unapproved natural health products. In addition, compliance and enforcement actions, such as voluntary stop-sales, forfeiture, destruction, and administrative seizure, cannot be implemented unless the labeling of the product indicates that it is to be used for consumption and its pharmacological effects.

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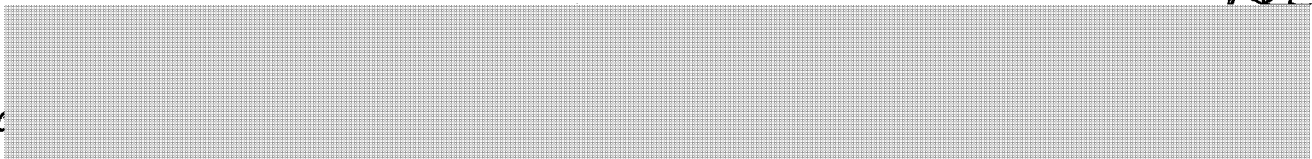
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The previous HPFB recommendation to schedule *S. divinorum* under the CDSA was likely based on a misunderstanding of the (previously-described) criteria upon which scheduling is based. In particular, it did not consider a number of factors, including potential for abuse and risk to public health and safety. The Office of Controlled Substances (OCS) was also not consulted by HPFB at the time this recommendation was made. In addition, among countries who have decided to control *S. divinorum* in some way, very little or no substantiation of the risks of *S. divinorum* upon which the decision was based are available.

decisions are made within HCSB

Neither *Salvia divinorum* nor salvinorin A meet the criteria for scheduling a substance under the CDSA. Despite being regulated in some jurisdictions, neither the plant nor salvinorin A are scheduled under any of the UN Drug Control Conventions. *S. divinorum* and salvinorin A are not structurally or pharmacologically similar to other substances included in the schedules to the CDSA. There are currently no legitimate therapeutic or industrial uses for *S. divinorum*. The abuse liability and potential for dependence of *S. divinorum* is not known as very few controlled scientific studies of its physical and psychotropic effects have been carried out on humans. The extent of actual abuse of *S. divinorum* is also largely unknown. Evidence of a risk to public health and safety is anecdotal in nature and not quantified in any way as there is a lack of information regarding abuse in Canada. Therefore, it would not be appropriate to include *S. divinorum* and/or salvinorin A under any of the Schedules to the CDSA at this time.

8. RECOMMENDATIONS



this is repeated below under Recommendation

<sup>57</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

<sup>58</sup> Munro, T. The Chemistry of *Salvia divinorum*. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

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s.21(1)(a)

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## 9. CONSULTATIONS

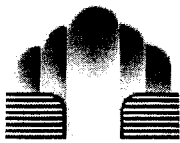
The Drug Analysis Services (DAS) was contacted in order to provide any data available regarding the identification of salvinorin A in samples submitted by law enforcement.

The Royal Canadian Mounted Police (RCMP) was contacted in order to establish their views with respect to *S. divinorum* use in Canada. The RCMP advised that though *S. divinorum* is readily available, it does not appear to pose a threat to public safety.

OCS has received a number of correspondences from Canada Border Service Agency (CBSA) officers concerning a lack of information regarding the status of *S. divinorum* and how the plant should be treated at the border. CBSA officers have also expressed concern regarding the plant's hallucinogenic properties. At present, only shipments of *S. divinorum* that are represented as health products/~~hallucinogens~~ can be refused for import under the NHPR.

*modifying organic functions*

## 10. IMPLEMENTATION AND EVALUATION



Jocelyn Kula/HC-SC/GC/CA

2010-07-12 11:35 AM

To Tiffany Thornton/HC-SC/GC/CA@HWC

cc tiana.branch@hc-sc.gc.ca, Stephanie  
Chandler/HC-SC/GC/CA@HWC

bcc

Subject Fw: Salvia IAS

History:  This message has been forwarded.

Hi Tiffany,

This doc is for circulation to CSS WG members. Correct me if I am wrong, but it is my understanding that salvia is not actually on our agenda this week, this is just to get people started reading before discussion at our next meeting. Just that I would like Stephanie (officer responsible here in OCS) to be there when it is discussed, and I think it will be critical to have at least NHPD there.

JK

---

Jocelyn Kula  
Manager/ Gestionnaire  
Policy and Regulatory Affairs Division/ Division des politiques et affaires réglementaires  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0125 Fax: (613) 946-4224

----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2010-07-12 11:33 AM -----



Stephanie  
Chandler/HC-SC/GC/CA

2010-07-12 10:26 AM

To Jocelyn Kula/HC-SC/GC/CA@HWC

cc

Subject Salvia IAS

Good morning Jocelyn,

Here is the updated draft of the Salvia IAS.



Draft Salvia Divinorum IAS\_July 12 2010.doc

Regards,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Policy and Regulatory Affairs Division/ Division des politiques et affaires réglementaires  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224

E-Mail: [stephanie.chandler@hc-sc.gc.ca](mailto:stephanie.chandler@hc-sc.gc.ca)



# Issue Analysis Summary

DRAFT

## Scheduling *Salvia Divinorum* and/or Salvinorin A under the CDSA

Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Controlled Substances and Tobacco and Drug

July 12, 2010

### CONTEN

- 1. API
- 2. ISSI *Input for Salvia IAS*
- 3. PUR
- 4. CON *NHPR section revisions from Robin*
- 5. ASSI *stats on international use? ODARS*
- 6. IDEN *side effects of Salvia - NIDA*
- 7. CON *publication - Bruna*
- 8. RECC
- 9. CONS *ketocyclazocine - cyclazocine*
- 10. IMPLI *excluded from CDSA Item 11*

- 1. APPRO *- status decision? Evelyn.*

This Issue Analy

Diane Allan, Dire  
Office of Control  
Tobacco and Drug

[DD/MM/20

### 2. ISSUE

Health Canada has received numerous or enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *S. divinorum* and/or its main active ingredient salvinorin A, neither of which are currently regulated under the *Controlled Drugs and Substances Act* (CDSA). These requests are further to reports from scientific and media sources suggesting that *S. divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has also noted an

# Issue Analysis Summary

DRAFT

## Scheduling *Salvia Divinorum* and/or Salvinorin A under the CDSA

Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Controlled Substances and Tobacco and Directorate

July 12, 2010

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### CONTENTS

1. APPROVALS
  2. ISSUE
  3. PURPOSE
  4. CONTEXT
  5. ASSESSMENT OF RISKS AND BENEFITS
  6. IDENTIFICATION AND ANALYSIS OF OPTIONS
  7. CONSIDERATIONS
  8. RECOMMENDATION(S)
  9. CONSULTATIONS
  10. IMPLEMENTATION AND EVALUATION
- 

### 1. APPROVALS

This Issue Analysis Summary is approved.

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Diane Allan, Director  
Office of Controlled Substances  
Tobacco and Drugs Directorate

---

[DD/MM/2010]

### 2. ISSUE

Health Canada has received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *S. divinorum* and/or its main active ingredient salvinorin A, neither of which are currently regulated under the *Controlled Drugs and Substances Act* (CDSA). These requests are further to reports from scientific and media sources suggesting that *S. divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has also noted an

ongoing media interest regarding the availability of *S. divinorum* in Canada.

### 3. PURPOSE

To assess *Salvia divinorum* and/or salvinorin A against the criteria for the addition of a substance to one of the Schedules to the CDSA, and determine whether one or both should be regulated as controlled substances in Canada.

### 4. CONTEXT

*Salvia divinorum* is a species of sage which belongs to the mint family, and which is found in the form of dried leaves, extract and plant cuttings. Also known as "diviner's sage", the plant is known to induce illusions and hallucinations when chewed or smoked. Salvinorin A, the psychoactive ingredient in *S. divinorum* (also referred to chemically as a neoclerodane diterpene) is found primarily in the leaves, and to a lesser extent in the stems.<sup>1</sup>

*S. divinorum* is widely touted as a "legal" hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs among adolescents and young adults.<sup>2</sup> While very little is known about how and where *S. divinorum* is sold in Canada, it is suspected that it is mainly purchased over the Internet and/or bought at head shops or alternative life style stores, etc.

The use of *S. divinorum* as a psychotropic agent first came to Health Canada's attention in 2002. In 2004, Health Canada received four adverse drug reaction (ADR) reports associated with the use of *S. divinorum* as a hallucinogen, with three being considered non-serious (requiring no medical attention) and the fourth being considered serious (medical intervention was required). The serious ADR report involved the concomitant use of alcohol in a person diagnosed with Attention Deficit Disorder.

Further to the receipt of the aforementioned ADRs, the Marketed Health Products Directorate (MHPD) and the Natural Health Products Directorate (NHPD) of the Health Products and Food Branch (HPFB) prepared an issue analysis summary (IAS), which recommended that *S. divinorum* and its active ingredient salvinorin A be regulated as controlled substances. This recommendation was maintained when the IAS was updated in November 2006.

Later, in December 2005, MHPD and NHPD prepared a Signal Assessment (SA) (updated in June 2007) that eventually led to the preparation of a Health Risk Assessment (HRA), which concluded that *S. divinorum* or salvinorin A-containing health products would constitute a Type II Health Risk according to the Health Hazard Classification of the Recall Policy of the Health

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<sup>1</sup> U.S. Department of Justice Drug Enforcement Administration. 2002. Drugs and Chemicals of Concern: Salvia Divinorum (salvinorin A, divinorin A) URL:

[http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm) Nov 2008

<sup>2</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.

Products and Food Branch Inspectorate (HBFBI). Such a risk is defined as “a situation in which the use of, or exposure to, a product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote”.

Further to an Assistant Deputy Minister (ADM) discussion in April 2007, the Drug Strategy and Controlled Substances Directorate (DSCSD) organized a meeting with MHPD, NHPD and HPFBI to discuss *S. divinorum*. HPFBI was to determine appropriate compliance activities regarding *S. divinorum* and consult with the Canada Border Services Agency (CBSA) regarding the movement of products containing *S. divinorum* into and out of Canada.

On September 13, 2007, a further meeting between DSCSD, MHPD, NHPD and HPFBI led to the conclusion that DSCSD would conduct a scheduling assessment of *S. divinorum* in order to explore the possibility of scheduling this substance under the CDSA.

In September 2008, the Director Generals of DSCSD, MHPD, TPD and the HPFBI agreed that media lines and an “It’s Your Health” article on *S. divinorum* would be prepared.

#### **4.1 Relevant Legislative Frameworks in Canada**

##### **4.1.1 Food and Drug Regulations (under the Food and Drugs Act)**

The *Food and Drug Regulations* (F&DR) serve to ensure the safety, efficacy, and quality of health products offered for sale in Canada, including drugs and medical devices. Prior to being given market authorization, a manufacturer must present substantive scientific evidence that a product is safe, efficacious and of high quality. For drugs, Health Canada reviews this information carefully and, if the review is satisfactory, a Notice of Compliance (NOC) is issued and appropriate Drug Identification Numbers (DINs) are assigned.

A “drug” is defined under the F&DR as any substance or mixture of substances manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
- (b) restoration, correction or modification of organic functions in human beings or animals, or
- (c) disinfection in premises in which food is manufactured, prepared or kept;

As no products containing *S. divinorum* or its extracts have been reviewed and approved by Health Canada as of July 2010, it is illegal to market *S. divinorum* when it is represented as a drug.

#### 4.1.2 Natural Health Products Regulations (under the Food and Drugs Act)

The *Natural Health Products Regulations* (NHPR) aim to provide Canadians with ready access to natural health products (NHPs) that are safe, effective, and of high quality, while respecting freedom of choice and philosophical and cultural diversity. The NHPR require that all licensed products display a Natural Product Number (NPN), or, in the case of a homeopathic medicine, Drug Identification Number - Homeopathic Medicine (DIN-HM), on their labels. These numbers are issued once a product is authorized for sale in Canada further to a *natural health product monograph* or submission of other evidence of safety and efficacy. The NHPR also require that all manufacturers, packagers, labelers, and importers be licensed which in turn requires the presence of procedures respecting distribution records, product recalls, product handling, storage and delivery, and manufacturing practices.

The definition of an NHP under the NHPR has both a function and substance component. The function component refers to those substances that are manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
- (b) restoring or correcting organic functions in humans; or
- (c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

The substance component refers to whether the product or medicinal ingredient therein is safe for consideration as an over-the-counter product, can be available for self-care and self-selection, and does not require a prescription to be sold. To be considered a NHP, no direct health claims need to be made regarding the substance. In the case of *S. divinorum*, it is generally marketed for its hallucinogenic properties which are considered a modification of an organic function. Therefore products containing it meet the definition of a NHP.

As of July 2010, no products containing *S. divinorum* have been reviewed and approved by Health Canada and no NPNs or DIN-HMs have been issued. Therefore sales of *S. divinorum* are illegal under the NHPR if it is represented for use as a hallucinogen or if other health claims in regards to modifying organic functions are made.

#### 4.1.3 Controlled Drugs and Substances Act and its Regulations

The CDSA provides a legislative framework for the control of substances that can alter mental processes and that may produce harm to the health of an individual or to society when diverted or misused. Except as authorized under its regulations, activities such as possession, possession for the purposes of trafficking, trafficking, importation, exportation, possession for the purposes of exportation and production of controlled substances are prohibited under the CDSA.

heck  
egs.  
schedule 1  
included  
substance  
nothing on  
sched 1  
(excluded)

state more clearly

non-compliance  
NHP

The substances regulated under the CDSA are grouped into eight Schedules, and each Schedule is associated with particular offences and penalties as described in Part I of the CDSA.

In determining whether a substance should be regulated as a controlled substance, and into which Schedule of the CDSA it should be placed, Health Canada considers the following factors:

- International requirements and trends in the control and/or scheduling of the substance;
- Chemical and/or pharmacological similarity to substances listed in the Schedules to the CDSA;
- Legitimate use of the substance, including therapeutic, scientific, industrial or commercial uses;
- Potential for abuse and/or addiction liability of the substance;
- Evidence of extent of actual abuse of the substance in Canada and internationally; and
- Risk to personal and public health and safety.

#### 4.2 Assessment of *Salvia Divinorum* for Scheduling Purposes

##### 4.2.1 International Requirements and Trends in the Control and/or Scheduling of the Substance

At the present time, neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and therefore do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

add  
not who is  
investigating

**Australia** request from TGA why it was scheduled.  
- ask JK, if not see Robin for employee from TGA.

- EU  
- WHO?  
- list of  
substance to  
assess.

In June 2002, Australia became the first country to prohibit the sale, supply, possession and use of *S. divinorum* and salvinorin A. Although both *S. divinorum* and salvinorin A are listed in Schedule 9 of Australia's Standard for the Uniform Scheduling of Drugs and Poisons on the basis of "high potential for abuse and risk to public health and safety", no substantiation of this risk was provided at the time of this scheduling decision.<sup>3</sup> Schedule 9 is Australia's most restrictive drug schedule, and includes "substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities."<sup>4</sup>

##### **Belgium**

A decree was passed in Belgium on October 22, 2006 which added *S. divinorum* to the list of controlled substances. This list includes substances such as psilocybin mushrooms, khat and

<sup>3</sup> <http://www.tga.gov.au/ndpsc/record/rr200111.pdf>

<sup>4</sup> [http://www.cognitiveliberty.org/news/salvia\\_australia.htm](http://www.cognitiveliberty.org/news/salvia_australia.htm)

peyote cactus.<sup>5</sup>

### **Denmark**

In 2003, Denmark added *S. divinorum* and salvinorin A to their list of “category B” controlled substances, a category which also includes psilocybin mushrooms, cocaine, amphetamine, and several others substances that are only legal for medicinal and scientific purposes. Illegal possession carries a penalty of up to two years in prison.

### **Germany**

*S. divinorum* (plant and plant parts) was added to Appendix I of the *Narcotics Act* in Germany on March 1, 2008, making it illegal to produce, traffic, or possess. The law does not specifically mention salvinorin A.

### **Italy**

On June 25, 2004, the Italian Ministry of Health issued an ordinance prohibiting the sale of *S. divinorum* and its active constituent salvinorin A. On January 11, 2005, the Ministry of Health made possession of *S. divinorum* and salvinorin A illegal by placing them in “*Tabella 1*” of the *Tabella Sostanze Stupefacenti o Psicotrope*.

### **Japan**

On November 9, 2006, the Japanese government added a group of thirty-three drugs to its list of controlled substances, including salvinorin A. The drugs are banned under a revised pharmaceutical law, under which persons involved in their illegal import, production, and sale, i.e. beyond medical treatment or research purposes, will be subject to up to five years imprisonment or a fine of up to five million yen.

### **Spain**

On January 28, 2004, the Spanish Ministry of Health and Consumption issued an order prohibiting the sale of *S. divinorum*. The regulation went into effect on May 6, 2004 and only prohibits activities related to commerce. Possession and/or use are not considered to be criminal offences.

### **Other Countries**

*Salvia divinorum* is illegal to possess or sell in Croatia, Latvia, Lithuania, Poland, Romania, South Korea and Sweden. In Russia it is illegal to grow or sell *S. divinorum*, but it is legal to

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<http://eldd.emcdda.europa.eu/html.cfm/index5176EN.html?pluginMethod=eldd.shownewsdetails&id=20/12/2006BELGIUM:%20New%20substances%20controlled%20include%20mCPP%20and%20khat>

possess it. In Estonia, Finland, Iceland and Norway, *S. divinorum* is treated as a medicinal herb and it is illegal to import it without a relevant prescription from a doctor.

### ***United States of America***

*S. divinorum* and salvinorin A are not included in the Schedules to the United States *Controlled Substances Act* although both *S. divinorum* and salvinorin A have been added to a list of chemicals "of concern" which has no legal implications. In addition, some individual states have implemented laws restricting its use, sale and/or distribution. As of July 2010, a number of states have enacted legislation placing regulatory controls on *S. divinorum* and/or salvinorin A including Delaware, Georgia, Florida, Hawaii, Illinois, Kansas, Kentucky, Maryland, Mississippi, Missouri, Nebraska, North Dakota, Ohio, Oklahoma, South Dakota, Wisconsin, Virginia, California, Louisiana, Maine, North Carolina, and Tennessee. More details regarding the regulation of *S. divinorum* in these last five states are provided below.

#### ***California***

As of January 1, 2009, the sale or distribution of *S. divinorum* or salvinorin A, or any substance or material containing *S. divinorum* or salvinorin A, to any person under 18 years of age is a misdemeanor punishable by imprisonment in a county jail for not more than six months, a fine of no more than \$1,000, or both.

#### ***Louisiana***

In 2005, Louisiana passed a bill which prohibits the possession, production, manufacture and distribution of a material, compound, mixture, or preparation intended for human consumption and that contains a hallucinogenic plant. A "hallucinogenic plant" is defined as "any part or portion" of a plant on a list of forty plants, which includes *S. divinorum*.

#### ***Maine***

In Maine, *S. divinorum* and salvinorin A are regulated in the same way as tobacco products; adults eighteen years of age or over can legally purchase and use the material, but selling or providing *S. divinorum* or salvinorin A to anyone under the age of eighteen is a criminal offence. Possession by a minor is a civil violation, punishable by a fine, community service, or both.

#### ***North Carolina***

On December 1, 2009, the North Carolina State Legislature brought a new law into force which made *Salvia divinorum* and salvinorin A illegal. The only legal *S. divinorum* activities are the growing for aesthetic, landscaping, or decorative purposes or university-affiliated medical or pharmacological research.



## *Tennessee*

On July 1, 2006, Tennessee classified the deliberate production, manufacture, distribution, or possession of the active chemical ingredient in the hallucinogenic plant *S. divinorum* as a Class A misdemeanor. It is not, however, a criminal offence to possess, plant, cultivate, grow, or harvest *S. divinorum* for aesthetic, landscaping, or decorative purposes. The law also does not apply to any dosage that is legally obtainable from a retail establishment without a prescription when (and if) it is recognized by the Food and Drug Administration as a homeopathic drug.

### 4.2.2 Chemical and/or Pharmacological Similarity to Substances listed in the Schedules to the CDSA

The psychoactive ingredient in *Salvia divinorum* is salvinorin A. Other plants which contain psychotropic terpenoids are *Artemisia absinthium* (wormwood) and *Cannabis sativa*. Salvinorin A is considered by some as ~~the most~~ potent natural hallucinogen ever isolated.<sup>6</sup> *as LSD.*  
*- as potent as LSD. (sp?)*

Unlike all other hallucinogens, salvinorin A is structurally distinct and does not interact with the serotonin-2A receptor or any other molecular target of classical hallucinogens. It thus affects the brain in a way that is quite unique.<sup>7</sup> Recent pharmacological screenings of receptors have found it to be a highly potent and selective  $\kappa$ -opioid receptor (KOR) agonist.<sup>8</sup>

The use of *S. divinorum* or salvinorin A can lead to a number of effects with variable onset and duration. These effects are generally accepted to be: sensation of becoming an object, visions of various two-dimensional surfaces, films and membranes, revisiting places of the past (particularly childhood), perceived loss of the body and/or identity, various sensations of motion (being pulled or twisted by a force of some kind), uncontrollable hysterical laughter, and overlapping realities (perceptions of being in more than one place).<sup>9</sup> Laughter, happiness, sense of well-being and dissociative effects were deemed the best aspects of *S. divinorum* by users, second only to the "trip" that the drug elicits.<sup>10</sup> Depersonalization, speaking gibberish, widening of consciousness and subjective illusions of rapid movement, flying or hovering have also been

<sup>6</sup> Ott J. Ethnopharmacognosy and human pharmacology of *Salvia divinorum* and salvinorin A. *Curare*. 1995 18: 103-129. Unofficial transcription available online. URL <http://www.sagewisdom.org/ott2.html>

<sup>7</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>8</sup> Roth BL, Baner K, Westkaemper R, Siebert D, Rice KC, Steinberg S, Ernsberger P, Rothman RB. Salvinorin A: a potent naturally occurring nonnitrogenous kappa opioid selective agonist. *Proc Natl Acad Sci U S A*. 2002 Sep 3;99(18):11934-9.

<sup>9</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>10</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

reported.<sup>11</sup>

The psychomimetic effects of *S. divinorum* closely resemble schizophrenia symptoms induced by lysergic acid diethylamide (LSD) or phencyclidine (PCP).<sup>12</sup> Yet, it is said to have only weak influence on the prevailing mood of the user which differentiates it from other hallucinogens such as LSD and psilocybin.<sup>13</sup> Its strong dissociative effects are often compared to those of ketamine. Users have reported that the psychedelic effects of *S. divinorum* were most similar to those caused by psilocybin mushrooms.<sup>14</sup> However, users familiar with the effects of other hallucinogens agree that despite certain similarities to classical hallucinogens, the visions and overall experience are quite unique.<sup>15</sup>

In addition, the psychedelic effects of *S. divinorum* are similar to those of classical psychedelics regarding changes in perception and somatic sensations. *S. divinorum* causes an unusually high degree of sedation, weakness and fatigue, while the increased de-realization is not commonly reported for classical psychedelics.<sup>16</sup> The combination of these effects seems to correlate with that of other KOR agonists such as pentazocine.<sup>17</sup>

#### 4.2.3 Legitimate Use of the Substance, including Therapeutic, Scientific, Industrial or Commercial Uses

*Salvia divinorum* has traditionally been used for spiritual and medicinal purposes by the Mazatec Indians in Oaxaca, Mexico,<sup>18</sup> where an infusion of the leaves or the leaves themselves are ingested to treat gastrointestinal problems, headaches, rheumatism, anemia and swelling of the stomach.<sup>19</sup> Its main use today is, however, for its psychoactive properties in the aid of producing

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<sup>11</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5 and Siebert DJ. *Salvia divinorum* and salvinin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>12</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>13</sup> Siebert DJ. *Salvia divinorum* and salvinin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>14</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>15</sup> Siebert DJ. *Salvia divinorum* and salvinin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6 and González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>16</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>17</sup> Arasteh K, Poudevida S, Farre M, Roset PN, Cami J. Response patterns of the Spanish version of the 49-item short form of the Addiction Research Center Inventory after the use of sedatives, stimulants, and opioids. *Drug Alcohol Depend*. 1999 Jun 1;55(1-2):117-25.

<sup>18</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>19</sup> Munro, T. The Chemistry of *Salvia divinorum*. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

- culture specific - not necessarily relevant to use in Canada.

- highlight traditional medical uses (they are legitimate) - don't differentiate b/w spiritual & medical treatment in traditional cultures.

"mystical" or hallucinogenic experiences as part of spiritual rituals.<sup>20</sup>

Although selective kappa receptor agonists have been shown to produce analgesic effects, adverse effects such as psychotomimesis, dysphoria and diuresis have been observed in studies investigating their therapeutic use.<sup>21</sup> In addition, while it has been speculated that KOR agonists may prove to be useful in the treatment of certain psychiatric disorders including Alzheimer's disease, schizophrenia, dementia and bipolar disorder,<sup>22</sup> much more research is needed in order to substantiate these hypotheses. Similarly, another study has suggested that chemical analogues of salvinorin A may be a useful treatment for those suffering from addiction to other substances.<sup>23</sup> That said, there are presently no legitimate medical uses for *S. divinorum* in Canada.

Similarly, there are no known industrial or commercial uses for *S. divinorum* in Canada. The plant is a semi-tropical perennial that can only grow outdoors in a humid climate where it will not encounter frost. Most websites offering *S. divinorum* cuttings and seeds for sale appear to do so in the context of growing the plant in order to utilize its psychoactive properties, rather than out of horticultural interest or for its esthetic appeal.

if to be an agonist for some claim in Canada, this use is not in the context of use in Canada.

- Rickter's seed company, check catalogue.

- claims for use as an incense - illegitimate - no evidence it has any fragrant properties that would legitimize its use as an incense

4.2.4 Potential for Abuse and/or Addiction Liability of the Substance

- Similar to LSD, which is a controlled substance.

Salvinorin A is a potent, selective agonist of the  $\kappa$ -opioid receptor (KOR), and in contrast to the euphoria produced by  $\mu$ -opioid receptor (MOR) agonists, KOR agonists are negatively reinforcing and aversive.<sup>24</sup> In addition, KOR agonists have analgesic properties but are not associated with respiratory depression like MOR agonists. Finally, while MOR agonists increase the release of dopamine, the activation of KOR decreases dopamine release in the nucleus accumbens.<sup>25</sup>

<sup>20</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage *Salvia divinorum*. *Life Sci.* 2005 Dec 22;78(5):527-31.

<sup>21</sup> Barker RL, Fawcett J, Barkin SJ. 2002. Chronic pain management with a focus on the role of newer antidepressants and centrally acting agents. In: *Pain Management: A Practical Guide for Clinicians*, 6th edition, Weiner RS ed. CRC Press, Boca Raton, FL. pp. 415-34 and Tidgewell et al., 2004. A facile method for the preparation of deuterium labelled salvinorin A: *Biorganic & Medicinal Chemistry Letters*, 14: 5099-5102.

<sup>22</sup> Sheffler DJ & Roth BL. Salvinorin A: the 'magic mint' hallucinogen finds a molecular target in the kappa opioid receptor. *Trends Pharmacol Sci.* 2003 Mar;24(3):107-109.

<sup>23</sup> Prisinzano TE. Natural products as tools for neuroscience: discovery and development of novel agents to treat drug abuse. *J Nat Prod.* 2009 Mar 27;72(3):581-7.

<sup>24</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590, Cooper S. Interactions between endogenous opioids and dopamine: Implications for reward and aversion. In: *The Mesolimbic Dopamine System: From Motivation to Action*. Willner P and Scheel-Kruger J (editors) Wiley, Chester, England, 1991, pp. 331-366, and Shippenberg TS, Herz A, Spanagel R, Bals-Kubik R, Stein C. Conditioning of opioid reinforcement: neuroanatomical and neurochemical substrates. *Ann N Y Acad Sci.* 1992 Jun 28;654:347-56.

<sup>25</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.

Physical dependence necessary for addiction - addiction potential low but not necessarily negligible

The onset and intensity of the effects of *Salvia divinorum* appear to be related to the route of administration.

Traditional uses generally produce mild effects because the leaves are rolled and chewed or crushed and prepared as a foamy infusion whereby the salvinorin A is degraded in the gastrointestinal system before being absorbed into the bloodstream. Hence, the level of effect relates quite closely to the length of time the material spends in the mouth, with the onset of effect generally taking 5-10 minutes. The effects build over the next hour and last for another hour before they begin to subside.<sup>26</sup>

Routes of administration that avoid the hepatic first-pass effect (i.e. inhalation, intravenous, intramuscular and sublingual use) are the quickest and most intense.<sup>27</sup> Salvinorin A can be isolated from the plant to make a powder which can be vaporized and inhaled. The onset of effects felt from vaporizing salvinorin A powder occurs in about 30 seconds and effects last for about 5-10 minutes and then subside over the next 30 minutes.<sup>28</sup>

Smoking is by far the most popular method of administration<sup>29</sup> and this is accomplished by smoking the dried leaves or a concentrated extract using a pipe or bong. Dried leaves may also be fortified with a concentrated extract of salvinorin A. A concentrated extract can also be used sublingually. Neither *S. divinorum* nor salvinorin A can be injected because the powder is insoluble in water.<sup>30</sup>

The aversive effects of previously studied KOR agonists predict that the risk of addiction to *S. divinorum* is negligible. However, very few controlled scientific studies of the physical and psychotropic effects of *S. divinorum* on humans have been carried out. Therefore, it is difficult to predict its potential for addiction and abuse. In studies that have been conducted, there is conflicting information around the addiction liability of *S. divinorum* in both animals and humans. Some users have noted that they require increasing doses of salvinorin A in order to achieve the desired effect and the stimulated cerebral KOR may act as a mechanism of tolerance.<sup>31</sup> Further studies in this area and on the mediated decrease of dopamine as well as the impact of dose on effects are also required.

<sup>26</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>27</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.

<sup>28</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>29</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62 and Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>30</sup> Valdés LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs.* 1994 Jul-Sep;26(3):277-83.

<sup>31</sup> Bucheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry.* 2005 Jan;38(1):1-5.

While concerns for the potential of abuse were once minimal because 1 kg of dried leaves yields only 3 to 6 human doses of salvinorin A, it was discovered that vaporizing and inhaling 200-500 micrograms had profound hallucinogenic effects.<sup>32</sup> The extraction of salvinorin A from the plant is very easy, and with care, approximately 1.5 grams of pure salvinorin A per kilogram of dried leaves (8kg of fresh leaves) can be isolated. This is enough substance to provide for 2000 human doses.<sup>33</sup>

#### 4.2.5 Evidence of Extent of Actual Abuse of the Substance in Canada and Internationally

In Canada, the extent of actual abuse of *Salvia divinorum* and/or salvinorin A is relatively unknown. There is, however, some data regarding the use of *Salvia divinorum* in Canada, despite the lack of legitimate uses for this plant. Questions about the use of *S. divinorum* were included in the 2008-2009 Youth Smoking Survey, the 2009 Canadian Alcohol and Drug Use Monitoring Survey and the 2009 Ontario Student Drug Use and Health Survey.

The results from the 2009 Ontario Student Drug Use and Health Survey were published on November 18, 2009 and indicate that:

- Among all responding students in Ontario, 4.4% reported using *Salvia divinorum* at least once in the past year. In comparison, 58.2% indicated they had used alcohol, 25.6% indicated they had used cannabis and 5.0% indicated they had used hallucinogens other than LSD and PCP in the past year;
- Males (6.2%) were significantly more likely than females (2.3%) to report using *Salvia divinorum*;
- There is significant grade variation, with *Salvia divinorum* use most likely among 11<sup>th</sup> graders (8.6%) and 12<sup>th</sup> graders (8.4%); and
- There are significant regional variations, with students in Northern Ontario (9.2%) most likely to use *Salvia divinorum*.

The results of the 2008-2009 Youth Smoking Survey were published on May 31, 2010 and indicate that:

- 4.9% of students stated that they had used *S. divinorum* in the last twelve months. In comparison, 53.0% indicated they had used alcohol, 27.3% indicated they had used cannabis and 6.9% indicated they had used other hallucinogens in the last twelve months;
- 2.6% of students in Grades 7-9 and 7.0% of students in Grades 10-12 had used *S. divinorum* in the last twelve months; and

<sup>32</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>33</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs.* 1994 Jul-Sep;26(3):277-83.

- too early to see a trend in use  
- 5% of youth use is significant

- legal to possess

- Males (6.6%) were more likely to have used *S. divinorum* in the past twelve months compared to females (3.2%).

The scope of the previously mentioned studies did not provide for any explanations regarding differences in usage between ages, genders and regions. In this regard, it is difficult to speculate on the causality of such differences.

The Canadian Alcohol and Drug Use Monitoring Survey specifically examined Salvia for the first time in 2009. An estimated 1.6% of Canadians, aged 15 years and older, reported that they had used salvia in their lifetime, and 0.2% reported using it in the past-year. In comparison, the prevalence of past-year cannabis use among Canadians 15 years of age and older was 10.6%. 1.2% of respondents reported using cocaine or crack in the past 12 months, 0.9% had used ecstasy and 0.7% used illicit hallucinogens.

- mainly adolescent use

Health Canada's Drug Analysis Services (DAS) has identified salvinorin A in a number of samples seized by law enforcement, as shown in the following table.

- theoretically samples would not be seized if LEA knew it was Salvia b/c not controlled

**NUMBER OF SAMPLES FOUND TO CONTAIN SALVINORIN A**

Year	Count
2006	9
2007	8
2008	4
2009	20
2010 (as of May 7)	8

The National Forensic Laboratory Information System (NFLIS) and the System to Retrieve Information from Drug Evidence (STRIDE) in the United States are Drug Enforcement Agency (DEA) databases that collect scientifically verified data on analyzed samples in state and local forensic labs as well as samples from DEA labs. The following table shows the quantity of *S. divinorum* products that were seized from 2000 through to 2009.

- CBSA seeing a lot of it cause shipped in.

**ANALYZED SALVIA DIVINORUM or SALVINORIN A SEIZURES**

(Number of Items/Exhibits)

Source	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009*
NFLIS-State/Local <sup>1</sup>	0	0	0	0	1	8	12	12	70	34
STRIDE <sup>2</sup>	0	0	1	1	1	0	0	0	N/A	N/A
<b>TOTAL</b>	0	0	1	1	2	8	12	12	70	34

Data Source: NFLIS & STRIDE, 2008 data queried 11/24/08, updated 06/10/2010

<sup>1</sup> NFLIS reported seizures of *Salvia divinorum* and/or salvinorin A

<sup>2</sup> STRIDE reported items of *Salvia divinorum*.

\* Includes only January – May data in 2009.

It is difficult to determine the extent of actual abuse of *S. divinorum* in Canada or elsewhere as there appear to be inconsistencies in the literature regarding risk aversion. For example, one

International Use Stats. ← Alison monitoring surveys

author states: "Many who have used salvinorin A find the experience extremely unnerving, frightening and overly intense and most have no desire to repeat the experience."<sup>34</sup> However, another study suggested that this is not the experience of all recreational users of *S. divinorum*.<sup>35</sup> Over eighty percent of users surveyed on a web-based questionnaire about their *S. divinorum* use said that they would probably or definitely use *S. divinorum* again.<sup>36</sup> Users have reported the negative effects of *S. divinorum* as: the short duration of action, lack of control over the experience, persisting negative effects (most often anxiety),<sup>37</sup> sweating, chills, increased diuresis, impaired vigilance,<sup>38</sup> and negative after-effects including tiredness, feeling head heavy, dizziness, physical exhaustion, and some degree of malaise or 'hangover' as they 'comedown' from the drug.<sup>39</sup>

#### 4.2.6 Risk to Personal and Public Health and Safety

personal risk is there

The increase in both the number of enquiries from various municipalities and members of the public and the amount of media interest regarding the availability of *Salvia divinorum* in Canada may be an indication that the recreational use of *S. divinorum* as a hallucinogen is on the rise. However, there are no available statistics that indicate there has been a significant increase in *S. divinorum* use in the Canadian population and, in comparison to the use of other drugs such as alcohol and cannabis, the actual use of *S. divinorum* is quite low.

The potential for harm to the user and/or other individuals is primarily related to the hallucinogenic properties of the substance. Users may get up and walk around without apparent awareness of their movements, behaviour or surroundings, and distinction between self and surroundings is often lost. At doses greater than 1mg of salvinorin A, out of body experiences are frequent and loss of consciousness has been reported.<sup>40</sup> There is little information regarding the social behaviours of persons under the influence of *S. divinorum* products, and what risks their activities such as operating a motorized vehicle may pose to the general public. There is also very little data regarding the toxicity, teratogenicity or other long-term effects of *S. divinorum* use.<sup>41</sup>

Not injected highlight. not used as party drug. dangers of smoking it.

<sup>34</sup> Turner DM. Salvinorin - The Psychedelic Essence of Salvia Divinorum. Panther Press, San Francisco, CA 1996.

<sup>35</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62, Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5, and Valdès LJ 3rd. Salvia divinorum and the unique diterpene hallucinogen, Salvinorin (divinorin) A. J Psychoactive Drugs. 1994 Jul-Sep;26(3):277-83.

<sup>36</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>37</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>38</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5.

<sup>39</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>40</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>41</sup> Grundmann O, Phipps SM, Zadezensky I, Butterweck V. Salvia divinorum and Salvinorin A: An Update on Pharmacology and Analytical Methodology. Planta Med 2007 Jun;73:1039-1046.

As far as law enforcement is concerned, the Department has only received a limited number of communications indicating concern with respect to *S. divinorum* and none of these have advised that the use of *S. divinorum* poses any threat to public safety. The Royal Canadian Mounted Police (RCMP) has stated that while *S. divinorum* is readily available, it has not become a popular drug in Canada, probably due to its aversive effects such as anxiety and introversion.

A handful of case reports regarding the use of *S. divinorum* have been published in the academic literature. One report was an international case report in which a young man (19 years of age) described his perceptions after inhaling smoke from *S. divinorum*. The peak psychotropic effects, including prickling of the skin, fever-like hot flashes, muscular tremor, and depersonalization, were reached in less than five minutes after inhalation of an unknown amount of smoke from burning dried leaves.<sup>42</sup> Another report involved a 15-year-old male who presented to psychiatric emergency services with acute onset of paranoia, déjà vu, blunted affect, difficulties in thought processing and slowed speech after smoking *Salvia divinorum* over an unknown period of time. During his hospitalization all symptoms improved significantly except the feeling of déjà vu. Based on this case presentation, the author suggested that the feelings of déjà vu may be a long-term effect of *S. divinorum* use.<sup>43</sup> However, given that this is the only case report in which déjà vu was associated with the use of *S. divinorum*, more reports are needed to substantiate this finding.

NIDA  
- compromise ability

In addition to the above-mentioned reports, in 2006, a case was reported in the U.S. in which a 17-year-old boy committed suicide after smoking *S. divinorum* for an unknown period of time.<sup>44</sup> It should be noted that alcohol and general depression were the main confounders in this case. After this case was reported, the state of Delaware passed a law which classified *S. divinorum* as a Schedule I controlled substance along with other hallucinogenic substances.

Like many drugs of abuse, users are often unaware of the potency and adulterants in the product they purchase. A study by Wolowich *et al.* (2006)<sup>45</sup>, showed that the salvinorin A content in five out of five *S. divinorum* products was falsely indicated on the label and 4 out of 5 products contained unidentified adulterants (i.e. vitamin E, caffeine).

- case report

Health Canada has only anecdotal information about the use and abuse of *S. divinorum* in Canada as well as the threat *S. divinorum* may pose to the health and safety of Canadians. Although reports of domestic adverse reactions related to the use of *S. divinorum* as a hallucinogen have been received through the Canada Vigilance database, it is important to note that the number of reports and the nature of reactions reported are not adequate to characterize the risk to the general population.

## 5. ASSESSMENT OF RISKS AND BENEFITS

- U.S. - 5.7%  
- monitoring the future

<sup>43</sup> Singh S. (2007) Adolescent salvia substance abuse. *Addiction*. 102, 823-824.

<sup>44</sup> <http://www.kvbc.com/Global/story.asp?S=4893692>

<sup>45</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

Journal of  
Emergency medicine  
- drug not used  
alcohol, other  
drugs  
- healthily could  
have LSD like  
flashbacks



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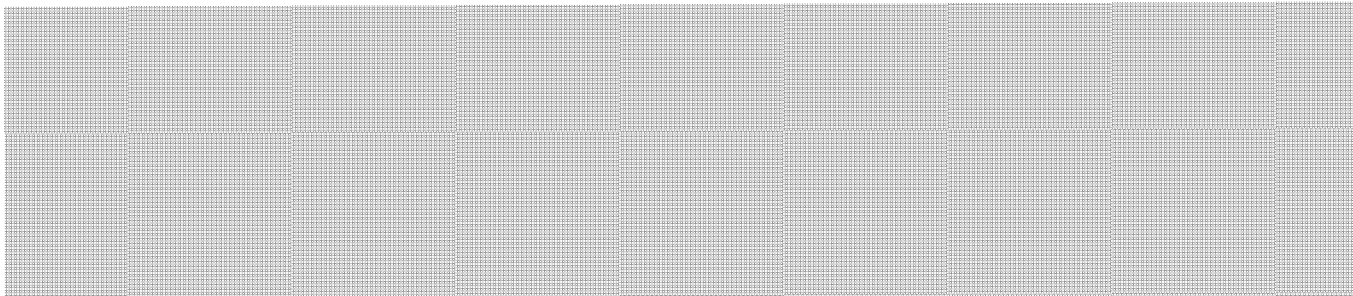
**Is(Are) exempted pursuant to section(s)  
est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**

s.21(1)(a)

s.21(1)(b)



elaborate on NHPR limit use to incense.

## 7. CONSIDERATIONS

The KOR-mediated aversive and dysphoric effects of *Salvia divinorum* do not appear to be hampering its use as young adults have begun smoking the leaves and leaf extract recreationally.<sup>46</sup> It can be purchased through online botanical companies and other drug promotion sites and is often touted as a legal alternative to substances such as cannabis and mescaline.<sup>47</sup> Interestingly, after being widely available for over a decade, the drug does not appear to have had the same social impact as LSD or ecstasy.<sup>48</sup>

While there has been an increase over the past few years in the number of enquiries from various municipalities and members of the public regarding the availability of *Salvia divinorum* as a hallucinogen, the reported use of *S. divinorum* by young Canadians is much lower than that of alcohol or cannabis, according to available statistics.

The NHPR are limited in their capacity to control the availability of *S. divinorum* in that *S. divinorum* products are often declared as incense and therefore cannot be considered unapproved natural health products. In addition, compliance and enforcement actions such as voluntary stop-sales, forfeiture, destruction, and administrative seizure, cannot be implemented unless the labeling of the product indicates that it is to be used for human consumption and can modify an organic function.

The previous HPFB recommendation to schedule *S. divinorum* under the CDSA was likely based on a misunderstanding of the (previously-described) criteria upon which scheduling decisions are made within the Healthy Environments and Consumer Safety Branch (HECSB). In particular, it did not consider a number of factors, including potential for abuse and risk to public health and safety. The Office of Controlled Substances (OCS) was also not consulted by HPFB at the time this recommendation was made. In addition, among countries who have decided to control *S. divinorum* in some way, very little or no substantiation of the risks of *S. divinorum* upon which the decision was based are available.

Neither *Salvia divinorum* nor salvinorin A meet the criteria for scheduling a substance under the CDSA. Despite being regulated in some jurisdictions, neither the plant nor salvinorin A are scheduled under any of the UN Drug Control Conventions. *S. divinorum* and salvinorin A are

<sup>46</sup> Hazelden Foundation, 2004. Drug Abuse Trends. June 2004. URL: [www.research.hazelden.org](http://www.research.hazelden.org).

<sup>47</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

<sup>48</sup> Munro, T. The Chemistry of *Salvia divinorum*. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

s.21(1)(a)

s.21(1)(b)

not structurally or pharmacologically similar to other substances included in the schedules to the CDSA. There are also currently no legitimate therapeutic or industrial uses for *S. divinorum*. The abuse liability and potential for dependence of *S. divinorum* is not known as very few controlled scientific studies of its physical and psychotropic effects have been carried out on humans. The extent of actual abuse of *S. divinorum* is also largely unknown. Evidence of a risk to public health and safety is anecdotal in nature and not quantified in any way as there is a lack of information regarding abuse in Canada.

## 8. RECOMMENDATIONS

## 9. CONSULTATIONS

The Drug Analysis Services (DAS) was contacted in order to provide any data available regarding the identification of salvinorin A in samples submitted by law enforcement.

The Royal Canadian Mounted Police (RCMP) was contacted in order to establish their views with respect to *S. divinorum* use in Canada. The RCMP advised that though *S. divinorum* is readily available, it does not appear to pose a threat to public safety.

OCS has received a number of correspondences from Canada Border Services Agency (CBSA) officers concerning a lack of information regarding the status of *S. divinorum* and how the plant should be treated at the border. CBSA officers have also expressed concern regarding the plant's hallucinogenic properties. At present, only shipments of *S. divinorum* that are represented as health products that modify organic functions can be refused for import under the NHPR.

## 10. IMPLEMENTATION AND EVALUATION

# Issue Analysis Summary

DRAFT

## Scheduling *Salvia Divinorum* and/or Salvinorin A under the CDSA

Regulatory Policy Division

Office of Controlled Substances

Controlled Substances and Tobacco and Directorate

July 12, 2010

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10. IMPLEMENTATION AND EVALUATION

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### 1. APPROVALS

This Issue Analysis Summary is approved.

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Diane Allan, Director  
Office of Controlled Substances  
Controlled Substances and Tobacco Directorate

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[DD/MM/2010]

### 2. ISSUE

Health Canada has received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *S. divinorum* and/or its main active ingredient salvinorin A, neither of which are currently regulated under the *Controlled Drugs and Substances Act* (CDSA). These requests are further to reports from scientific and media sources suggesting that *S. divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has also noted an

1

ongoing media interest regarding the availability of *S. divinorum* in Canada.

### 3. PURPOSE

To assess *Salvia divinorum* and/or salvinorin A against the criteria for the addition of a substance to one of the Schedules to the CDSA, and determine whether one or both should be regulated as controlled substances in Canada.

### 4. CONTEXT

*Salvia divinorum* is a species of sage which belongs to the mint family, and which is found in the form of dried leaves, extract and plant cuttings. Also known as "diviner's sage", the plant is known to induce illusions and hallucinations when chewed or smoked. Salvinorin A, the psychoactive ingredient in *S. divinorum* (also referred to chemically as a neoclerodane diterpene) is found primarily in the leaves, and to a lesser extent in the stems.<sup>1</sup>

*S. divinorum* is widely touted as a "legal" hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs among adolescents and young adults.<sup>2</sup> While very little is known about how and where *S. divinorum* is sold in Canada, it is suspected that it is mainly purchased over the Internet and/or bought at head shops or alternative life style stores, etc.

The use of *S. divinorum* as a psychotropic agent first came to Health Canada's attention in 2002. In 2004, Health Canada received four adverse drug reaction (ADR) reports associated with the use of *S. divinorum* as a hallucinogen, with three being considered non-serious (requiring no medical attention) and the fourth being considered serious (medical intervention was required). The serious ADR report involved the concomitant use of alcohol in a person diagnosed with Attention Deficit Disorder.

Further to the receipt of the aforementioned ADRs, the Marketed Health Products Directorate (MHPD) and the Natural Health Products Directorate (NHPD) of the Health Products and Food Branch (HPFB) prepared an issue analysis summary (IAS), which recommended that *S. divinorum* and its active ingredient salvinorin A be regulated as controlled substances. This recommendation was maintained when the IAS was updated in November 2006.

Later, in December 2005, MHPD and NHPD prepared a Signal Assessment (SA) (updated in June 2007) that eventually led to the preparation of a Health Risk Assessment (HRA), which concluded that *S. divinorum* or salvinorin A-containing health products would constitute a Type II Health Risk according to the Health Hazard Classification of the Recall Policy of the Health

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<sup>1</sup> U.S. Department of Justice Drug Enforcement Administration. 2002. Drugs and Chemicals of Concern: Salvia Divinorum (salvinorin A, divinorin A) URL: [http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm) Nov 2008

<sup>2</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.

Products and Food Branch Inspectorate (HBFBI). Such a risk is defined as “a situation in which the use of, or exposure to, a product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote”.

Further to an Assistant Deputy Minister (ADM) discussion in April 2007, the Drug Strategy and Controlled Substances Directorate (DSCSD) organized a meeting with MHPD, NHPD and HPFBI to discuss *S. divinorum*. HPFBI was to determine appropriate compliance activities regarding *S. divinorum* and consult with the Canada Border Services Agency (CBSA) regarding the movement of products containing *S. divinorum* into and out of Canada.

On September 13, 2007, a further meeting between DSCSD, MHPD, NHPD and HPFBI led to the conclusion that DSCSD would conduct a scheduling assessment of *S. divinorum* in order to explore the possibility of scheduling this substance under the CDSA.

In September 2008, the Director Generals of DSCSD, MHPD, TPD and the HPFBI agreed that media lines and an “It’s Your Health” article on *S. divinorum* would be prepared.

#### **4.1 Relevant Legislative Frameworks in Canada**

##### **4.1.1 Food and Drug Regulations (under the Food and Drugs Act)**

The *Food and Drug Regulations* (F&DR) serve to ensure the safety, efficacy, and quality of health products offered for sale in Canada, including drugs and medical devices. Prior to being given market authorization, a manufacturer must present substantive scientific evidence that that product is safe, efficacious and of high quality. For drugs, Health Canada reviews this information carefully and, if the review is satisfactory, a Notice of Compliance (NOC) is issued and appropriate Drug Identification Numbers (DINs) are assigned.

A “drug” is defined under the F&DR as any substance or mixture of substances manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
- (b) restoration, correction or modification of organic functions in human beings or animals, or
- (c) disinfection in premises in which food is manufactured, prepared or kept;

As no products containing *S. divinorum* or its extracts have been reviewed and approved by Health Canada as of July 2010, it is illegal to market *S. divinorum* when it is represented as a drug.

#### 4.1.2 Natural Health Products Regulations (under the Food and Drugs Act)

The *Natural Health Products Regulations* (NHPR) aim to provide Canadians with ready access to natural health products (NHPs) that are safe, effective, and of high quality, while respecting freedom of choice and philosophical and cultural diversity. The NHPR require that all licensed products display a Natural Product Number (NPN), or, in the case of a homeopathic medicine, a Drug Identification Number - Homeopathic Medicine (DIN-HM), on their labels. These numbers are issued once a product is authorized for sale in Canada further to the submission of a product license application in which the applicant attests to all of the conditions set out in a *natural health product monograph* prepared and published by the Natural Health Products Directorate or submission of a product license application that provides sufficient evidence of quality, safety and efficacy that is assessed and approved by NHPD by the non-compendial route. The NHPR also require that all manufacturers, packagers, labelers, and importers be licensed which in turn requires the presence of procedures respecting distribution records, product recalls, product handling, storage and delivery, and all other aspects of Good Manufacturing Practices as set out in the NHPR.

The definition of an NHP under the NHPR has both a function and substance component. The function component refers to those substances that are manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
- (b) restoring or correcting organic functions in humans; or
- (c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

The substance component refers to the requirement that all of the medicinal ingredients of an NHP must be substances set out in Schedule 1 to the NHPR, which is a list of included substances, substances that are traditional medicines or that are homeopathic medicines, and that none of the ingredients are substances set out on Schedule 2 which is a list of excluded substances, e.g. any substance listed on Schedules I to V of the Controlled Drugs and Substances Act. Section 2(2) of the NHPR excludes those substances (except homeopathic medicines) whose sale is required to be pursuant to a prescription as per Section C.01.043 and thus Schedule F to the F&DR. As per section 93(1)(b)(vi) of the NHPR, every natural health product must be labeled with its authorized recommended use or purpose. In the case of *S. divinorum*, it is generally marketed for its hallucinogenic properties which are considered a modification of an organic function. Therefore products containing it and manufactured, sold or represented for that purpose meet the definition of an NHP.

As of July 2010, no products containing *S. divinorum* have been reviewed and approved by Health Canada and no NPNs or DIN-HMs have been issued. Therefore sales of *S. divinorum* are

illegal under the NHPR if it is represented for use as a hallucinogen or if other health claims such as with regard to modifying organic functions are made.

#### 4.1.3 Controlled Drugs and Substances Act and its Regulations

The CDSA provides a legislative framework for the control of substances that can alter mental processes and that may produce harm to the health of an individual or to society when diverted or misused. Except as authorized under its regulations, activities such as possession, possession for the purposes of trafficking, trafficking, importation, exportation, possession for the purposes of exportation and production of controlled substances are prohibited under the CDSA.

The substances regulated under the CDSA are grouped into eight Schedules, and each Schedule is associated with particular offences and penalties as described in Part I of the CDSA.

In determining whether a substance should be regulated as a controlled substance, and into which Schedule of the CDSA it should be placed, Health Canada considers the following factors:

- International requirements and trends in the control and/or scheduling of the substance;
- Chemical and/or pharmacological similarity to substances listed in the Schedules to the CDSA;
- Legitimate use of the substance, including therapeutic, scientific, industrial or commercial uses;
- Potential for abuse and/or addiction liability of the substance;
- Evidence of extent of actual abuse of the substance in Canada and internationally; and
- Risk to personal and public health and safety.

#### 4.2 **Assessment of *Salvia Divinorum* for Scheduling Purposes**

##### 4.2.1 International Requirements and Trends in the Control and/or Scheduling of the Substance

At the present time, neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and therefore do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

##### ***Australia***

In June 2002, Australia became the first country to prohibit the sale, supply, possession and use of *S. divinorum* and salvinorin A. Although both *S. divinorum* and salvinorin A are listed in Schedule 9 of Australia's Standard for the Uniform Scheduling of Drugs and Poisons on the basis of "high potential for abuse and risk to public health and safety", no substantiation of this risk was provided at the time of this scheduling decision.<sup>3</sup> Schedule 9 is Australia's most restrictive drug schedule, and includes "substances which may be abused or misused, the

<sup>3</sup> <http://www.tga.gov.au/ndpsc/record/rr200111.pdf>



manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities.”<sup>4</sup>

### **Belgium**

A decree was passed in Belgium on October 22, 2006 which added *S. divinorum* to the list of controlled substances. This list includes substances such as psilocybin mushrooms, khat and peyote cactus.<sup>5</sup>

### **Denmark**

In 2003, Denmark added *S. divinorum* and salvinorin A to their list of “category B” controlled substances, a category which also includes psilocybin mushrooms, cocaine, amphetamine, and several others substances that are only legal for medicinal and scientific purposes. Illegal possession carries a penalty of up to two years in prison.

### **Germany**

*S. divinorum* (plant and plant parts) was added to Appendix I of the *Narcotics Act* in Germany on March 1, 2008, making it illegal to produce, traffic, or possess. The law does not specifically mention salvinorin A.

### **Italy**

On June 25, 2004, the Italian Ministry of Health issued an ordinance prohibiting the sale of *S. divinorum* and its active constituent salvinorin A. On January 11, 2005, the Ministry of Health made possession of *S. divinorum* and salvinorin A illegal by placing them in “*Tabella I*” of the *Tabella Sostanze Stupefacenti o Psicotrope*.

### **Japan**

On November 9, 2006, the Japanese government added a group of thirty-three drugs to its list of controlled substances, including salvinorin A. The drugs are banned under a revised pharmaceutical law, under which persons involved in their illegal import, production, and sale, i.e. beyond medical treatment or research purposes, will be subject to up to five years imprisonment or a fine of up to five million yen.

### **Spain**

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<sup>4</sup> [http://www.cognitiveliberty.org/news/salvia\\_australia.htm](http://www.cognitiveliberty.org/news/salvia_australia.htm)

<sup>5</sup>

<http://eldd.emcdda.europa.eu/html.cfm/index5176EN.html?pluginMethod=eldd.shownewsdetails&id=20/12/2006BELGIUM:%20New%20substances%20controlled%20include%20mCPP%20and%20khat>

On January 28, 2004, the Spanish Ministry of Health and Consumption issued an order prohibiting the sale of *S. divinorum*. The regulation went into effect on May 6, 2004 and only prohibits activities related to commerce. Possession and/or use are not considered to be criminal offences.

#### ***Other Countries***

*Salvia divinorum* is illegal to possess or sell in Croatia, Latvia, Lithuania, Poland, Romania, South Korea and Sweden. In Russia it is illegal to grow or sell *S. divinorum*, but it is legal to possess it. In Estonia, Finland, Iceland and Norway, *S. divinorum* is treated as a medicinal herb and it is illegal to import it without a relevant prescription from a doctor.

#### ***United States of America***

*S. divinorum* and salvinorin A are not included in the Schedules to the United States *Controlled Substances Act* although both *S. divinorum* and salvinorin A have been added to a list of chemicals "of concern" which has no legal implications.. In addition, some individual states have implemented laws restricting its use, sale and/or distribution. As of July 2010, a number of states have enacted legislation placing regulatory controls on *S. divinorum* and/or salvinorin A including Delaware, , Georgia, Florida, Hawaii, Illinois, Kansas, Kentucky, Maryland, Mississippi, Missouri, Nebraska, North Dakota, Ohio, Oklahoma, South Dakota, Wisconsin, Virginia, California, Louisiana, Maine, North Carolina, and Tennessee. More details regarding the regulation of *S. divinorum* in these last five states are provided below.

##### ***California***

As of January 1, 2009, the sale or distribution of *S. divinorum* or salvinorin A, or any substance or material containing *S. divinorum* or salvinorin A, to any person under 18 years of age is a misdemeanor punishable by imprisonment in a county jail for not more than six months, a fine of no more than \$1,000, or both.

##### ***Louisiana***

In 2005, Louisiana passed a bill which prohibits the possession, production, manufacture and distribution of a material, compound, mixture, or preparation intended for human consumption and that contains a hallucinogenic plant. A "hallucinogenic plant" is defined as "any part or portion" of a plant on a list of forty plants, which includes *S. divinorum*.

##### ***Maine***

In Maine, *S. divinorum* and salvinorin A are regulated in the same way as tobacco products; adults eighteen years of age or over can legally purchase and use the material, but selling or providing *S. divinorum* or salvinorin A to anyone under the age of eighteen

is a criminal offence. Possession by a minor is a civil violation, punishable by a fine, community service, or both.

### *North Carolina*

On December 1, 2009, the North Carolina State Legislature brought a new law into force which made *Salvia divinorum* and salvinorin A illegal. The only legal *S. divinorum* activities are the growing for aesthetic, landscaping, or decorative purposes or university-affiliated medical or pharmacological research.

### *Tennessee*

On July 1, 2006, Tennessee classified the deliberate production, manufacture, distribution, or possession of the active chemical ingredient in the hallucinogenic plant *S. divinorum* as a Class A misdemeanor. It is not, however, a criminal offence to possess, plant, cultivate, grow, or harvest *S. divinorum* for aesthetic, landscaping, or decorative purposes. The law also does not apply to any dosage that is legally obtainable from a retail establishment without a prescription when (and if) it is recognized by the Food and Drug Administration as a homeopathic drug.

#### 44.2.2 Chemical and/or Pharmacological Similarity to Substances Listed in the Schedules to the CDSA

The psychoactive ingredient in *Salvia divinorum* is the neoclerodane diterpene salvinorin A {need reference}. Other plants which contain psychotropic terpenoids are *Artemisia absinthium* (wormwood) and *Cannabis sativa* {reference needed}. Salvinorin A is considered by some as the most potent natural hallucinogen ever isolated.<sup>6</sup>

Unlike all other hallucinogens, salvinorin A is structurally distinct and does not interact with the serotonin-2A receptor or any other molecular target of classical hallucinogens {reference?}. Instead, the available research suggests the psychotropic effects of salvinorin A are mediated by its agonistic actions at  $\kappa$ -opioid (KOR) receptor.<sup>7</sup> Its mechanism of action is therefore unique.<sup>8</sup>

The psychoactive effects of *S. divinorum* vary in onset and duration and include the sensation of becoming an object, visions of various two-dimensional surfaces, films and membranes, revisiting places of the past (particularly childhood), perceived loss of the body and/or identity,

<sup>6</sup> Ott J. Ethnopharmacognosy and human pharmacology of *Salvia divinorum* and salvinorin A. *Curare*. 1995 18: 103-129. Unofficial transcription available online. URL <http://www.sagewisdom.org/ott2.html>

<sup>7</sup> Roth BL, Baner K, Westkaemper R, Siebert D, Rice KC, Steinberg S, Ernsberger P, Rothman RB. Salvinorin A: a potent naturally occurring nonnitrogenous kappa opioid selective agonist. *Proc Natl Acad Sci U S A*. 2002 Sep 3;99(18):11934-9.

<sup>8</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>10</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

**Comment [HABR1]:** What is the potency relative to other hallucinogens?

**Deleted:** It thus affects the brain in a way that is quite unique

**Deleted:** Recent pharmacological screenings of receptors have found it to be a highly potent and selective  $\kappa$ -opioid receptor (KOR) agonist.

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**Deleted:** The use of *S. divinorum* or salvinorin A can lead to a number of effects with variable onset and duration. These effects are generally accepted to

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various sensations of motion (being pulled or twisted by a force of some kind), uncontrollable hysterical laughter, and overlapping realities (perceptions of being in more than one place).<sup>10</sup> Laughter, happiness, sense of well-being and dissociative effects were deemed the most positive aspects of *S. divinorum* by users, second only to the "trip" that the drug elicits.<sup>11</sup> Depersonalization, speaking gibberish, widening of consciousness and subjective illusions of rapid movement, flying or hovering have also been reported.<sup>12</sup>

The psychotomimetic effects of *S. divinorum* closely resemble schizoid symptoms induced by lysergic acid diethylamide (LSD) or phencyclidine (PCP).<sup>13</sup> Yet, it is said to have only weak influence on the prevailing mood of the user which differentiates it from other hallucinogens such as LSD and psilocybin.<sup>14</sup> Its strong dissociative effects are often compared to those of ketamine {reference needed}. Users have reported that the psychedelic effects of *S. divinorum* were most similar to those caused by psilocybin mushrooms.<sup>15</sup> However, users familiar with the effects of other hallucinogens agree that despite certain similarities to classical hallucinogens, the visions and overall experience are quite unique.<sup>16</sup>

Comment [HABR3]: Definition ?

*S. divinorum* causes an unusually high degree of sedation, weakness and fatigue, while the increased de-realization is not commonly reported for classical psychedelics.<sup>17</sup> The combination of these effects seems to correlate with that of other KOR agonists such as pentazocine.<sup>18</sup>

Comment [HABR4]: Are these psychedelic effects??

The onset and intensity of the effects of *Salvia divinorum* appear to be related to the route of administration. Traditional uses generally produce mild effects because the leaves are rolled and chewed or crushed and prepared as a foamy infusion whereby the salvinorin A is degraded in the gastrointestinal system before being absorbed into the bloodstream. Hence, the level of effect relates quite closely to the length of time the material spends in the mouth, with the onset of

<sup>11</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>12</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry.* 2005 Jan;38(1):1-5 and Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>13</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry.* 2005 Jan;38(1):1-5.

<sup>14</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>15</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>16</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6 and González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>17</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>18</sup> Arasteh K, Poudevida S, Farre M, Roset PN, Cami J. Response patterns of the Spanish version of the 49-item short form of the Addiction Research Center Inventory after the use of sedatives, stimulants, and opioids. *Drug Alcohol Depend.* 1999 Jun 1;55(1-2):117-25.

effect generally taking 5-10 minutes. The effects build over the next hour and last for another hour before they begin to subside.<sup>19</sup>

Routes of administration that avoid the hepatic first-pass effect (i.e. inhalation, intravenous, intramuscular and sublingual use) are the quickest and most intense.<sup>20</sup> Salvinorin A can be isolated from the plant to make a powder which can be vaporized and inhaled. The onset of effects felt from vaporizing salvinorin A powder occurs in about 30 seconds and effects last for about 5-10 minutes and then subside over the next 30 minutes.<sup>21</sup>

Smoking is by far the most popular method of administration<sup>22</sup> and this is accomplished by smoking the dried leaves or a concentrated extract using a pipe or bong. Dried leaves may also be fortified with a concentrated extract of salvinorin A. A concentrated extract can also be used sublingually. Neither *S. divinorum* nor salvinorin A can be injected because the powder is insoluble in water.<sup>23</sup>

#### 4.2.3 Legitimate Use of the Substance, including Therapeutic, Scientific, Industrial or Commercial Uses

*Salvia divinorum* has traditionally been used for spiritual and medicinal purposes by the Mazatec Indians in Oaxaca, Mexico,<sup>24</sup> where an infusion of the leaves or the leaves themselves are ingested to treat gastrointestinal problems, headaches, rheumatism, anemia and swelling of the stomach.<sup>25</sup> Its main use today is, however, for its psychedelic properties in the aid of producing "mystical" or hallucinogenic experiences as part of spiritual rituals.<sup>26</sup>

Although selective kappa receptor agonists have been shown to produce analgesic effects, adverse effects such as psychotomimesis, dysphoria and diuresis have been observed in studies investigating their therapeutic use.<sup>27</sup> In addition, while it has been speculated that KOR agonists

<sup>19</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>20</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.

<sup>21</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>22</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62 and Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>23</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs.* 1994 Jul-Sep;26(3):277-83.

<sup>24</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>25</sup> Munro, T. The Chemistry of *Salvia divinorum*. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

<sup>26</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage *Salvia divinorum*. *Life Sci.* 2005 Dec 22;78(5):527-31.

<sup>27</sup> Barker RL, Fawcett J, Barkin SJ. 2002. Chronic pain management with a focus on the role of newer antidepressants and centrally acting agents. In: *Pain Management: A Practical Guide for Clinicians*, 6th edition,

may be useful in the treatment of certain psychiatric disorders including Alzheimer's disease, schizophrenia, dementia and bipolar disorder, <sup>28</sup> much more research is needed in order to substantiate these hypotheses. Similarly, another study has suggested that chemical analogues of salvinorin A may be a useful treatment for those suffering from addiction to other substances. <sup>29</sup> That said there are presently no legitimate medical uses for *S. divinorum* in Canada.

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Similarly, there are no known industrial or commercial uses for *S. divinorum* in Canada. The plant is a semi-tropical perennial that can only grow outdoors in a humid climate where it will not encounter frost. Most websites offering *S. divinorum* cuttings and seeds for sale appear to do so in the context of growing the plant for "recreational" purposes, rather than out of horticultural interest or for its esthetic appeal.

Comment [HABR5]: So?

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#### 4.2.4 Potential for Abuse and/or Addiction Liability of the Substance

Salvinorin A is a potent, selective agonist of the  $\kappa$ -opioid receptor (KOR), and in contrast to the euphoria produced by  $\mu$ -opioid receptor (MOR) agonists such as morphine, KOR agonists are negatively reinforcing and aversive. <sup>30</sup> In addition, KOR agonists have analgesic properties but are not associated with respiratory depression like MOR agonists. Finally, while MOR agonists increase the release of dopamine, the activation of KOR decreases dopamine release in the nucleus accumbens. <sup>31</sup>

Comment [HABR6]: This paragraph needs a sentence or two which links these scientific findings to a rationale for why salvia is not addictive. There is much scientific information here but it needs to be explained. For example, why is the decrease in dopamine release in the nucleus accumbens important? What does this have to do with addiction or abuse?

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Weiner RS ed. CRC Press, Boca Raton, FL. pp. 415-34 and Tidgewell et al., 2004. A facile method for the preparation of deuterium labelled salvinorin A: *Biorganic & Medicinal Chemistry Letters*, 14: 5099-5102.

<sup>28</sup> Sheffler DJ & Roth BL. Salvinorin A: the 'magic mint' hallucinogen finds a molecular target in the kappa opioid receptor. *Trends Pharmacol Sci.* 2003 Mar;24(3):107-109.

<sup>29</sup> Prisinzano TE. Natural products as tools for neuroscience: discovery and development of novel agents to treat drug abuse. *J Nat Prod.* 2009 Mar 27;72(3):581-7.

<sup>30</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590, Cooper S. Interactions between endogenous opioids and dopamine: Implications for reward and aversion. In: *The Mesolimbic Dopamine System: From Motivation to Action*. Willner P and Scheel-Kruger J (editors) Wiley, Chester, England, 1991, pp. 331-366, and Shippenberg TS, Herz A, Spanagel R, Bals-Kubik R, Stein C. Conditioning of opioid reinforcement: neuroanatomical and neurochemical substrates. *Ann N Y Acad Sci.* 1992 Jun 28;654:347-56.

<sup>31</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.

<sup>37</sup> Bucheler R, Gleiter CH, Schworer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry.* 2005 Jan;38(1):1-5.

The aversive effects of KOR agonists suggest that the risk of addiction to *S. divinorum* is negligible. However, very few controlled scientific studies of the physical and psychotropic effects of *S. divinorum* on humans have been carried out. Therefore, it is difficult to predict with certainty its potential for addiction and abuse. In studies that have been conducted, there is conflicting information around the addiction liability of *S. divinorum* in both animals and humans. Some users have noted that they require increasing doses of salvinorin A in order to achieve the desired effect and the stimulated cerebral KOR may act as a mechanism of tolerance.<sup>37</sup> Further studies in this area and on the mediated decrease of dopamine as well as the impact of dose on effects are also required.

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While concerns for the potential of abuse were once minimal because 1 kg of dried leaves yields only 3 to 6 human doses of salvinorin A, it was discovered that vaporizing and inhaling 200-500 micrograms had profound hallucinogenic effects.<sup>38</sup> The extraction of salvinorin A from the plant is simple, and with care, approximately 1.5 grams of pure salvinorin A per kilogram of dried leaves (8kg of fresh leaves) can be isolated. This is enough for 2000 human doses.<sup>39</sup>

Comment [HABR7]: Can this sentence be summarized somehow and made more convincing? So what we're trying to say is that the potential for abuse is high because we need very small doses.

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#### 4.2.5 Evidence of Extent of Actual Abuse of the Substance in Canada and Internationally

In Canada, the extent of actual abuse of *Salvia divinorum* and/or salvinorin A is relatively unknown. There is, however, some data regarding the prevalence of use of *Salvia divinorum* in Canada, despite the lack of legitimate uses for this plant. Questions about the use of *S. divinorum* were included in the 2009 Ontario Student Drug Use and Health Survey, the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey.

The results from the 2009 Ontario Student Drug Use and Health Survey were published on November 18, 2009 and indicate that:

- Among all responding students in Ontario, 4.4% reported using *Salvia divinorum* at least once in the past year. In comparison, 58.2% indicated they had used alcohol, 25.6% indicated they had used cannabis and 5.0% indicated they had used hallucinogens other than LSD and PCP in the past year;
- Males (6.2%) were significantly more likely than females (2.3%) to report using *Salvia divinorum*;
- There is significant grade variation, with *Salvia divinorum* use most likely among 11<sup>th</sup> graders (8.6%) and 12<sup>th</sup> graders (8.4%); and
- There are significant regional variations, with students in Northern Ontario (9.2%) most likely to use *Salvia divinorum*.

<sup>38</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>39</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs.* 1994 Jul-Sep;26(3):277-83.

The results of the 2008-2009 Youth Smoking Survey were published on May 31, 2010 and indicate that:

- 4.9% of students stated that they had used *S. divinorum* in the last twelve months. In comparison, 53.0% indicated they had used alcohol, 27.3% indicated they had used cannabis and 6.9% indicated they had used other hallucinogens in the last twelve months;
- 2.6% of students in Grades 7-9 and 7.0% of students in Grades 10-12 had used *S. divinorum* in the last twelve months; and
- Males (6.6%) were more likely to have used *S. divinorum* in the past twelve months compared to females (3.2%).

The scope of the previously mentioned studies did not provide for any explanations regarding differences in usage between ages, genders and regions. In this regard, it is difficult to speculate on the causality of such differences.

The Canadian Alcohol and Drug Use Monitoring Survey specifically examined Salvia for the first time in 2009. An estimated 1.6% of Canadians, aged 15 years and older, reported that they had used salvia in their lifetime, and 0.2% reported using it in the past-year. In comparison, the prevalence of past-year cannabis use among Canadians 15 years of age and older was 10.6%. 1.2% of respondents reported using cocaine or crack in the past 12 months, 0.9% had used ecstasy and 0.7% used illicit hallucinogens.

Health Canada's Drug Analysis Services (DAS) has identified salvinorin A in a number of samples seized by law enforcement, as shown in the following table.

**NUMBER OF SAMPLES FOUND TO CONTAIN SALVINORIN A**

Year	Count
2006	9
2007	8
2008	4
2009	20
2010 (as of May 7)	8

**Comment [HABRS]:** Why is this important? What is the message we are trying to convey here?

The National Forensic Laboratory Information System (NFLIS) and the System to Retrieve Information from Drug Evidence (STRIDE) in the United States are Drug Enforcement Agency (DEA) databases that collect scientifically verified data on analyzed samples in state and local forensic labs as well as samples from DEA labs. The following table shows the quantity of *S. divinorum* products that were seized from 2000 through to 2009.

**ANALYZED SALVIA DIVINORUM or SALVINORIN A SEIZURES**

(Number of Items/Exhibits)

Source	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009*
NFLIS-State/Local <sup>1</sup>	0	0	0	0	1	8	12	12	70	34



<b>STRIDE<sup>2</sup></b>	0	0	1	1	1	0	0	0	N/A	N/A
<b>TOTAL</b>	0	0	1	1	2	8	12	12	70	34

Data Source: NFLIS & STRIDE, 2008 data queried 11/24/08, updated 06/10/2010

<sup>1</sup> NFLIS reported seizures of *Salvia divinorum* and/or salvinorin A

<sup>2</sup> STRIDE reported items of *Salvia divinorum*.

\* Includes only January – May data in 2009.

It is difficult to determine the extent of actual abuse of *S. divinorum* in Canada or elsewhere as there appear to be inconsistencies in the literature regarding risk aversion. For example, one author states: "Many who have used salvinorin A find the experience extremely unnerving, frightening and overly intense and most have no desire to repeat the experience."<sup>40</sup> However, another study suggested that this is not the experience of all recreational users of *S. divinorum*.<sup>41</sup> Over eighty percent of users surveyed on a web-based questionnaire about their *S. divinorum* use said that they would probably or definitely use *S. divinorum* again.<sup>42</sup> Users have reported the negative effects of *S. divinorum* as: the short duration of action, lack of control over the experience, persisting negative effects (most often anxiety),<sup>43</sup> sweating, chills, increased diuresis, impaired vigilance,<sup>44</sup> and negative after-effects including tiredness, feeling head heavy, dizziness, physical exhaustion, and some degree of malaise or 'hangover' as they 'comedown' from the drug.<sup>45</sup>

**Comment [HABR9]:** Why is this here at the end and what is its connection to seizure data? This should be placed higher up in the section.

#### 4.2.6 Risk to Personal and Public Health and Safety

The increase in both the number of enquiries from various municipalities and members of the public and the amount of media interest regarding the availability of *Salvia divinorum* in Canada may be an indication that the recreational use of *S. divinorum* as a hallucinogen is on the rise. However, there are no available statistics that indicate there has been a significant increase in *S. divinorum* use in the Canadian population and, in comparison to the use of other drugs such as alcohol and cannabis, the actual use of *S. divinorum* is quite low.

The potential for harm to the user and/or other individuals is primarily related to the hallucinogenic properties of the substance. Users may get up and walk around without apparent awareness of their movements, behaviour or surroundings, and distinction between self and surroundings is often lost. At doses greater than 1mg of salvinorin A, out of body experiences

<sup>40</sup> Turner DM. Salvinorin - The Psychedelic Essence of Salvia Divinorum. Panther Press, San Francisco, CA 1996.

<sup>41</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62, Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5, and Valdès LJ 3rd. Salvia divinorum and the unique diterpene hallucinogen, Salvinorin (divinorin) A. J Psychoactive Drugs. 1994 Jul-Sep;26(3):277-83.

<sup>42</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>43</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>44</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5.

<sup>45</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

are frequent and loss of consciousness has been reported.<sup>46</sup> There is little information regarding the social behaviours of persons under the influence of *S. divinorum* products, and what risks their activities such as operating a motorized vehicle may pose to the general public. There is also very little data regarding the toxicity, teratogenicity or other long-term effects of *S. divinorum* use.<sup>47</sup>

As far as law enforcement is concerned, the Department has only received a limited number of communications indicating concern with respect to *S. divinorum* and none of these have advised that the use of *S. divinorum* poses any threat to public safety. The Royal Canadian Mounted Police (RCMP) has stated that while *S. divinorum* is readily available, it has not become a popular drug in Canada, probably due to its aversive effects such as anxiety and introversion.

A handful of case reports regarding the physiological and psychotropic effects of *S. divinorum* use have been published in the academic literature. An international case report described the perceptions of a 19 year-old man after inhaling *S. divinorum* smoke. The peak psychotropic effects, including prickling of the skin, fever-like hot flashes, muscular tremor, and depersonalization, were reached in less than five minutes after inhalation of an unknown amount of smoke from burning dried leaves.<sup>48</sup> Another report involved a 15-year-old male who presented to psychiatric emergency services with acute onset of paranoia, déjà vu, blunted affect, difficulties in thought processing and slowed speech after smoking *Salvia divinorum* over an unknown period of time. During his hospitalization all symptoms improved significantly except the feeling of déjà vu. Based on this case presentation, the author suggested that the feelings of déjà vu may be a long-term effect of *S. divinorum* use.<sup>49</sup> However, given that this is the only case report in which déjà vu was associated with the use of *S. divinorum*, more reports are needed to substantiate this finding.

In addition to the above-mentioned reports, in 2006, a case was reported in the U.S. in which a 17-year-old boy committed suicide after smoking *S. divinorum* for an unknown period of time.<sup>50</sup> It should be noted that alcohol and general depression were the main confounders in this case. After this case was reported, the state of Delaware passed a law which classified *S. divinorum* as a Schedule I controlled substance along with other hallucinogenic substances.

Like many drugs of abuse, users are often unaware of the potency and adulterants in the product they purchase. A study by Wolowich *et al.* (2006)<sup>51</sup>, showed that the salvinorin A content in five out of five *S. divinorum* products was falsely indicated on the label and 4 out of 5 products contained unidentified adulterants (i.e. vitamin E, caffeine).

Health Canada has only anecdotal information about the use and abuse of *S. divinorum* in Canada

<sup>46</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>47</sup> Grundmann O, Phipps SM, Zadezensky I, Butterweck V. *Salvia divinorum* and Salvinorin A: An Update on Pharmacology and Analytical Methodology. *Planta Med* 2007 Jun;73:1039-1046.

<sup>49</sup> Singh S. (2007) Adolescent salvia substance abuse. *Addiction.* 102, 823-824.

<sup>50</sup> <http://www.kvbc.com/Global/story.asp?S=4893692>

<sup>51</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.

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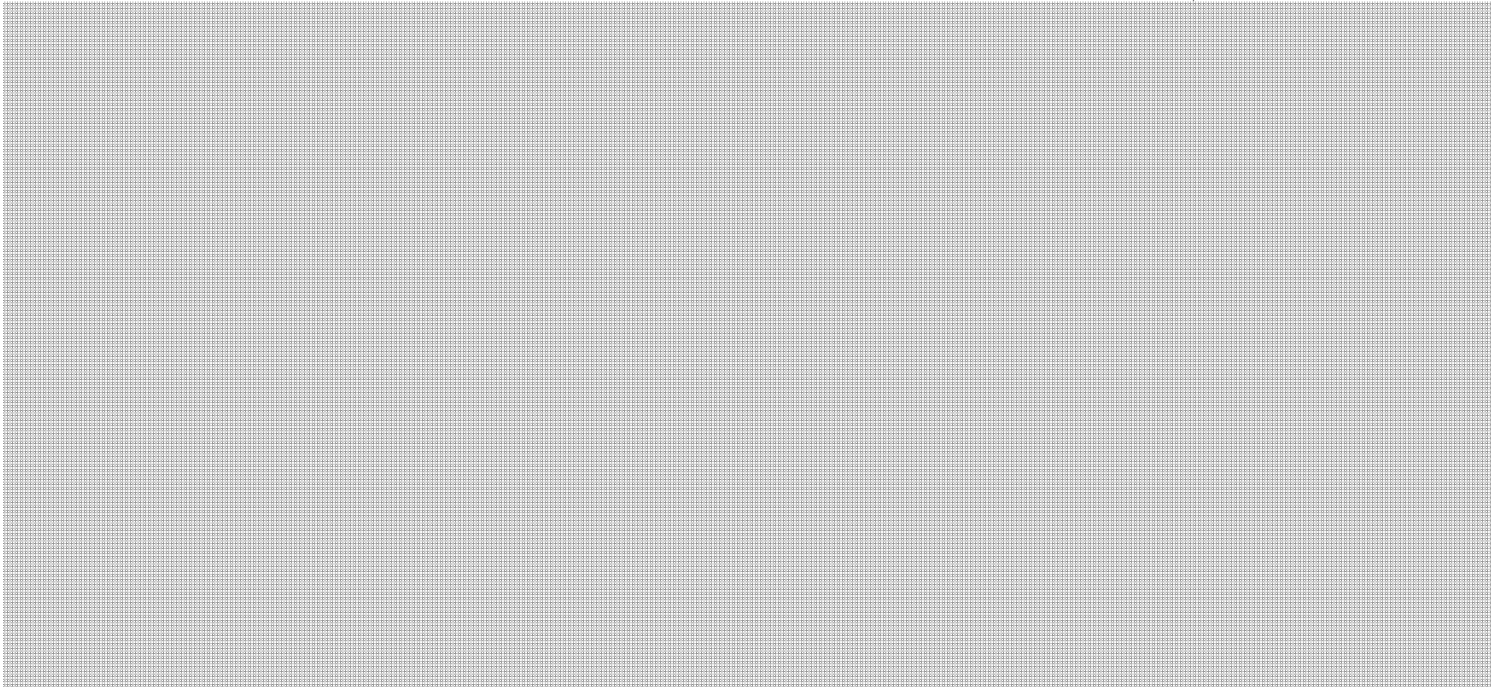
as well as the threat *S. divinorum* may pose to the health and safety of Canadians. There are several reports of domestic adverse reactions related to the use of *S. divinorum* that have been received through the Canada Vigilance database. However, this does not reflect true incidence due to under-reporting. Considering also the limited population exposure information, it is not possible to adequately characterize the risk to the general population.

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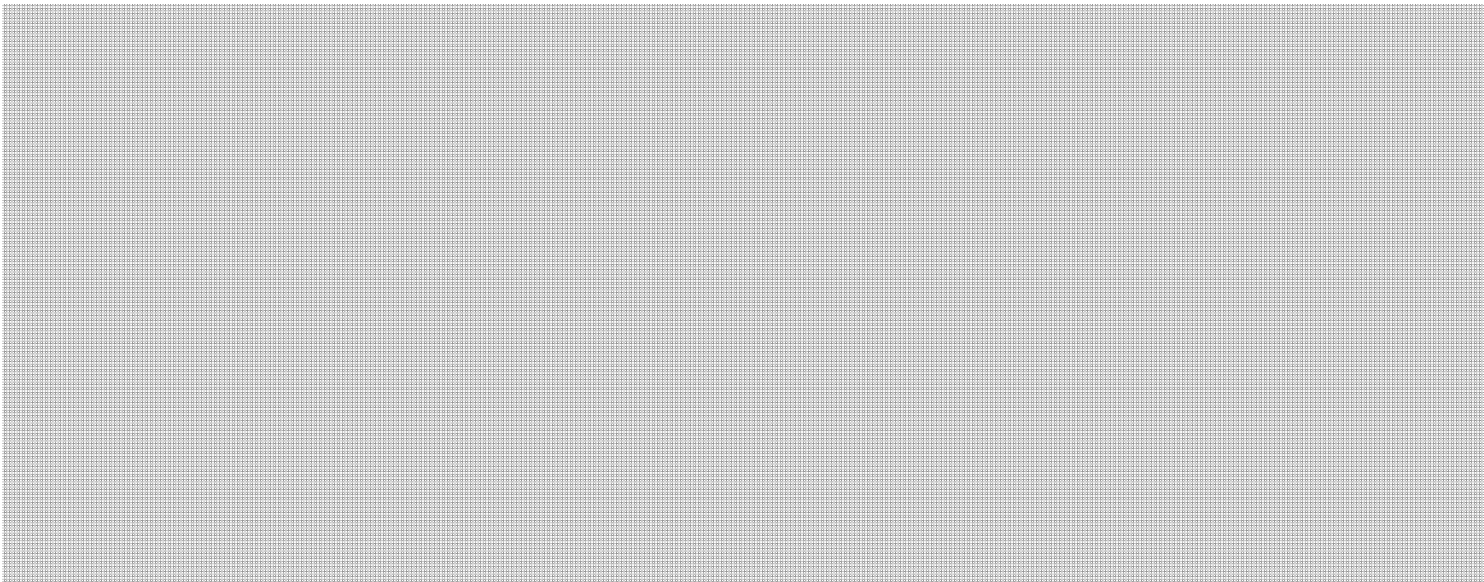
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## 5. ASSESSMENT OF RISKS AND BENEFITS



## 6. IDENTIFICATION AND ANALYSIS OF OPTIONS



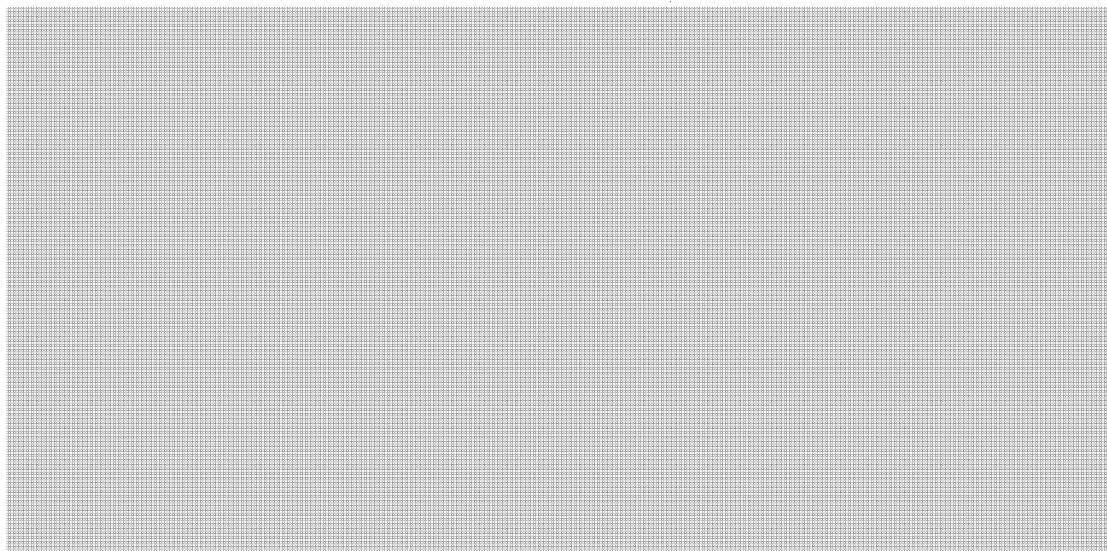
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**of the Access to Information Act  
de la Loi sur l'accès à l'information**

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## 7. CONSIDERATIONS

The KOR-mediated aversive and dysphoric effects of *Salvia divinorum* do not appear to be hampering its use as young adults have begun smoking the leaves and leaf extract recreationally.<sup>52</sup> It can be purchased through online botanical companies and other drug promotion sites and is often touted as a legal alternative to substances such as cannabis and mescaline.<sup>53</sup> Interestingly, after being widely available for over a decade, the drug does not appear to have had the same social impact as LSD or ecstasy.<sup>54</sup>

While there has been an increase over the past few years in the number of enquiries from various municipalities and members of the public regarding the availability of *Salvia divinorum* as a hallucinogen, according to available statistics, the reported use of *S. divinorum* by young Canadians is much lower than that of alcohol or cannabis.

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The NHPR are limited in their capacity to control the availability of *S. divinorum* in that *S. divinorum* products are often declared as incense and therefore cannot be considered unapproved natural health products. In addition, compliance and enforcement actions such as voluntary stop-sales, forfeiture, destruction, and administrative seizure, cannot be implemented unless the labeling of the product indicates that it is to be used for human consumption and can modify an organic function.

The previous HPFB recommendation to schedule *S. divinorum* under the CDSA was likely based on a misunderstanding of the (previously-described) criteria upon which scheduling decisions are made within the Healthy Environments and Consumer Safety Branch (HECSB). In particular, it did not consider a number of factors, including potential for abuse and risk to public health and

<sup>52</sup> Hazelden Foundation, 2004. Drug Abuse Trends. June 2004. URL: [www.research.hazelden.org](http://www.research.hazelden.org).

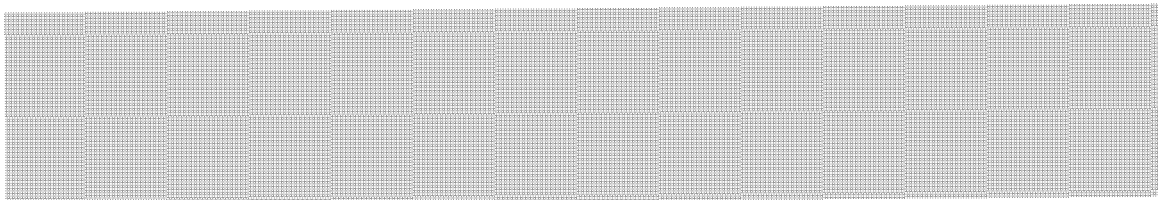
<sup>53</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

<sup>54</sup> Munro, T. The Chemistry of *Salvia divinorum*. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

safety. The Office of Controlled Substances (OCS) was also not consulted by HPFB at the time this recommendation was made. In addition, among countries who have decided to control *S. divinorum* in some way, very little or no substantiation of the risks of *S. divinorum* upon which the decision was based are available.

Neither *Salvia divinorum* nor salvinorin A meet the criteria for scheduling a substance under the CDSA. Despite being regulated in some jurisdictions, neither the plant nor salvinorin A are scheduled under any of the UN Drug Control Conventions. *S. divinorum* and salvinorin A are not structurally or pharmacologically similar to other substances included in the schedules to the CDSA. There are also currently no legitimate therapeutic or industrial uses for *S. divinorum*. The abuse liability and potential for dependence of *S. divinorum* is not known as very few controlled scientific studies of its physical and psychotropic effects have been carried out on humans. The extent of actual abuse of *S. divinorum* is also largely unknown. Evidence of a risk to public health and safety is anecdotal in nature and not quantified in any way as there is a lack of information regarding abuse in Canada.

## 8. RECOMMENDATIONS



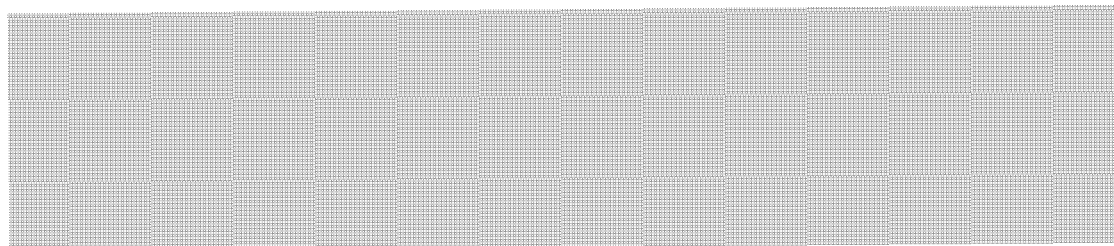
## 9. CONSULTATIONS

The Drug Analysis Services (DAS) was contacted in order to provide any data available regarding the identification of salvinorin A in samples submitted by law enforcement.

The Royal Canadian Mounted Police (RCMP) was contacted in order to establish their views with respect to *S. divinorum* use in Canada. The RCMP advised that though *S. divinorum* is readily available, it does not appear to pose a threat to public safety.

OCS has received a number of correspondences from Canada Border Services Agency (CBSA) officers concerning a lack of information regarding the status of *S. divinorum* and how the plant should be treated at the border. CBSA officers have also expressed concern regarding the plant's hallucinogenic properties. At present, only shipments of *S. divinorum* that are represented as health products that modify organic functions can be refused for import under the NHPR.

## 10. IMPLEMENTATION AND EVALUATION



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**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**

# Issue Analysis Summary

DRAFT

## Scheduling *Salvia Divinorum* and/or Salvinorin A under the CDSA

Policy and Regulatory Affairs Division

Office of Controlled Substances

Controlled Substances and Tobacco and Directorate

July 12, 2010

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#### 1. APPROVALS

This Issue Analysis Summary is approved.

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Diane Allan, Director  
Office of Controlled Substances  
Tobacco and Drugs Directorate

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[DD/MM/2010]

#### 2. ISSUE

Health Canada has received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *S. divinorum* and/or its main active ingredient salvinorin A, neither of which are currently regulated under the *Controlled Drugs and Substances Act* (CDSA). These requests are further to reports from scientific and media sources suggesting that *S. divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has also noted an

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ongoing media interest regarding the availability of *S. divinorum* in Canada.

### 3. PURPOSE

To assess *Salvia divinorum* and/or salvinorin A against the criteria for the addition of a substance to one of the Schedules to the CDSA, and determine whether one or both should be regulated as controlled substances in Canada.

### 4. CONTEXT

*Salvia divinorum* is a species of sage which belongs to the mint family, and which is found in the form of dried leaves, extract and plant cuttings. Also known as "diviner's sage", the plant is known to induce illusions and hallucinations when chewed or smoked. Salvinorin A, the psychoactive ingredient in *S. divinorum* (also referred to chemically as a neoclerodane diterpene) is found primarily in the leaves, and to a lesser extent in the stems.<sup>1</sup>

*S. divinorum* is widely touted as a "legal" hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs among adolescents and young adults.<sup>2</sup> While very little is known about how and where *S. divinorum* is sold in Canada, it is suspected that it is mainly purchased over the Internet and/or bought at head shops or alternative life style stores, etc.

The use of *S. divinorum* as a psychotropic agent first came to Health Canada's attention in 2002. In 2004, Health Canada received four adverse drug reaction (ADR) reports associated with the use of *S. divinorum* as a hallucinogen, with three being considered non-serious (requiring no medical attention) and the fourth being considered serious (medical intervention was required). The serious ADR report involved the concomitant use of alcohol in a person diagnosed with Attention Deficit Disorder.

Further to the receipt of the aforementioned ADRs, the Marketed Health Products Directorate (MHPD) and the Natural Health Products Directorate (NHPD) of the Health Products and Food Branch (HPFB) prepared an issue analysis summary (IAS), which recommended that *S. divinorum* and its active ingredient salvinorin A be regulated as controlled substances. This recommendation was maintained when the IAS was updated in November 2006.

Later, in December 2005, MHPD and NHPD prepared a Signal Assessment (SA) (updated in June 2007) that eventually led to the preparation of a Health Risk Assessment (HRA), which concluded that *S. divinorum* or salvinorin A-containing health products would constitute a Type II Health Risk according to the Health Hazard Classification of the Recall Policy of the Health

<sup>1</sup> U.S. Department of Justice Drug Enforcement Administration. 2002. Drugs and Chemicals of Concern: Salvia Divinorum (salvinorin A, divinorin A) URL:

[http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm) Nov 2008

<sup>2</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.

Products and Food Branch Inspectorate (HBFBI). Such a risk is defined as “a situation in which the use of, or exposure to, a product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote”.

Further to an Assistant Deputy Minister (ADM) discussion in April 2007, the Drug Strategy and Controlled Substances Directorate (DSCSD) organized a meeting with MHPD, NHPD and HPFBI to discuss *S. divinorum*. HPFBI was to determine appropriate compliance activities regarding *S. divinorum* and consult with the Canada Border Services Agency (CBSA) regarding the movement of products containing *S. divinorum* into and out of Canada.

On September 13, 2007, a further meeting between DSCSD, MHPD, NHPD and HPFBI led to the conclusion that DSCSD would conduct a scheduling assessment of *S. divinorum* in order to explore the possibility of scheduling this substance under the CDSA.

In September 2008, the Director Generals of DSCSD, MHPD, TPD and the HPFBI agreed that media lines and an “It’s Your Health” article on *S. divinorum* would be prepared.

#### **4.1 Relevant Legislative Frameworks in Canada**

##### **4.1.1 Food and Drug Regulations (under the Food and Drugs Act)**

The *Food and Drug Regulations* (F&DR) serve to ensure the safety, efficacy, and quality of health products offered for sale in Canada, including drugs and medical devices. Prior to being given market authorization, a manufacturer must present substantive scientific evidence that a product is safe, efficacious and of high quality. For drugs, Health Canada reviews this information carefully and, if the review is satisfactory, a Notice of Compliance (NOC) is issued and appropriate Drug Identification Numbers (DINs) are assigned.

A “drug” is defined under the F&DR as any substance or mixture of substances manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
- (b) restoration, correction or modification of organic functions in human beings or animals, or
- (c) disinfection in premises in which food is manufactured, prepared or kept;

As no products containing *S. divinorum* or its extracts have been reviewed and approved by Health Canada as of July 2010, it is illegal to market *S. divinorum* when it is represented as a drug.

#### 4.1.2 Natural Health Products Regulations (under the Food and Drugs Act)

The *Natural Health Products Regulations* (NHPR) aim to provide Canadians with ready access to natural health products (NHPs) that are safe, effective, and of high quality, while respecting freedom of choice and philosophical and cultural diversity. The NHPR require that all licensed products display a Natural Product Number (NPN), or, in the case of a homeopathic medicine, Drug Identification Number - Homeopathic Medicine (DIN-HM), on their labels. These numbers are issued once a product is authorized for sale in Canada further to a *natural health product monograph* or submission of other evidence of safety and efficacy. The NHPR also require that all manufacturers, packagers, labelers, and importers be licensed which in turn requires the presence of procedures respecting distribution records, product recalls, product handling, storage and delivery, and manufacturing practices.

The definition of an NHP under the NHPR has both a function and substance component. The function component refers to those substances that are manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
- (b) restoring or correcting organic functions in humans; or
- (c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

The substance component refers to whether the product or medicinal ingredient therein is safe for consideration as an over-the-counter product, can be available for self-care and self-selection, and does not require a prescription to be sold. To be considered a NHP, no direct health claims need to be made regarding the substance. In the case of *S. divinorum*, it is generally marketed for its hallucinogenic properties which are considered a modification of an organic function. Therefore products containing it meet the definition of a NHP.

As of July 2010, no products containing *S. divinorum* have been reviewed and approved by Health Canada and no NPNs or DIN-HMs have been issued. Therefore sales of *S. divinorum* are illegal under the NHPR if it is represented for use as a hallucinogen or if other health claims in regards to modifying organic functions are made.

#### 4.1.3 Controlled Drugs and Substances Act and its Regulations

The CDSA provides a legislative framework for the control of substances that can alter mental processes and that may produce harm to the health of an individual or to society when diverted or misused. Except as authorized under its regulations, activities such as possession, possession for the purposes of trafficking, trafficking, importation, exportation, possession for the purposes of exportation and production of controlled substances are prohibited under the CDSA.

The substances regulated under the CDSA are grouped into eight Schedules, and each Schedule is associated with particular offences and penalties as described in Part I of the CDSA.

In determining whether a substance should be regulated as a controlled substance, and into which Schedule of the CDSA it should be placed, Health Canada considers the following factors:

- International requirements and trends in the control and/or scheduling of the substance;
- Chemical and/or pharmacological similarity to substances listed in the Schedules to the CDSA;
- Legitimate use of the substance, including therapeutic, scientific, industrial or commercial uses;
- Potential for abuse and/or addiction liability of the substance;
- Evidence of extent of actual abuse of the substance in Canada and internationally; and
- Risk to personal and public health and safety.

## **4.2 Assessment of *Salvia Divinorum* for Scheduling Purposes**

### **4.2.1 International Requirements and Trends in the Control and/or Scheduling of the Substance**

At the present time, neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and therefore do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

#### ***Australia***

In June 2002, Australia became the first country to prohibit the sale, supply, possession and use of *S. divinorum* and salvinorin A. Although both *S. divinorum* and salvinorin A are listed in Schedule 9 of Australia's Standard for the Uniform Scheduling of Drugs and Poisons on the basis of "high potential for abuse and risk to public health and safety", no substantiation of this risk was provided at the time of this scheduling decision.<sup>3</sup> Schedule 9 is Australia's most restrictive drug schedule, and includes "substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities."<sup>4</sup>

#### ***Belgium***

A decree was passed in Belgium on October 22, 2006 which added *S. divinorum* to the list of controlled substances. This list includes substances such as psilocybin mushrooms, khat and

<sup>3</sup> <http://www.tga.gov.au/ndpsc/record/rr200111.pdf>

<sup>4</sup> [http://www.cognitiveliberty.org/news/salvia\\_australia.htm](http://www.cognitiveliberty.org/news/salvia_australia.htm)

peyote cactus.<sup>5</sup>

### **Denmark**

In 2003, Denmark added *S. divinorum* and salvinorin A to their list of “category B” controlled substances, a category which also includes psilocybin mushrooms, cocaine, amphetamine, and several others substances that are only legal for medicinal and scientific purposes. Illegal possession carries a penalty of up to two years in prison.

### **Germany**

*S. divinorum* (plant and plant parts) was added to Appendix I of the *Narcotics Act* in Germany on March 1, 2008, making it illegal to produce, traffic, or possess. The law does not specifically mention salvinorin A.

### **Italy**

On June 25, 2004, the Italian Ministry of Health issued an ordinance prohibiting the sale of *S. divinorum* and its active constituent salvinorin A. On January 11, 2005, the Ministry of Health made possession of *S. divinorum* and salvinorin A illegal by placing them in “*Tabella I*” of the *Tabella Sostanze Stupefacenti o Psicotrope*.

### **Japan**

On November 9, 2006, the Japanese government added a group of thirty-three drugs to its list of controlled substances, including salvinorin A. The drugs are banned under a revised pharmaceutical law, under which persons involved in their illegal import, production, and sale, i.e. beyond medical treatment or research purposes, will be subject to up to five years imprisonment or a fine of up to five million yen.

### **Spain**

On January 28, 2004, the Spanish Ministry of Health and Consumption issued an order prohibiting the sale of *S. divinorum*. The regulation went into effect on May 6, 2004 and only prohibits activities related to commerce. Possession and/or use are not considered to be criminal offences.

### **Other Countries**

*Salvia divinorum* is illegal to possess or sell in Croatia, Latvia, Lithuania, Poland, Romania, South Korea and Sweden. In Russia it is illegal to grow or sell *S. divinorum*, but it is legal to

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<http://eldd.emcdda.europa.eu/html.cfm/index5176EN.html?pluginMethod=eldd.shownewsdetails&id=20/12/2006BELGIUM:%20New%20substances%20controlled%20include%20mCPP%20and%20khat>

possess it. In Estonia, Finland, Iceland and Norway, *S. divinorum* is treated as a medicinal herb and it is illegal to import it without a relevant prescription from a doctor.

### ***United States of America***

*S. divinorum* and salvinorin A are not included in the Schedules to the United States *Controlled Substances Act* although both *S. divinorum* and salvinorin A have been added to a list of chemicals "of concern" which has no legal implications. In addition, some individual states have implemented laws restricting its use, sale and/or distribution. As of July 2010, a number of states have enacted legislation placing regulatory controls on *S. divinorum* and/or salvinorin A including Delaware, Georgia, Florida, Hawaii, Illinois, Kansas, Kentucky, Maryland, Mississippi, Missouri, Nebraska, North Dakota, Ohio, Oklahoma, South Dakota, Wisconsin, Virginia, California, Louisiana, Maine, North Carolina, and Tennessee. More details regarding the regulation of *S. divinorum* in these last five states are provided below.

#### ***California***

As of January 1, 2009, the sale or distribution of *S. divinorum* or salvinorin A, or any substance or material containing *S. divinorum* or salvinorin A, to any person under 18 years of age is a misdemeanor punishable by imprisonment in a county jail for not more than six months, a fine of no more than \$1,000, or both.

#### ***Louisiana***

In 2005, Louisiana passed a bill which prohibits the possession, production, manufacture and distribution of a material, compound, mixture, or preparation intended for human consumption and that contains a hallucinogenic plant. A "hallucinogenic plant" is defined as "any part or portion" of a plant on a list of forty plants, which includes *S. divinorum*.

#### ***Maine***

In Maine, *S. divinorum* and salvinorin A are regulated in the same way as tobacco products; adults eighteen years of age or over can legally purchase and use the material, but selling or providing *S. divinorum* or salvinorin A to anyone under the age of eighteen is a criminal offence. Possession by a minor is a civil violation, punishable by a fine, community service, or both.

#### ***North Carolina***

On December 1, 2009, the North Carolina State Legislature brought a new law into force which made *Salvia divinorum* and salvinorin A illegal. The only legal *S. divinorum* activities are the growing for aesthetic, landscaping, or decorative purposes or university-affiliated medical or pharmacological research.

**Tennessee**

On July 1, 2006, Tennessee classified the deliberate production, manufacture, distribution, or possession of the active chemical ingredient in the hallucinogenic plant *S. divinorum* as a Class A misdemeanor. It is not, however, a criminal offence to possess, plant, cultivate, grow, or harvest *S. divinorum* for aesthetic, landscaping, or decorative purposes. The law also does not apply to any dosage that is legally obtainable from a retail establishment without a prescription when (and if) it is recognized by the Food and Drug Administration as a homeopathic drug.

**4.2.2 Chemical and/or Pharmacological Similarity to Substances Listed in the Schedules to the CDSA**

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The psychoactive ingredient in *Salvia divinorum* is the neoclerodane diterpene salvinorin A {need reference}. Other plants which contain psychotropic terpenoids are *Artemisia absinthium* (wormwood) and *Cannabis sativa* {reference needed}. Salvinorin A is considered by some as the most potent natural hallucinogen ever isolated.<sup>6</sup>

**Comment [HABR1]:** What is the potency relative to other hallucinogens?

Unlike all other hallucinogens, salvinorin A is structurally distinct and does not interact with the serotonin-2A receptor or any other molecular target of classical hallucinogens {reference?}. Instead, the available research suggests the psychotropic effects of salvinorin A are mediated by its agonistic actions at κ-opioid (KOR) receptor {ref}. Its mechanism of action is therefore unique.<sup>7 8</sup>

**Deleted:** It thus affects the brain in a way that is quite unique

The psychoactive effects of *S. divinorum* vary in onset and duration and include the sensation of becoming an object, visions of various two-dimensional surfaces, films and membranes, revisiting places of the past (particularly childhood), perceived loss of the body and/or identity, various sensations of motion (being pulled or twisted by a force of some kind), uncontrollable hysterical laughter, and overlapping realities (perceptions of being in more than one place).<sup>9</sup> Laughter, happiness, sense of well-being and dissociative effects were deemed the best aspects of

**Deleted:** Recent pharmacological screenings of receptors have found it to be a highly potent and selective κ-opioid receptor (KOR) agonist.

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**Deleted:** The use of *S. divinorum* or salvinorin A can lead to a number of effects with variable onset and duration. These effects are generally accepted to

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**Comment [HABR2]:** Can we qualify that? What does "best" mean in this case?

<sup>6</sup> Ott J. Ethnopharmacognosy and human pharmacology of *Salvia divinorum* and salvinorin A. *Curare*. 1995 18: 103-129. Unofficial transcription available online. URL <http://www.sagewisdom.org/ott2.html>

<sup>7</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>8</sup> Roth BL, Baner K, Westkaemper R, Siebert D, Rice KC, Steinberg S, Ernsberger P, Rothman RB. Salvinorin A: a potent naturally occurring nonnitrogenous kappa opioid selective agonist. *Proc Natl Acad Sci U S A*. 2002 Sep 3;99(18):11934-9.

<sup>9</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

*S. divinorum* by users, second only to the "trip" that the drug elicits.<sup>10</sup> Depersonalization, speaking gibberish, widening of consciousness and subjective illusions of rapid movement, flying or hovering have also been reported.<sup>11</sup>

The psychomimetic (psychotomimetic) effects of *S. divinorum* closely resemble schizophrenia symptoms induced by lysergic acid diethylamide (LSD) or phencyclidine (PCP).<sup>12</sup> Yet, it is said to have only weak influence on the prevailing mood of the user which differentiates it from other hallucinogens such as LSD and psilocybin.<sup>13</sup> Its strong dissociative effects are often compared to those of ketamine {reference needed}. Users have reported that the psychedelic effects of *S. divinorum* were most similar to those caused by psilocybin mushrooms.<sup>14</sup> However, users familiar with the effects of other hallucinogens agree that despite certain similarities to classical hallucinogens, the visions and overall experience are quite unique.<sup>15</sup>

**Comment [HABR3]:** We have too many "psycho" terms. Psychoactive, psychomimetic, psychotropic, psychedelic. Either we use one or we have to define them. Are they different?

**Comment [HABR4]:** I think we should perhaps say "schizoid" not schizophrenia.

**Comment [HABR5]:** Definition ?

In addition, the psychedelic effects of *S. divinorum* are similar to those of classical psychedelics regarding changes in perception and somatic sensations {reference needed}. *S. divinorum* causes an unusually high degree of sedation, weakness and fatigue, while the increased de-realization is not commonly reported for classical psychedelics.<sup>16</sup> The combination of these effects seems to correlate with that of other KOR agonists such as pentazocine.<sup>17</sup>

**Comment [HABR6]:** Are these psychedelic effects??

**Comment [HABR7]:** Too many ideas in this paragraph. In addition, we say that Salvia's properties are unique, but here we seem to imply that it shares some properties to other KORs such as pentazocine.

#### 4.2.3 Legitimate Use of the Substance, including Therapeutic, Scientific, Industrial or Commercial Uses

*Salvia divinorum* has traditionally been used for spiritual and medicinal purposes by the Mazatec Indians in Oaxaca, Mexico,<sup>18</sup> where an infusion of the leaves or the leaves themselves are

<sup>10</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>11</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5 and Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>12</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5.

<sup>13</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>14</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>15</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6 and González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>16</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>17</sup> Arasteh K, Poudevida S, Farre M, Roset PN, Cami J. Response patterns of the Spanish version of the 49-item short form of the Addiction Research Center Inventory after the use of sedatives, stimulants, and opioids. Drug Alcohol Depend. 1999 Jun 1;55(1-2):117-25.

<sup>18</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.



ingested to treat gastrointestinal problems, headaches, rheumatism, anemia and swelling of the stomach.<sup>19</sup> Its main use today is, however, for its psychoactive properties in the aid of producing "mystical" or hallucinogenic experiences as part of spiritual rituals.<sup>20</sup>

**Comment [HABR8]:** Similar comment as above on the meaning and interchangeability of the terms psychoactive, psychedelic etc.... Psychedelic may be more appropriate here since it may refer to transcendental or mystical experiences.

Although selective kappa receptor agonists have been shown to produce analgesic effects, adverse effects such as psychotomimesis, dysphoria and diuresis have been observed in studies investigating their therapeutic use.<sup>21</sup> In addition, while it has been speculated that KOR agonists may be useful in the treatment of certain psychiatric disorders including Alzheimer's disease, schizophrenia, dementia and bipolar disorder,<sup>22</sup> much more research is needed in order to substantiate these hypotheses. Similarly, another study has suggested that chemical analogues of salvinorin A may be a useful treatment for those suffering from addiction to other substances.<sup>23</sup> That said, there are presently no legitimate medical uses for *S. divinorum* in Canada.

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Similarly, there are no known industrial or commercial uses for *S. divinorum* in Canada. The plant is a semi-tropical perennial that can only grow outdoors in a humid climate where it will not encounter frost. Most websites offering *S. divinorum* cuttings and seeds for sale appear to do so in the context of growing the plant for "recreational" purposes, rather than out of horticultural interest or for its esthetic appeal.

**Comment [HABR9]:** So?

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#### 4.2.4 Potential for Abuse and/or Addiction Liability of the Substance

Salvinorin A is a potent, selective agonist of the  $\kappa$ -opioid receptor (KOR), and in contrast to the euphoria produced by  $\mu$ -opioid receptor (MOR) agonists such as morphine (?), KOR agonists are negatively reinforcing and aversive.<sup>24</sup> In addition, KOR agonists have analgesic properties but are not associated with respiratory depression like MOR agonists. Finally, while MOR agonists increase the release of dopamine, the activation of KOR decreases dopamine release in the

<sup>19</sup> Munro, T. The Chemistry of Salvia divinorum. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

<sup>20</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage Salvia divinorum. Life Sci. 2005 Dec 22;78(5):527-31.

<sup>21</sup> Barker RL, Fawcett J, Barkin SJ. 2002. Chronic pain management with a focus on the role of newer antidepressants and centrally acting agents. In: Pain Management: A Practical Guide for Clinicians, 6th edition, Weiner RS ed. CRC Press, Boca Raton, FL. pp. 415-34 and Tidgewell et al., 2004. A facile method for the preparation of deuterium labelled salvinorin A: Biorganic & Medicinal Chemistry Letters, 14: 5099-5102.

<sup>22</sup> Sheffler DJ & Roth BL. Salvinorin A: the 'magic mint' hallucinogen finds a molecular target in the kappa opioid receptor. Trends Pharmacol Sci. 2003 Mar;24(3):107-109.

<sup>23</sup> Prisinzano TE. Natural products as tools for neuroscience: discovery and development of novel agents to treat drug abuse. J Nat Prod. 2009 Mar 27;72(3):581-7.

<sup>24</sup> Gustein HB & Akil H. Opioid Analgesics. In: Goodman and Gilman's The Pharmacological Basis of Therapeutics 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590, Cooper S. Interactions between endogenous opioids and dopamine: Implications for reward and aversion. In: The Mesolimbic Dopamine System: From Motivation to Action. Willner P and Scheel-Kruger J (editors) Wiley, Chester, England, 1991, pp. 331-366, and Shippenberg TS, Herz A, Spanagel R, Bals-Kubik R, Stein C. Conditioning of opioid reinforcement: neuroanatomical and neurochemical substrates. Ann N Y Acad Sci. 1992 Jun 28;654:347-56.

nucleus accumbens.<sup>25</sup>

The onset and intensity of the effects of *Salvia divinorum* appear to be related to the route of administration.

Traditional uses generally produce mild effects because the leaves are rolled and chewed or crushed and prepared as a foamy infusion whereby the salvinorin A is degraded in the gastrointestinal system before being absorbed into the bloodstream. Hence, the level of effect relates quite closely to the length of time the material spends in the mouth, with the onset of effect generally taking 5-10 minutes. The effects build over the next hour and last for another hour before they begin to subside.<sup>26</sup>

Routes of administration that avoid the hepatic first-pass effect (i.e. inhalation, intravenous, intramuscular and sublingual use) are the quickest and most intense.<sup>27</sup> Salvinorin A can be isolated from the plant to make a powder which can be vaporized and inhaled. The onset of effects felt from vaporizing salvinorin A powder occurs in about 30 seconds and effects last for about 5-10 minutes and then subside over the next 30 minutes.<sup>28</sup>

Smoking is by far the most popular method of administration<sup>29</sup> and this is accomplished by smoking the dried leaves or a concentrated extract using a pipe or bong. Dried leaves may also be fortified with a concentrated extract of salvinorin A. A concentrated extract can also be used sublingually. Neither *S. divinorum* nor salvinorin A can be injected because the powder is insoluble in water.<sup>30</sup>

The aversive effects of KOR agonists suggest that the risk of addiction to *S. divinorum* is negligible. However, very few controlled scientific studies of the physical and psychotropic effects of *S. divinorum* on humans have been carried out. Therefore, it is difficult to predict with certainty its potential for addiction and abuse. In studies that have been conducted, there is conflicting information around the addiction liability of *S. divinorum* in both animals and humans. Some users have noted that they require increasing doses of salvinorin A in order to achieve the desired effect and the stimulated cerebral KOR may act as a mechanism of

**Comment [HABR10]:** This paragraph needs a sentence or two which links these scientific findings to a rationale for why salvia is not addictive. There is much scientific information here but it needs to be explained. For example, why is the decrease in dopamine release in the nucleus accumbens important? What does this have to do with addiction or abuse?

**Comment [HABR11]:** Why is this important?

**Comment [HABR12]:** How does this relate to potential for abuse or addiction liability? This paragraph belongs more in the section on pharmacology.

**Comment [HABR13]:** This para belongs in the pharmacology section.

**Comment [HABR14]:** What does this have to do with potential for abuse or addiction liability?

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<sup>25</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.

<sup>26</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>27</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.

<sup>28</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>29</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62 and Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>30</sup> Valdés LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs.* 1994 Jul-Sep;26(3):277-83.

tolerance.<sup>31</sup> Further studies in this area and on the mediated decrease of dopamine as well as the impact of dose on effects are also required.

While concerns for the potential of abuse were once minimal because 1 kg of dried leaves yields only 3 to 6 human doses of salvinorin A, it was discovered that vaporizing and inhaling 200-500 micrograms had profound hallucinogenic effects.<sup>32</sup> The extraction of salvinorin A from the plant is simple, and with care, approximately 1.5 grams of pure salvinorin A per kilogram of dried leaves (8kg of fresh leaves) can be isolated. This is enough for 2000 human doses.<sup>33</sup>

**Comment [HABR15]:** Can this sentence be summarized somehow and made more convincing? So what we're trying to say is that the potential for abuse is high because we need very small doses.

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#### 4.2.5 Evidence of Extent of Actual Abuse of the Substance in Canada and Internationally

In Canada, the extent of actual abuse of *Salvia divinorum* and/or salvinorin A is relatively unknown. There is, however, some data regarding the prevalence of use of *Salvia divinorum* in Canada, despite the lack of legitimate uses for this plant. Questions about the use of *S. divinorum* were included in the 2008-2009 Youth Smoking Survey, the 2009 Canadian Alcohol and Drug Use Monitoring Survey and the 2009 Ontario Student Drug Use and Health Survey.

**Comment [HABR16]:** Need to re-order these in the order that they are presented below.

The results from the 2009 Ontario Student Drug Use and Health Survey were published on November 18, 2009 and indicate that:

- Among all responding students in Ontario, 4.4% reported using *Salvia divinorum* at least once in the past year. In comparison, 58.2% indicated they had used alcohol, 25.6% indicated they had used cannabis and 5.0% indicated they had used hallucinogens other than LSD and PCP in the past year;
- Males (6.2%) were significantly more likely than females (2.3%) to report using *Salvia divinorum*;
- There is significant grade variation, with *Salvia divinorum* use most likely among 11<sup>th</sup> graders (8.6%) and 12<sup>th</sup> graders (8.4%); and
- There are significant regional variations, with students in Northern Ontario (9.2%) most likely to use *Salvia divinorum*.

<sup>31</sup> Bucheler R, Gleiter CH, Schworer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>32</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>33</sup> Valdés LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs*. 1994 Jul-Sep;26(3):277-83.

The results of the 2008-2009 Youth Smoking Survey were published on May 31, 2010 and indicate that:

- 4.9% of students stated that they had used *S. divinorum* in the last twelve months. In comparison, 53.0% indicated they had used alcohol, 27.3% indicated they had used cannabis and 6.9% indicated they had used other hallucinogens in the last twelve months;
- 2.6% of students in Grades 7-9 and 7.0% of students in Grades 10-12 had used *S. divinorum* in the last twelve months; and
- Males (6.6%) were more likely to have used *S. divinorum* in the past twelve months compared to females (3.2%).

The scope of the previously mentioned studies did not provide for any explanations regarding differences in usage between ages, genders and regions. In this regard, it is difficult to speculate on the causality of such differences.

The Canadian Alcohol and Drug Use Monitoring Survey specifically examined Salvia for the first time in 2009. An estimated 1.6% of Canadians, aged 15 years and older, reported that they had used salvia in their lifetime, and 0.2% reported using it in the past-year. In comparison, the prevalence of past-year cannabis use among Canadians 15 years of age and older was 10.6%. 1.2% of respondents reported using cocaine or crack in the past 12 months, 0.9% had used ecstasy and 0.7% used illicit hallucinogens.

Health Canada's Drug Analysis Services (DAS) has identified salvinorin A in a number of samples seized by law enforcement, as shown in the following table:

**NUMBER OF SAMPLES FOUND TO CONTAIN SALVINORIN A**

Year	Count
2006	9
2007	8
2008	4
2009	20
2010 (as of May 7)	8

**Comment [HABR17]:** Why is this important? What is the message we are trying to convey here?

The National Forensic Laboratory Information System (NFLIS) and the System to Retrieve Information from Drug Evidence (STRIDE) in the United States are Drug Enforcement Agency (DEA) databases that collect scientifically verified data on analyzed samples in state and local forensic labs as well as samples from DEA labs. The following table shows the quantity of *S. divinorum* products that were seized from 2000 through to 2009.

**ANALYZED SALVIA DIVINORUM or SALVINORIN A SEIZURES**

(Number of Items/Exhibits)

Source	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009*
NFLIS-State/Local <sup>1</sup>	0	0	0	0	1	8	12	12	70	34
STRIDE <sup>2</sup>	0	0	1	1	1	0	0	0	N/A	N/A

<b>TOTAL</b>	0	0	1	1	2	8	12	12	70	<b>34</b>
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Data Source: NFLIS & STRIDE, 2008 data queried 11/24/08, updated 06/10/2010

<sup>1</sup> NFLIS reported seizures of *Salvia divinorum* and/or salvinorin A

<sup>2</sup> STRIDE reported items of *Salvia divinorum*.

\* Includes only January – May data in 2009.

It is difficult to determine the extent of actual abuse of *S. divinorum* in Canada or elsewhere as there appear to be inconsistencies in the literature regarding risk aversion. For example, one author states: "Many who have used salvinorin A find the experience extremely unnerving, frightening and overly intense and most have no desire to repeat the experience."<sup>34</sup> However, another study suggested that this is not the experience of all recreational users of *S. divinorum*.<sup>35</sup> Over eighty percent of users surveyed on a web-based questionnaire about their *S. divinorum* use said that they would probably or definitely use *S. divinorum* again.<sup>36</sup> Users have reported the negative effects of *S. divinorum* as: the short duration of action, lack of control over the experience, persisting negative effects (most often anxiety),<sup>37</sup> sweating, chills, increased diuresis, impaired vigilance,<sup>38</sup> and negative after-effects including tiredness, feeling head heavy, dizziness, physical exhaustion, and some degree of malaise or 'hangover' as they 'comedown' from the drug.<sup>39</sup>

**Comment [HABR18]:** Why is this here at the end and what is its connection to seizure data? This should be placed higher up in the section.

#### 4.2.6 Risk to Personal and Public Health and Safety

The increase in both the number of enquiries from various municipalities and members of the public and the amount of media interest regarding the availability of *Salvia divinorum* in Canada may be an indication that the recreational use of *S. divinorum* as a hallucinogen is on the rise. However, there are no available statistics that indicate there has been a significant increase in *S. divinorum* use in the Canadian population and, in comparison to the use of other drugs such as alcohol and cannabis, the actual use of *S. divinorum* is quite low.

The potential for harm to the user and/or other individuals is primarily related to the hallucinogenic properties of the substance. Users may get up and walk around without apparent awareness of their movements, behaviour or surroundings, and distinction between self and surroundings is often lost. At doses greater than 1mg of salvinorin A, out of body experiences

<sup>34</sup> Turner DM. Salvinorin - The Psychedelic Essence of Salvia Divinorum. Panther Press, San Francisco, CA 1996.

<sup>35</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62, Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5, and Valdés LJ 3rd. Salvia divinorum and the unique diterpene hallucinogen, Salvinorin (divinorin) A. J Psychoactive Drugs. 1994 Jul-Sep;26(3):277-83.

<sup>36</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>37</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>38</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5.

<sup>39</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

are frequent and loss of consciousness has been reported.<sup>40</sup> There is little information regarding the social behaviours of persons under the influence of *S. divinorum* products, and what risks their activities such as operating a motorized vehicle may pose to the general public. There is also very little data regarding the toxicity, teratogenicity or other long-term effects of *S. divinorum* use.<sup>41</sup>

As far as law enforcement is concerned, the Department has only received a limited number of communications indicating concern with respect to *S. divinorum* and none of these have advised that the use of *S. divinorum* poses any threat to public safety. The Royal Canadian Mounted Police (RCMP) has stated that while *S. divinorum* is readily available, it has not become a popular drug in Canada, probably due to its aversive effects such as anxiety and introversion.

A handful of case reports regarding the use of *S. divinorum* have been published in the academic literature. An international case report described the perceptions of a 19 year-old man after inhaling *S. divinorum* smoke. The peak psychotropic effects, including prickling of the skin, fever-like hot flashes, muscular tremor, and depersonalization, were reached in less than five minutes after inhalation of an unknown amount of smoke from burning dried leaves.<sup>42</sup> Another report involved a 15-year-old male who presented to psychiatric emergency services with acute onset of paranoia, déjà vu, blunted affect, difficulties in thought processing and slowed speech after smoking *Salvia divinorum* over an unknown period of time. During his hospitalization all symptoms improved significantly except the feeling of déjà vu. Based on this case presentation, the author suggested that the feelings of déjà vu may be a long-term effect of *S. divinorum* use.<sup>43</sup> However, given that this is the only case report in which déjà vu was associated with the use of *S. divinorum*, more reports are needed to substantiate this finding.

**Comment [HABR19]:** The case reports cited below do not relate to use but rather to the physiological and psychotropic effects of *S. divinorum* use.

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In addition to the above-mentioned reports, in 2006, a case was reported in the U.S. in which a 17-year-old boy committed suicide after smoking *S. divinorum* for an unknown period of time.<sup>44</sup> It should be noted that alcohol and general depression were the main confounders in this case. After this case was reported, the state of Delaware passed a law which classified *S. divinorum* as a Schedule I controlled substance along with other hallucinogenic substances.

Like many drugs of abuse, users are often unaware of the potency and adulterants in the product they purchase. A study by Wolowich *et al.* (2006)<sup>45</sup>, showed that the salvinorin A content in five out of five *S. divinorum* products was falsely indicated on the label and 4 out of 5 products contained unidentified adulterants (i.e. vitamin E, caffeine).

Health Canada has only anecdotal information about the use and abuse of *S. divinorum* in Canada as well as the threat *S. divinorum* may pose to the health and safety of Canadians. Although

<sup>40</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>41</sup> Grundmann O, Phipps SM, Zadezensky I, Butterweck V. *Salvia divinorum* and Salvinorin A: An Update on Pharmacology and Analytical Methodology. *Planta Med* 2007 Jun;73:1039-1046.

<sup>43</sup> Singh S. (2007) Adolescent salvia substance abuse. *Addiction.* 102, 823-824.

<sup>44</sup> <http://www.kvbc.com/Global/story.asp?S=4893692>

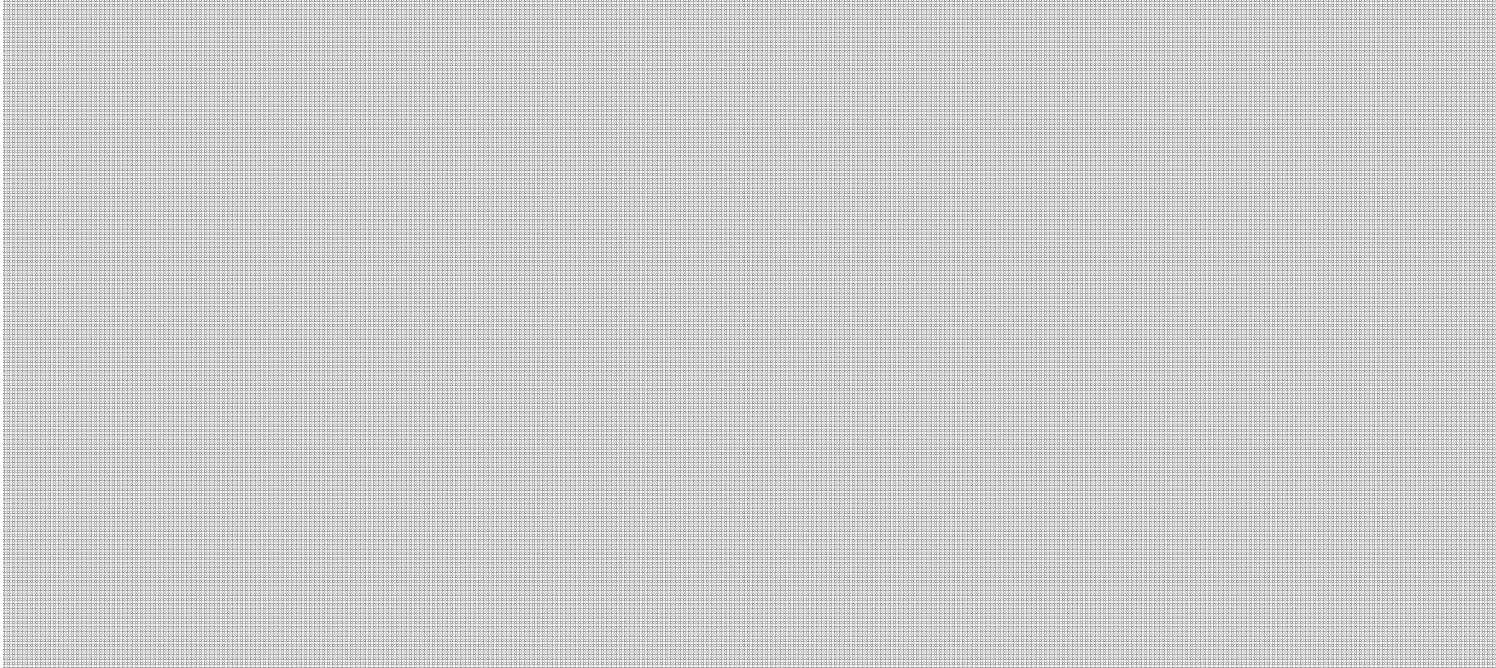
<sup>45</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.

**s.21(1)(a)**

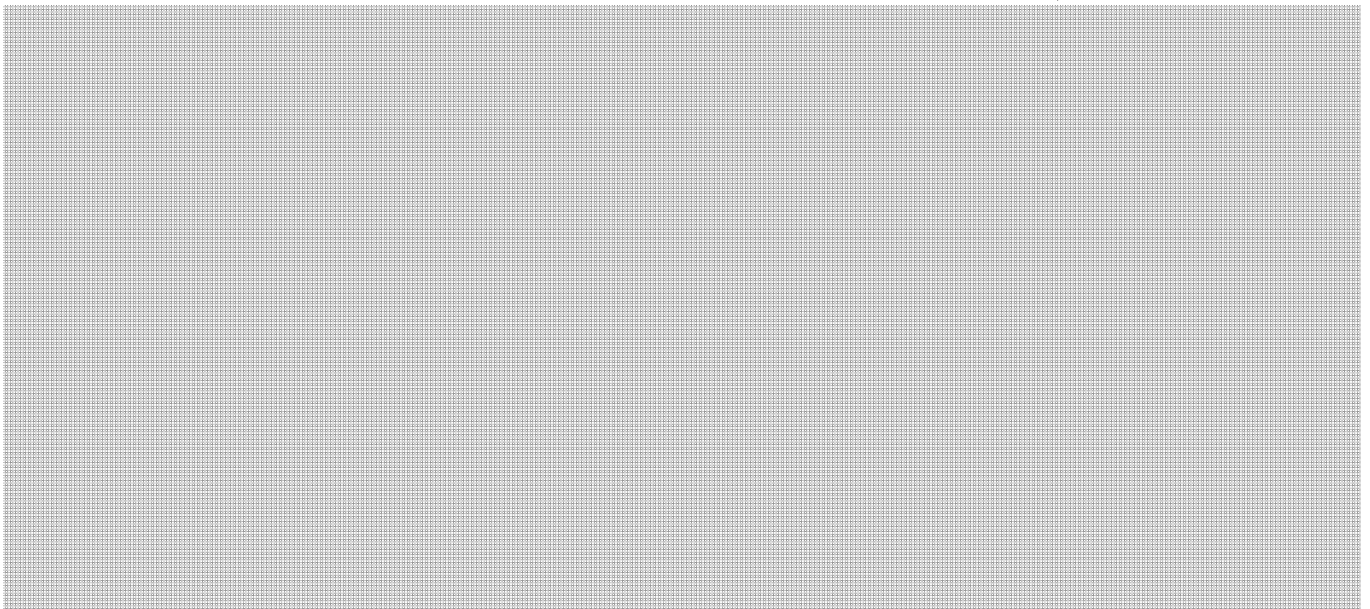
**s.21(1)(b)**

reports of domestic adverse reactions related to the use of *S. divinorum* as a hallucinogen have been received through the Canada Vigilance database, it is important to note that the number of reports and the nature of reactions reported are not adequate to characterize the risk to the general population.

**5. ASSESSMENT OF RISKS AND BENEFITS**



**6. IDENTIFICATION AND ANALYSIS OF OPTIONS**



**Page(s) 001064 to\à 001064**

**Is(Are) exempted pursuant to section(s)  
est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**



s.21(1)(a)  
s.21(1)(b)

## 7. CONSIDERATIONS

The KOR-mediated aversive and dysphoric effects of *Salvia divinorum* do not appear to be hampering its use as young adults have begun smoking the leaves and leaf extract recreationally.<sup>46</sup> It can be purchased through online botanical companies and other drug promotion sites and is often touted as a legal alternative to substances such as cannabis and mescaline.<sup>47</sup> Interestingly, after being widely available for over a decade, the drug does not appear to have had the same social impact as LSD or ecstasy.<sup>48</sup>

While there has been an increase over the past few years in the number of enquiries from various municipalities and members of the public regarding the availability of *Salvia divinorum* as a hallucinogen, according to available statistics, the reported use of *S. divinorum* by young Canadians is much lower than that of alcohol or cannabis.

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The NHPR are limited in their capacity to control the availability of *S. divinorum* in that *S. divinorum* products are often declared as incense and therefore cannot be considered unapproved natural health products. In addition, compliance and enforcement actions such as voluntary stop-sales, forfeiture, destruction, and administrative seizure, cannot be implemented unless the labeling of the product indicates that it is to be used for human consumption and can modify an organic function.

The previous HPFB recommendation to schedule *S. divinorum* under the CDSA was likely based on a misunderstanding of the (previously-described) criteria upon which scheduling decisions are made within the Healthy Environments and Consumer Safety Branch (HECSB). In particular, it did not consider a number of factors, including potential for abuse and risk to public health and safety. The Office of Controlled Substances (OCS) was also not consulted by HPFB at the time

<sup>46</sup> Hazelden Foundation, 2004. Drug Abuse Trends. June 2004. URL: [www.research.hazelden.org](http://www.research.hazelden.org).

<sup>47</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

<sup>48</sup> Munro, T. The Chemistry of *Salvia divinorum*. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

this recommendation was made. In addition, among countries who have decided to control *S. divinorum* in some way, very little or no substantiation of the risks of *S. divinorum* upon which the decision was based are available.

s.21(1)(a)  
s.21(1)(b)

Neither *Salvia divinorum* nor salvinorin A meet the criteria for scheduling a substance under the CDSA. Despite being regulated in some jurisdictions, neither the plant nor salvinorin A are scheduled under any of the UN Drug Control Conventions. *S. divinorum* and salvinorin A are not structurally or pharmacologically similar to other substances included in the schedules to the CDSA. There are also currently no legitimate therapeutic or industrial uses for *S. divinorum*. The abuse liability and potential for dependence of *S. divinorum* is not known as very few controlled scientific studies of its physical and psychotropic effects have been carried out on humans. The extent of actual abuse of *S. divinorum* is also largely unknown. Evidence of a risk to public health and safety is anecdotal in nature and not quantified in any way as there is a lack of information regarding abuse in Canada.

## 8. RECOMMENDATIONS

## 9. CONSULTATIONS

The Drug Analysis Services (DAS) was contacted in order to provide any data available regarding the identification of salvinorin A in samples submitted by law enforcement.

The Royal Canadian Mounted Police (RCMP) was contacted in order to establish their views with respect to *S. divinorum* use in Canada. The RCMP advised that though *S. divinorum* is readily available, it does not appear to pose a threat to public safety.

OCS has received a number of correspondences from Canada Border Services Agency (CBSA) officers concerning a lack of information regarding the status of *S. divinorum* and how the plant should be treated at the border. CBSA officers have also expressed concern regarding the plant's hallucinogenic properties. At present, only shipments of *S. divinorum* that are represented as health products that modify organic functions can be refused for import under the NHPR.

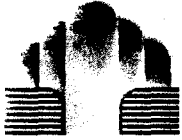
## 10. IMPLEMENTATION AND EVALUATION

**Page(s) 001067 to\à 001067**

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est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**



Jocelyn Kula/HC-SC/GC/CA  
2010-08-03 10:16 AM

To Mark Kozlowski/HC-SC/GC/CA@HWC  
cc Stephanie Chandler/HC-SC/GC/CA@HWC, Daniel  
Galarneau/HC-SC/GC/CA@HWC  
bcc

Subject Re: Fw: DATELINE DEA: July 30, 2010 

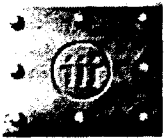
Thanks MK,

I am pretty sure we have reviewed a copy of the DEA Fact Sheet in the preparation of our IAS and also the IYH article that is currently in approvals but am copying Stephanie just in case the content on the site has been updated etc.

JK

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Jocelyn Kula  
Manager/ Gestionnaire  
Policy and Regulatory Affairs Division/ Division des politiques et affaires réglementaires  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0125 Fax: (613) 946-4224  
Mark Kozlowski/HC-SC/GC/CA



Mark  
Kozlowski/HC-SC/GC/CA  
2010-08-03 08:48 AM

To Jocelyn Kula/HC-SC/GC/CA@HWC  
cc

Subject Fw: DATELINE DEA: July 30, 2010

Interesting link on the bottom about Salvia.

MK

----- Forwarded by Mark Kozlowski/HC-SC/GC/CA on 08/03/2010 08:48 AM -----



"U.S. Drug Enforcement  
Administration"  
<dea@govdelivery.com>

07/29/2010 12:53 PM

Please respond to  
"U.S. Drug Enforcement  
Administration"  
<dea@govdelivery.com>

To mark.kozlowski@hc-sc.gc.ca  
cc

Subject DATELINE DEA: July 30, 2010

---

## **Dateline DEA**

DEA's Biweekly E-mail Informant

001068

July 30, 2010

Top Stories from the Drug Enforcement Administration July 17 to July 30, 2010

---

**Top FARC Commander Sentenced to 27 Years**

On July 22, DEA New York Special Agent in Charge John P. Gilbride and Preet Bharara, the U.S. Attorney for the Southern District of New York, announced that Gerardo Aguilar Ramirez, aka "Cesar," a former front commander in the Fuerzas Armadas Revolucionarias de Colombia (Revolutionary Armed Forces of Colombia, or "FARC"), was sentenced to 27 years in U.S. prison for conspiring to import ton-quantities of cocaine into the United States.

Aguilar Ramirez was responsible for all of the Front's criminal activities and among other things, he conspired with others to manufacture and distribute thousands of tons of cocaine in Colombia, with the knowledge and intent that such cocaine would be imported into the United States.

[Click Here to Read the DEA Press Release](#)

**DEA Nabs Drug Lord After 10-Year Chase**

Caribbean Division Special Agents, with significant assistance from the DEA New York Field Division, arrested Puerto Rico's and the Dominican Republic's most wanted fugitive, Jose David Figueroa-Agosto alias Jr. Capsula, on July 17 in San Juan, PR.

Figueroa-Agosto was wanted by the U.S. Marshals Service's Puerto Rico Fugitive Task Force for escaping from a Commonwealth of Puerto Rico Correctional Facility about 10 years ago where he was serving a 209-year sentence for kidnapping and murder.

---

[Click Here to Read the DEA Press Release](#)

### **51 Suspected Gang Members Arrested**

On July 23, DEA Los Angeles Special Agent in Charge Timothy J. Landrum, Santa Barbara County Sheriff Bill Brown, and Santa Maria Police Chief Danny Macagni announced the culmination of a joint investigation that resulted in the arrest of 51 suspected gang members and their associates with ties to drug trafficking throughout the Central Coast of California.

The investigation also resulted in the seizure of more than 19 pounds of methamphetamine, a methamphetamine conversion laboratory, 1.5 kilograms of cocaine, small amounts of crack cocaine, 25 pounds of marijuana, 35 firearms, \$800,000 in U. S. currency, and property.

[Click Here to Read the DEA Press Release](#)

---

### **DID YOU KNOW?**

The DEA is in the process of studying the effects of Salvia, an herbal supplement that is rapidly gaining popularity among teens who are smoking it to get high. The plant is very dangerous when abused and when smoked it causes powerful hallucinations. To read more about Salvia click [here](#).

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DESCRIPTION/OVERVIEW

Salvia divinorum is a perennial herb in the mint family native to certain areas of the Sierra Mazateca region of Oaxaca, Mexico. The plant, which can grow to over three feet in height, has large green leaves, hollow square stems and white flowers with purple calyces, can also be grown successfully outside of this region. Salvia divinorum has been used by the Mazatec Indians for its ritual divination and healing. The active constituent of Salvia divinorum has been identified as salvinorin A. Currently, neither Salvia divinorum nor any of its constituents, including salvinorin A, are controlled under the federal Controlled Substances Act (CSA). However, the abuse of Salvia Divinorum is gaining popularity in the United States, particularly by adolescents and young adults.

Description/O
Control Status
Street Names
Short-Term Ef
Long-Term Eff
Trafficking Tre
Use/User Pop
Arrests/Sente
Drug Seizures
Legislation
Treatment Res
Photos
Related News
Useful Links

CONTROL STATUS

Salvia divinorum and salvinorin A are not currently controlled under the CSA. number of states have placed controls on Salvia divinorum and/or salvinorin A legislation section of this page for more information.

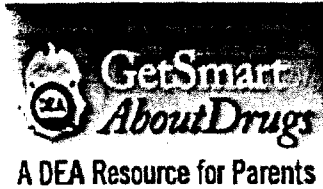
STREET NAMES

Maria Pastora, Sage of the Seers, Diviner's Sage, Salvia, Sally-D, Magic Mint

SHORT-TERM EFFECTS

A limited number of studies have reported the effects of using either plant mat salvinorin A. Psychic effects include perceptions of bright lights, vivid colors ; well as body movements and body or object distortions. Other effects include uncontrolled laughter, a sense of loss of body, overlapping realities, and halluc (seeing objects that are not present). Adverse physical effects may include inco dizziness, and slurred speech.

Scientific studies show that salvinorin A is a potent and selective kappa opioid 001071



agonist. Other drugs that act at the kappa opioid receptor also produce hallucin and dysphoria similar to that produced by salvinorin A. Salvinorin A does not serotonin 2A receptor, which mediates the effects of other schedule I hallucin

Due to the hallucinogenic effects there is a substantial risk of injury or death of impaired judgment due to disruptions of sensory and cognitive functions

**LONG-TERM EFFECTS**

**TRAFFICKING TRENDS**

Salvia divinorum is grown domestically and imported from Mexico and Central America. The Internet is used for the promotion and distribution of Salvia divinorum sold as seeds, plant cuttings, whole plants, fresh and dried leaves, extract-enhancers of various strengths (e.g., 5x, 10x, 20x, 30x), and liquid extracts purported to contain salvinorin A. These products are also sold at local shops (e.g., head shops and smoke shops) and over the internet as a "legal alternative to controlled hallucinogens". DEA is not aware of any legitimate medical use.

**USE/USER POPULATION**

According to a National Survey on Drug Use and Health Report published by SAMHSA in February 2008, it is estimated that 1.8 million persons aged 12 or older used Salvia divinorum in their lifetime, approximately 750,000 did so in the past year. Use is most common among young adults (18 to 25 years old) as opposed to older adults (26 to 50 years of age). Young adults were 3 times more likely than youths aged 12 to 17 to have used Salvia divinorum in the past year. Use is more common in males than females.

**ARRESTS/SENTENCING**

**DEA DRUG SEIZURES**

**LEGISLATION**

As of November 2008, thirteen states have enacted legislation placing regulatory controls on Salvia divinorum and/or salvinorin A. Delaware, Florida, Illinois, Kansas, Missouri, North Dakota, Oklahoma, and Virginia have placed Salvia divinorum and salvinorin A into schedule I of state law. California, Louisiana, Maine and Tennessee have enacted other forms of legislation restricting the distribution of the plant. State legislative bills proposing regulatory controls that have not passed are in Alabama, Alaska, Hawaii, Iowa, Minnesota, Nebraska, Oregon, South Carolina, and Utah. Legislative bills proposing regulatory controls are pending in Michigan, New Jersey, New York, Ohio, Pennsylvania, and Rhode Island.



Texas and Wisconsin.

Salvinorin A and/or Salvia divinorum have been placed under regulatory control in  
Australia, Belgium, Denmark, Estonia, Finland, Italy, Japan, Spain, and Sweden.

**TREATMENT RESOURCES**

**PHOTOS**

**RELATED NEWS RELEASES**

**USEFUL LINKS**

- ▶ Salvia Divinorum Fact Sheet
- ▶ One Pager

**SOURCES**



## *Salvia divinorum* and salvinorin A

---



*Salvia divinorum* is a perennial herb in the mint family native to certain areas of the Sierra Mazateca region of Oaxaca, Mexico. It is not controlled under the federal Controlled Substances Act (CSA). The plant has large green leaves, hollow square stems and white flowers with purple calyces. Street names for *Salvia divinorum* are Maria Pastora, Sage of the Seers, Diviner's Sage, Salvia, Sally-D, and Magic Mint. The active constituent of *Salvia divinorum* has been identified as salvinorin A, also called Divinorin A. Salvinorin A is believed to be the ingredient responsible for the hallucinogenic effects of *Salvia divinorum*. The active ingredient is a neoclerodane diterpene found primarily in the leaves, and to a lesser extent in the stems. *Salvia divinorum* is imported from Mexico and Central and South America is sold through the internet or local shops (e.g., head shops and tobacco shops) as seeds, plant cuttings, whole plants, fresh and dried leaves, extract-enhanced leaves of various strengths (e.g., 5x, 10x, 20x, 30x), and liquid extracts. As of November 2008, thirteen states have enacted legislation to place regulatory controls on *Salvia divinorum* and/or salvinorin A. Delaware, Florida, Illinois, Kansas, Mississippi, Missouri, North Dakota, Oklahoma, and Virginia have placed the drug and/or its constituent into schedule I of state law. The states of California, Louisiana, Maine and Tennessee enacted other forms of legislation restricting distribution of the plant. States in which legislative bills proposing regulatory controls died are Alabama, Alaska, Hawaii, Indiana, Iowa, Minnesota, Nebraska, Oregon, South Carolina, and Utah. Legislative bills proposing regulatory controls are pending in Michigan, New Jersey, New York, Ohio, Pennsylvania, Texas, and Wisconsin.

*Salvia divinorum* was first discovered in the late 1930s by anthropologists studying medicinal and magical cures in Mexico. It has been used by the Mazatec Indians for its ritual divination and healing. In the United States, the plant material is typically chewed or smoked. When chewed, the leaf mass and juice are absorbed across the lining of the oral mucosa (buccal). Effects first appear within 5 to 10 minutes. Dried leaves and extract-enhanced leaves are smoked. When an individual smokes pure salvinorin A, at a dose of 200 to 500 micrograms, effects are experienced within 30 seconds and last about 30 minutes. A limited number of studies have reported using either plant material or salvinorin A. Psychic effects include perceptions of bright lights, vivid colors and shapes, as well as body movements and body or object distortions. Other effects include dysphoria, uncontrolled laughter, a sense of loss of

## *Salvia divinorum*

### *Drug Fact Sheet*

body, overlapping realities, and hallucinations. Adverse physical effects may include incoordination, dizziness, and slurred speech.

The **National Survey on Drug Use and Health** (formerly the National Household Survey on Drug Abuse) is a Substance Abuse and Mental Health Services Administration (SAMSHA) database which measures drug use by people living in U.S. households. According to the first NSDUH report on *Salvia divinorum*, published by SAMHSA in February 2008, it is estimated that 1.8 million persons aged 12 or older used *Salvia divinorum* in their lifetime; 756,000 used the drug in the past year. Use was more common among young adults (18 to 25 years old), as opposed to older adults (> 26 years of age). Young adults were three times more likely than youth aged 12 to 17 to have used *Salvia divinorum* in the past year. Males aged 12 to 17 were three times more likely to use *Salvia divinorum* than females, while males ages 18 to 25 were four times more likely to use the drug.

A National Institute on Drug Abuse-funded study conducted by the University of Michigan, **Monitoring the Future**, measures prevalence of drug use among eighth, tenth, and twelfth graders. Data for *Salvia divinorum* is not collected in this study.

The **National Forensic Laboratory Information System (NFLIS)/System to Retrieve Information from Drug Evidence (STRIDE)** is a DEA database that collects scientifically verified data on analyzed samples in state and local forensic labs. It also includes data from STRIDE, which are analyzed samples from DEA labs. The following table shows *Salvia divinorum* items seized from 2000 through 2008.

#### **ANALYZED SALVIA DIVINORUM or SALVINORIN A SEIZURES** (Number of Items/Exhibits)

<b>SOURCE</b>	<b>2000</b>	<b>2001</b>	<b>2002</b>	<b>2003</b>	<b>2004</b>	<b>2005</b>	<b>2006</b>	<b>2007</b>	<b>2008*</b>
<b>NFLIS- State/Local</b> <sup>1</sup>	0	0	0	0	1	8	12	12	32
<b>STRIDE</b> <sup>2</sup>	0	0	1	1	1	0	0	0	0
<b>TOTAL</b>	0	0	1	1	2	8	12	12	32

Data Source: NFLIS & STRIDE, 2008 data queried 11/24/2008

<sup>1</sup> NFLIS reported items of salvinorin A

<sup>2</sup> STRIDE reported items of *Salvia divinorum*.

\*Includes only January – September data in 2008

---

DEA establishes the ~~Aggregate Production Quota~~ for the maximum amount of Schedule I and II substances which may be manufactured in the United States for legitimate

## ***Salvia divinorum***

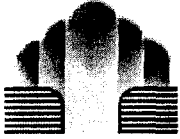
### ***Drug Fact Sheet***

national scientific, medical and export needs, and for the maintenance of stocks. *Salvia divinorum* is not a controlled substance in the United States and does not have approved medical use; therefore, there is no production quota permitted by the Drug Enforcement Administration.

IMS National Prescription Audit Plus™, a provider database managed by IMS America, estimates total U.S. dispensed prescriptions. *Salvia divinorum* is not reported in this database of prescription drugs.

Another SAMSHA database, Drug Abuse Warning Network (DAWN), provides data on drug-related episodes reported by hospital emergency rooms (ERs). *Salvia divinorum* is not currently reported in either the DAWN emergency room or Medical Examiner (ME) database.

For additional information contact ODE at 202-307-7183.



Jocelyn Kula/HC-SC/GC/CA  
2010-08-13 07:47 PM

To Omar Lockhat/HC-SC/GC/CA@HWC  
cc Andrée Bernard/HC-SC/GC/CA@HWC, Christine  
Leckie/HC-SC/GC/CA@HWC, Diane  
Allan/HC-SC/GC/CA@HWC, Ken  
bcc

Subject Re: Fw: Salvia IAS 

Right, and my point is that we hadn't charted a course in which all Inspectorate staff were being provided with an opportunity to provide comments; I am trying to find out exactly how this document got circulated so widely but suspect, as I said in my last message, that it was the HPFBI rep to the CSS WG being a bit keen and not informing us of his plans.

Won't comment on the BZP IAS as there again, I did not know it had been circulated wider than the CSS WG.

Clearly something I will have to take up with our HPFBI contact.....

As for your providing input/ accessing final IAS', I think we just have to come up with a process that works for all, and if you would like to propose something, I will be happy to consider it. I will tell you that I am not keen on our draft documents being posted in your database as then we get version control issues and potentially different HC staff (in different locations) referencing documents that are out of date. You can certainly post our final IAS' though as once they go through discussion by the CSS WG and are signed off by Diane, they are considered final and should not be changing in the future.

Here is the one for BZP:



FINAL (signed) BZP-TFMPP IAS 2010-07-13.pdf

Cheers  
Jocelyn

PS Out of the office for two weeks of holiday/ business travel; feel free to send comments on the Salvia IAS to Stephanie Chandler.

---

Jocelyn Kula  
Manager/ Gestionnaire  
Policy and Regulatory Affairs Division/ Division des politiques et affaires réglementaires  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0125 Fax: (613) 946-4224  
Omar Lockhat/HC-SC/GC/CA


Omar Lockhat/HC-SC/GC/CA  
2010-08-13 07:38 PM


To Jocelyn Kula/HC-SC/GC/CA@HWC  
cc Richard Prevost/HC-SC/GC/CA@HWC, Diane  
Allan/HC-SC/GC/CA@HWC, Andrée  
Bernard/HC-SC/GC/CA@HWC, Christine  
Leckie/HC-SC/GC/CA@HWC, Ken  
Moore/HC-SC/GC/CA@HWC

Subject Re: Fw: Salvia IAS 



Thanks Jocelyn, it's odd, since a day prior to Ian's email from MB, someone in BC also printed me a copy of this and left it outside my office. Then of course the next day I get the email from Ian, which I fwd' on.

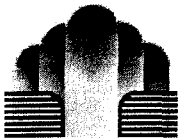
I simply think that if all the Inspectorate staff are being given an opportunity to provide comments, then Controlled Substances staff in the regions should too. Something similar occurred with the Draft BZP IAS, which I also received through the inspectorate. 

FYI- I would like to post in our database the final versions of the IAS' , is there a way for me to tap into these and post for Controlled Substances staff in the region?

I appreciate the clarification and understand the intent was not to share with all at this time. Anyway, thanks again and enjoy your weekend.

Omar Lockhat  
Manager, Western Canada  
Controlled Substances Program  
Compliance and Enforcement - Health Canada  
Tel: 604-666-8941 Fax: 604-666-5741  
Omar.Lockhat@hc-sc.gc.ca

Jocelyn Kula/HC-SC/GC/CA




Jocelyn Kula/HC-SC/GC/CA

2010-08-13 08:07 AM

To Omar Lockhat/HC-SC/GC/CA@HWC

cc Andrée Bernard/HC-SC/GC/CA@HWC, Christine Leckie/HC-SC/GC/CA@HWC, Diane Allan/HC-SC/GC/CA@HWC, Ken Moore/HC-SC/GC/CA@HWC, Richard Prevost/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC, Daniel Galarneau/HC-SC/GC/CA@HWC

Subject Re: Fw: Salvia IAS 

Hi Omar

I am as confused as you are by the message below as while we have circulated our draft IAS on salvia to our Controlled Substances Scheduling Working Group (an interbranch working group that helps us with scheduling decision), and there is a rep from HPFBI on it, the WG itself has not yet met to discuss the IAS and I was not aware nor would I have said it was appropriate for the HPFBI to have circulated this document without asking us first. That said, I can only assume that the doc was circulated so that the HPFBI rep could be better informed at the CSS WG meeting next week.

While it was our intention to circulate the IAS to the Controlled Substance Program inspectors in RAPB once it had been through the CSS WG, I suppose you are all free to provide input now that you have the document in hand.

Please note that any comments should be addressed to Stephanie Chandler.

Jocelyn

Jocelyn Kula  
Manager/ Gestionnaire  
Policy and Regulatory Affairs Division/ Division des politiques et affaires réglementaires  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0125 Fax: (613) 946-4224  
Omar Lockhat/HC-SC/GC/CA



Omar  
Lockhat/HC-SC/GC/CA  
2010-08-11 03:56 PM

To Jocelyn Kula/HC-SC/GC/CA@HWC  
cc Christine Leckie/HC-SC/GC/CA@HWC, Andrée  
Bernard/HC-SC/GC/CA@HWC, Richard  
Prevost/HC-SC/GC/CA@HWC, Ken  
Moore/HC-SC/GC/CA@HWC, Diane  
Allan/HC-SC/GC/CA@HWC  
Subject Fw: Salvia IAS

Hi Jocelyn, I was wondering if the Controlled Substances Program in the regions can also get on the OCS mailing list. Often we hear about these draft/final IAS' through our inspectorate colleagues, I am hopeful we can get this directly from our national office instead.

Thanks,

Omar Lockhat  
Manager, Western Canada  
Controlled Substances Program  
Compliance and Enforcement - Health Canada  
Tel: 604-666-8941 Fax: 604-666-5741  
Omar.Lockhat@hc-sc.gc.ca

----- Forwarded by Omar Lockhat/HC-SC/GC/CA on 2010-08-11 12:50 PM -----



Ian Findlay/HC-SC/GC/CA  
2010-08-11 06:33 AM

To Omar Lockhat/HC-SC/GC/CA@HWC  
cc  
Subject Fw: Salvia IAS

FYI,  
Ian

----- Forwarded by Ian Findlay/HC-SC/GC/CA on 11/08/2010 08:30 AM -----



Lisa Stewart/HC-SC/GC/CA  
10/08/2010 04:32 PM

To Insp-MASA, Ian Findlay/HC-SC/GC/CA@HWC  
cc  
Subject Fw: Salvia IAS

Below is the IAS document from OCS on Salvia....let me know if you have any questions/comments by  
Aug 19 (Thurs).

Thanks  
Lisa

----- Forwarded by Lisa Stewart/HC-SC/GC/CA on 2010-08-10 04:30 PM -----

**Irshad Mulla/HC-SC/GC/CA**

2010-08-10 09:25 AM

To Christine Zaczynski/HC-SC/GC/CA@HWC, Collin  
Pinto/HC-SC/GC/CA@HWC, Francine  
Ménard/HC-SC/GC/CA@HWC, Ian  
Grimwood/HC-SC/GC/CA@HWC, Jean Saint  
Pierre/HC-SC/GC/CA@HWC, Justin  
Budgell/HC-SC/GC/CA@HWC, Kim  
Seeling/HC-SC/GC/CA@HWC, Lawrence  
Cheung/HC-SC/GC/CA@HWC, Marie  
LaSalle/HC-SC/GC/CA@HWC, Nicholas  
Shiple/HC-SC/GC/CA@HWC, Robyn  
Ewing/HC-SC/GC/CA@HWC, Yogesh  
Sharma/HC-SC/GC/CA@HWC, Mark  
Tempest/HC-SC/GC/CA@HWC, Carolina  
Ulloa/HC-SC/GC/CA@HWC, Neeraj  
Pandey/HC-SC/GC/CA@HWC, Dina  
Aly/HC-SC/GC/CA@HWC, Cecilia  
Bong/HC-SC/GC/CA@HWC, Johanne  
Lussier/HC-SC/GC/CA@HWC, Lisa  
Stewart/HC-SC/GC/CA@HWC

cc

Subject Fw: Salvia IAS

Hello DCVI-SC members,

Could you please provide me with comments on the document below by Thursday?

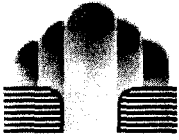
OCS's recommendation is to not schedule *Salvia divinorum* or its main active *salvinorin A* to the CDSA at  
this time.



Draft Salvia Divinorum IAS\_July 12 2010.doc

Thank you,  
Irshad Mulla





Jocelyn Kula/HC-SC/GC/CA

2010-08-14 12:58 PM

To Collin Pinto/HC-SC/GC/CA@HWC

cc Irshad Mulla/HC-SC/GC/CA@HWC, Stephanie  
Chandler/HC-SC/GC/CA@HWC, Tiffany  
Thornton/HC-SC/GC/CA@HWC

bcc

Subject Re: Fw: Salvia IAS

No worries Collin, and Irshad, certainly don't stop anyone from providing input. I think the issue here is that irrespective of what the process used with the BZP IAS was, I just wasn't aware that it was being followed for Salvia, and the way that I found out about it was because one of the CDSA inspectors got the IAS from one of the DSCIV members and then asked me why they had not received it directly. Just kind of put me in an awkward position.

No matter, and now that we know how the HPFBI likes to get input, we are good.

I too will not be at the next CSS WG meeting but Stephanie will be there to track the discussion and accept everyone's feedback.

Cheers  
Jocelyn  
Sent by blackberry

Jocelyn Kula  
Manager/ Gestionnaire  
Policy and Regulatory Affairs Division/ Division des politiques et affaires reglementaires  
Collin Pinto

----- Original Message -----

**From:** Collin Pinto  
**Sent:** 2010-08-14 11:02 AM EDT  
**To:** Jocelyn Kula  
**Cc:** Irshad Mulla; Stephanie Chandler; Tiffany Thornton  
**Subject:** Re: Fw: Salvia IAS

s.16(2)(c)

Hi Jocelyn

As Irshad is the SCDI representative I had asked him to share with the regions as this was the Inspectorate process followed for the draft BZP IAS. I have included the most recent invitation and note from the CSS WG below. Though perhaps the intent, it did not specify that the document was to be kept internal to the CSS-WG. I was aiming to have some preliminary feedback from the Inspectorate for discussion at the next meeting. My apologies if I jumped the gun and the intention was to review internally (CSS-WG) prior to distributing. As you noted, perhaps the process can be made more clear by including any temporary restrictions to sharing in the future.

Please also note that I have delegated the next meeting to Irshad as I will be away on holidays this week.

Irshad - can you kindly inform the regions that another draft/opportunity to review will be forthcoming and they may disregard my request to review at this time.

Tiffany - are these the telecon coordinates? [redacted] conference code [redacted] If not, could you please forward to Irshad?

My apologies for any headaches!  
Collin

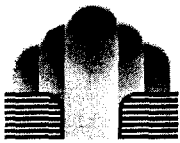
In preparation for the next meeting, please find the attached the current draft of the IAS on Salvia for review. The agenda and the ROD from July will be send prior to the meeting. Should you have any further questions, please do not hesitate to contact me.

[attachment "Draft Salvia Divinorum IAS\_July 12 2010.doc" deleted by Jocelyn Kula/HC-SC/GC/CA]

Thank you,  
Tiffany  
946-3590

---

Jocelyn Kula/HC-SC/GC/CA



Jocelyn Kula/HC-SC/GC/CA

2010-08-13 08:35 PM

To Irshad Mulla/HC-SC/GC/CA@HWC

cc Collin Pinto/HC-SC/GC/CA@HWC, Stephanie  
Chandler/HC-SC/GC/CA@HWC

Subject Fw: Salvia IAS

Hi Irshad,

I am wondering if you can tell me how you obtained a copy of the draft IAS on salvia included in the message below? Just that our office is the author of the document and the only group to whom the document has been circulated yet is to our Controlled Substances Scheduling Working Group (CSS-WG), an inter-branch working group that helps with scheduling-related issues. Not that we don't welcome input from a cross-section of HPCFB employees, it just isn't part of our process to get that input at this point, as to us, the document is still what we would consider an internal draft, and we had intended to have it go through at least one round of discussion within the CSS-WG before circulating the document for wider input.

In this regard, perhaps we can work together on a better process for this type of interaction in the future.

That said, now that the document is out there, of course, we welcome any comments your committee may have. Any such comments can be directed to Stephanie Chandler, as she is the lead on this file in my office.

Regards  
Jocelyn

---

Jocelyn Kula  
Manager/ Gestionnaire  
Policy and Regulatory Affairs Division/ Division des politiques et affaires réglementaires  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0125 Fax: (613) 946-4224  
----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2010-08-13 07:48 PM -----



Lisa Stewart/HC-SC/GC/CA

10/08/2010 04:32 PM

To Insp-MASA, Ian Findlay/HC-SC/GC/CA@HWC

001082



cc

Subject Fw: Salvia IAS

Below is the IAS document from OCS on Salvia....let me know if you have any questions/comments by Aug 19 (Thurs).

Thanks  
Lisa

----- Forwarded by Lisa Stewart/HC-SC/GC/CA on 2010-08-10 04:30 PM -----

Irshad Mulla/HC-SC/GC/CA

2010-08-10 09:25 AM

To Christine Zaczynski/HC-SC/GC/CA@HWC, Collin  
Pinto/HC-SC/GC/CA@HWC, Francine  
Ménard/HC-SC/GC/CA@HWC, Ian  
Grimwood/HC-SC/GC/CA@HWC, Jean Saint  
Pierre/HC-SC/GC/CA@HWC, Justin  
Budgell/HC-SC/GC/CA@HWC, Kim  
Seeling/HC-SC/GC/CA@HWC, Lawrence  
Cheung/HC-SC/GC/CA@HWC, Marie  
LaSalle/HC-SC/GC/CA@HWC, Nicholas  
Shipley/HC-SC/GC/CA@HWC, Robyn  
Ewing/HC-SC/GC/CA@HWC, Yogesh  
Sharma/HC-SC/GC/CA@HWC, Mark  
Tempest/HC-SC/GC/CA@HWC, Carolina  
Ulloa/HC-SC/GC/CA@HWC, Neeraj  
Pandey/HC-SC/GC/CA@HWC, Dina  
Aly/HC-SC/GC/CA@HWC, Cecilia  
Bong/HC-SC/GC/CA@HWC, Johanne  
Lussier/HC-SC/GC/CA@HWC, Lisa  
Stewart/HC-SC/GC/CA@HWC

cc

Subject Fw: Salvia IAS

Hello DCVI-SC members,

Could you please provide me with comments on the document below by Thursday?

OCS's recommendation is to not schedule *Salvia divinorum* or its main active *salvinorin A* to the CDSA at this time.

[attachment "Draft Salvia Divinorum IAS\_July 12 2010.doc" deleted by Jocelyn Kula/HC-SC/GC/CA]

Thank you,  
Irshad Mulla

Stephanie  
Chandler/HC-SC/GC/CA  
2010-08-17 10:06 AM

To Daniel Galarneau/HC-SC/GC/CA@HWC  
cc  
bcc  
Subject Fw: CSS-WG Meeting: August 18th

----- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2010-08-17 10:05 AM -----

Tiffany  
Thornton/HC-SC/GC/CA  
2010-08-17 10:01 AM

To Bruna Brands/HC-SC/GC/CA@HWC, Colette Strnad/HC-SC/GC/CA@HWC, Collin Pinto/HC-SC/GC/CA@HWC, Evelyn Soo/HC-SC/GC/CA@HWC, Hanan Abramovici/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Robin Marles/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC, Tanja Kalajdzic/HC-SC/GC/CA@HWC, Tiana Branch/HC-SC/GC/CA@HWC, Irshad Mulla/HC-SC/GC/CA@HWC  
cc Isabel Shanahan/HC-SC/GC/CA@HWC, Laura Cooney/HC-SC/GC/CA@HWC, Valence Nebie/HC-SC/GC/CA@HWC  
Subject CSS-WG Meeting: August 18th

*next mtg  
Sept 15/2010*

Hi everyone,

Please find attached the draft agenda and ROD for your review in preparation for tomorrow's meeting Wednesday August 18th 10-11:30am in Rm 405A, 123 Slater. If you need to participate via teleconference please let me know prior to the meeting ( I will be out of the office from 8am-9:45 so please contact me today).

**Draft Agenda:**

- 1- Members' introduction
- 2- Approval of Agenda
- 3 - Approval of ROD from July 18th
- 4- Discussion on Salvia (Stephanie/Israd/All)
- 5- Next steps i.e next meeting scheduled September 15, 2010 Rm 405A

*review table items*



Draft Salvia Divinorum IAS\_July 12 2010.doc



CSS-WG July 2010 Meeting ROD\_TBinput.doc

Thank you,  
Tiffany

----- Forwarded by Tiffany Thornton/HC-SC/GC/CA on 2010-08-17 09:42 AM -----

Calendar Entry  
**Meeting**



<b>Subject</b>	CSS-WG Meeting
----------------	----------------

<b>Chair</b>	Tiffany Thornton/HC-SC/GC/CA
--------------	------------------------------

<b>When</b>	<b>Starts</b>	2010-08-18 Wed	10:00 AM	1 hr 30 mins
	<b>Ends</b>	2010-08-18 Wed	11:30 AM	

<b>Where</b>	<b>Location</b>	123 Slater Rm 405
	<b>Reserved</b>	No rooms or resources have been reserved

<b>Invitees</b>	<b>Invited</b>	The following invitees have been invited
	<b>Required (to)</b>	<p>Bruna Brands/HC-SC/GC/CA@HWC,          Colette Strnad/HC-SC/GC/CA@HWC,          Collin Pinto/HC-SC/GC/CA@HWC,          Evelyn Soo/HC-SC/GC/CA@HWC,          Hanan Abramovici/HC-SC/GC/CA@HWC,          Jocelyn Kula/HC-SC/GC/CA@HWC,          Robin Marles/HC-SC/GC/CA@HWC,          Stephanie Chandler/HC-SC/GC/CA@HWC,          Suzanne Desjardins/HC-SC/GC/CA@HWC, Tanja Kalajdzic/HC-SC/GC/CA@HWC, Tiana Branch/HC-SC/GC/CA@HWC</p>
	<b>Optional (cc)</b>	<p>Isabel Shanahan/HC-SC/GC/CA@HWC,          Laura Cooney/HC-SC/GC/CA@HWC</p>

<b>Categorize</b>	
-------------------	--

<b>Description</b>	
--------------------	--

In preparation for the next meeting, please find the attached the current draft of the IAS on Salvia for review. The agenda and the ROD from July will be send prior to the meeting. Should you have any further questions, please do not hesitate to contact me.



Draft Salvia Divinorum IAS\_July 12 2010.doc

Thank you,  
 Tiffany  
 946-3590

<b>Your Notes</b>	
-------------------	--

# Protected B Draft

**Record of Discussion (ROD)**  
**Controlled Substances Scheduling (CSS) Working Group Meeting**  
**Thursday July 15, 2010, 10-11:00am**  
**123 Slater Street, Rm 505A**

***Present:***

- Suzanne Desjardins, Office of Drugs and Alcohol Research and Surveillance (ODARS), Controlled Substances and Tobacco Directorate (CSTD), Healthy Environments Consumer Safety Branch (HECSB) (Chair)
- Bruna Brands, ODARS, CSTD, HECSB via phone
- Tanja Kalajdzic, Marketed Pharmaceuticals & Medical Devices Division, Marketed Health Products Directorate, Health Products and Food Branch (HPFB)
- Colette Strnad, Office of Science, Therapeutic Products Directorate (TPD), HPFB via phone
- Cathy Petersen, Bureau of Cardiology, Allergy and Neurological Sciences, TPD, HPFB
- Korian Soumano, Bureau of Cardiology, Allergy and Neurological Sciences, TPD, HPFB
- Tiana Branch, OCS, CSTD, HECSB
- Nathan J Isotalo, OCS, CSTD, HECSB
- Secretariat- Tiffany Thornton, ODARS, CSTD, HECSB

- Denis Arsenault, OCS, CSTD, HECSB
- Collin Pinto, Drug Compliance, Verification and Investigation Unit, Health Products and Food Branch Inspectorate (HPFBI)

***Regrets:***

- Robin Marles, Bureau of Clinical Trials and Health Sciences, Natural Health Products Directorate (NHPD), HPFB
- Hanan Abromovici, ODARS, CSTD, HECSB
- Jocelyn Kula, OCS, CSTD, HECSB
- Evelyn Soo, OCS, CSTD, HECSB

**1. Welcome & Introductions**

Suzanne welcomed the working group members and invited guests Cathy Petersen and Korian Soumano from the TPD.

**2. Approval of Agenda Items**

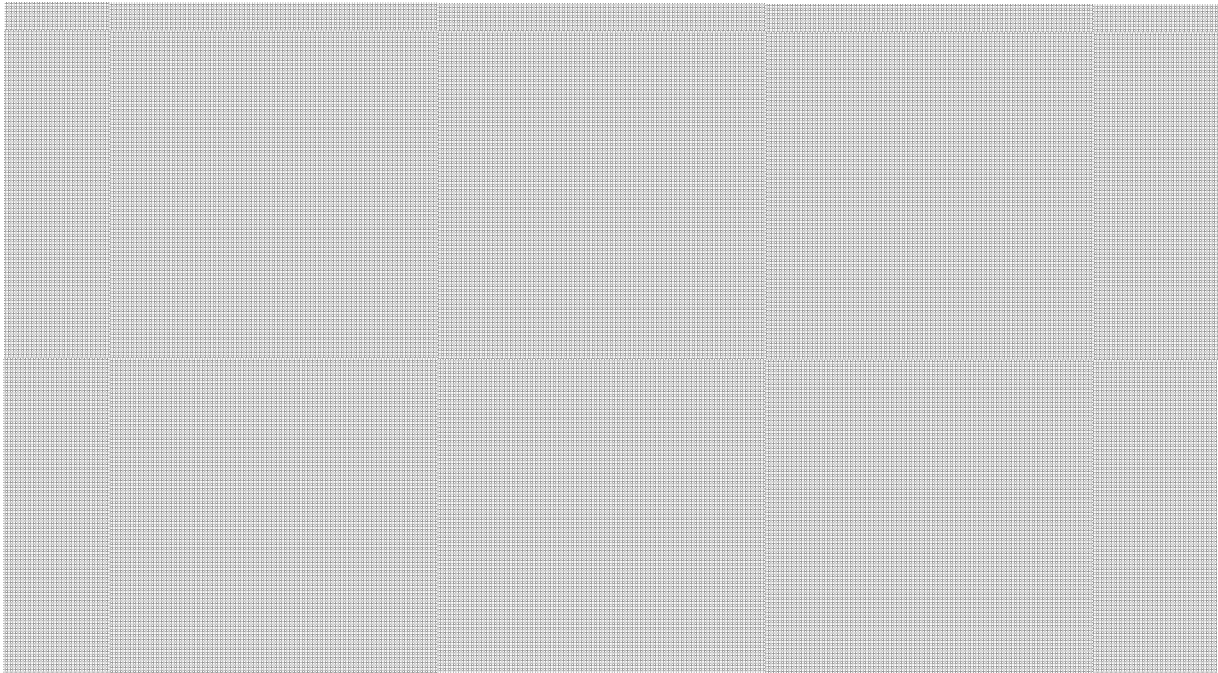
- Agenda approved.

s.21(1)(a)

**3. Approval of ROD from June, 2010**

The ROD for the June 16<sup>th</sup> meeting was approved.

s.21(1)(b)



**6. Next Steps**

The next meeting scheduled for August 18<sup>th</sup> from 10-11:30am in Rm 405A. The CSS-WG will discuss the IAS on Salvia.

**Actions:**

- Tiffany to circulate the updated IAS on Salvia along with the invitation, agenda and ROD for the next meeting.

# Issue Analysis Summary

DRAFT

Scheduling *Salvia Divinorum* and/or Salvinorin A under the CDSA

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Policy and Regulatory Affairs Division  
Office of Controlled Substances

Controlled Substances and Tobacco and Directorate

July 12, 2010

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## CONTENTS

1. APPROVALS
2. ISSUE
3. PURPOSE
4. CONTEXT
5. ASSESSMENT OF RISKS AND BENEFITS
6. IDENTIFICATION AND ANALYSIS OF OPTIONS
7. CONSIDERATIONS
8. RECOMMENDATION(S)
9. CONSULTATIONS
10. IMPLEMENTATION AND EVALUATION

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### 1. APPROVALS

This Issue Analysis Summary is approved.

Diane Allan, Director  
Office of Controlled Substances  
Tobacco and Drugs Directorate

[DD/MM/2010]

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1. ISSUE¶
2. PURPOSE¶
3. CONTEXT¶
4. ASSESSMENT OF RISKS AND BENEFITS¶
5. IDENTIFICATION AND ANALYSIS OF OPTIONS¶
6. CONSULTATIONS¶
7. CONSIDERATIONS¶
8. SELECTED STRATEGY¶
9. IMPLEMENTATION AND EVALUATION¶
10. OUTCOME EVALUATION¶

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### 2. ISSUE

Health Canada has received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *S. divinorum* and/or its main active ingredient salvinorin A, neither of which are currently regulated under the *Controlled Drugs and Substances Act* (CDSA). These requests are further to reports from scientific and media sources suggesting that *S. divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has also noted an

Deleted: In Canada, neither the herb *Salvia divinorum* (*S. divinorum*) nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA).

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ongoing media interest regarding the availability of *S. divinorum* in Canada.

3. PURPOSE

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To assess *Salvia divinorum* and/or salvinorin A against the criteria for the addition of a substance to one of the Schedules to the CDSA, and determine whether one or both should be regulated as controlled substances in Canada.

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4. CONTEXT

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*Salvia divinorum* is a species of sage which belongs to the mint family, and which is found in the form of dried leaves, extract and plant cuttings. Also known as "diviner's sage", the plant is known to induce illusions and hallucinations when chewed or smoked. Salvinorin A, the psychoactive ingredient in *S. divinorum* (also referred to chemically as a neoclerodane diterpene) is found primarily in the leaves, and to a lesser extent in the stems.<sup>1</sup>

*S. divinorum* is widely touted as a "legal" hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs among adolescents and young adults.<sup>2</sup> While very little is known about how and where *S. divinorum* is sold in Canada, it is suspected that it is mainly purchased over the Internet and/or bought at head shops or alternative life style stores, etc.

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The use of *S. divinorum* as a psychotropic agent first came to Health Canada's attention in 2002. In 2004, Health Canada received four adverse drug reaction (ADR) reports associated with the use of *S. divinorum* as a hallucinogen, with three being considered non-serious (requiring no medical attention) and the fourth being considered serious (medical intervention was required). The serious ADR report involved the concomitant use of alcohol in a person diagnosed with Attention Deficit Disorder.

Further to the receipt of the aforementioned ADRs, the Marketed Health Products Directorate (MHPD) and the Natural Health Products Directorate (NHPD) of the Health Products and Food Branch (HPFB) prepared an issue analysis summary (IAS), which recommended that *S. divinorum* and its active ingredient salvinorin A be regulated as controlled substances. This recommendation was maintained when the IAS was updated in November 2006.

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Later, in December 2005, MHPD and NHPD prepared a Signal Assessment (SA) (updated in June 2007) that eventually led to the preparation of a Health Risk Assessment (HRA), which concluded that *S. divinorum* or salvinorin A-containing health products would constitute a Type II Health Risk according to the Health Hazard Classification of the Recall Policy of the Health

Deleted: should be restricted from over-the-counter use. Should any such unauthorized health products be found on the Canadian market, they should be removed from sale. Such products

<sup>1</sup> U.S. Department of Justice Drug Enforcement Administration. 2002. Drugs and Chemicals of Concern: Salvia Divinorum (salvinorin A, divinorin A) URL:

[http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm) Nov 2008

<sup>2</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.

Products and Food Branch Inspectorate (HBFBI). Such a risk is defined as “a situation in which the use of, or exposure to, a product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote”.

Further to an Assistant Deputy Minister (ADM) discussion in April 2007, the Drug Strategy and Controlled Substances Directorate (DSCSD) organized a meeting with MHPD, NHPD and HPFBI to discuss *S. divinorum*. HPFBI was to determine appropriate compliance activities regarding *S. divinorum* and consult with the Canada Border Services Agency (CBSA) regarding the movement of products containing *S. divinorum* into and out of Canada.

On September 13, 2007, a further meeting between DSCSD, MHPD, NHPD and HPFBI led to the conclusion that DSCSD would conduct a scheduling assessment of *S. divinorum* in order to explore the possibility of scheduling this substance under the CDSA.

In September 2008, the Director Generals of DSCSD, MHPD, TPD and the HPFBI agreed that media lines and an “It’s Your Health” article on *S. divinorum* would be prepared.

#### 4.1 Relevant Legislative Frameworks in Canada

##### 4.1.1 Food and Drug Regulations (under the Food and Drugs Act)

The Food and Drug Regulations (F&DR) serve to ensure the safety, efficacy, and quality of health products offered for sale in Canada, including drugs and medical devices. Prior to being given market authorization, a manufacturer must present substantive scientific evidence that a product is safe, efficacious and of high quality. For drugs, Health Canada reviews this information carefully and, if the review is satisfactory, a Notice of Compliance (NOC) is issued and appropriate Drug Identification Numbers (DINs) are assigned.

A “drug” is defined under the F&DR as any substance or mixture of substances manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
- (b) restoration, correction or modification of organic functions in human beings or animals, or
- (c) disinfection in premises in which food is manufactured, prepared or kept;

As no products containing *S. divinorum* or its extracts have been reviewed and approved by Health Canada as of July 2010, it is illegal to market *S. divinorum* when it is represented as a drug.

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comments to this section from NHPD

4.1.2 Natural Health Products Regulations (under the Food and Drugs Act)

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The Natural Health Products Regulations (NHPR) aim to provide Canadians with ready access to natural health products (NHPs) that are safe, effective, and of high quality, while respecting freedom of choice and philosophical and cultural diversity. The NHPR require that all licensed products display a Natural Product Number (NPN), or, in the case of a homeopathic medicine, Drug Identification Number - Homeopathic Medicine (DIN-HM), on their labels. These numbers are issued once a product is authorized for sale in Canada further to a natural health product monograph or submission of other evidence of safety and efficacy. The NHPR also require that all manufacturers, packagers, labelers, and importers be licensed, which in turn requires the presence of procedures respecting distribution records, product recalls, product handling, storage and delivery, and manufacturing practices.

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The definition of an NHP under the NHPR has both a function and substance component. The function component refers to those substances that are manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
(b) restoring or correcting organic functions in humans; or
(c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

The substance component refers to whether the product or medicinal ingredient therein is safe for consideration as an over-the-counter product, can be available for self-care and self-selection, and does not require a prescription to be sold. To be considered a NHP (no direct) health claims need to be made regarding the substance. In the case of S. divinorum, it is generally marketed for its hallucinogenic properties which are considered a modification of an organic function.

Therefore, products containing it meet the definition of a NHP.

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As of July 2010, no products containing S. divinorum have been reviewed and approved by Health Canada and no NPNs or DIN-HMs have been issued. Therefore sales of S. divinorum are illegal under the NHPR if it is represented for use as a hallucinogen or if other health claims in regards to modifying organic functions are made.

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4.1.3 Controlled Drugs and Substances Act and its Regulations

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The CDSA provides a legislative framework for the control of substances that can alter mental processes and that may produce harm to the health of an individual or to society when diverted or misused. Except as authorized under its regulations, activities such as possession, possession for the purposes of trafficking, trafficking, importation, exportation, possession for the purposes of exportation and production of controlled substances are prohibited under the CDSA.

The substances regulated under the CDSA are grouped into eight Schedules, and each Schedule is associated with particular offences and penalties as described in Part I of the CDSA.

In determining whether a substance should be regulated as a controlled substance, and into which Schedule of the CDSA it should be placed, Health Canada considers the following factors:

- (+/-) • International requirements and trends in the control and/or scheduling of the substance;
- (+) • Chemical and/or pharmacological similarity to substances listed in the Schedules to the CDSA;
  - Legitimate use of the substance, including therapeutic, scientific, industrial or commercial uses;
  - Potential for abuse and/or addiction liability of the substance;
  - Evidence of extent of actual abuse of the substance in Canada and internationally; and
  - Risk to personal and public health and safety.

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#### 4.2 Assessment of *Salvia Divinorum* for Scheduling Purposes

##### 4.2.1 International Requirements and Trends in the Control and/or Scheduling of the Substance

At the present time, neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and therefore do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

##### Australia

In June 2002, Australia became the first country to prohibit the sale, supply, possession and use of *S. divinorum* and salvinorin A. Although both *S. divinorum* and salvinorin A are listed in Schedule 9 of Australia's Standard for the Uniform Scheduling of Drugs and Poisons on the basis of "high potential for abuse and risk to public health and safety", no substantiation of this risk was provided at the time of this scheduling decision.<sup>3</sup> Schedule 9 is Australia's most restrictive drug schedule, and includes "substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities."<sup>4</sup>

**Deleted:** International requirements and trends in control/scheduling;¶  
 • Chemical and pharmacological similarity to other substances already scheduled under the CDSA;¶  
 • Legitimate uses of the substance (i.e. therapeutic, industrial or commercial);¶  
 • Potential for abuse and/or addiction liability of the substance;¶  
 • Extent of actual abuse in Canada and internationally; and¶  
 • Overall risk to public health and safety of Canadians.

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##### ✓ Belgium

A decree was passed in Belgium on October 22, 2006 which added *S. divinorum* to the list of controlled substances. This list includes substances such as psilocybin mushrooms, khat and

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<sup>3</sup> <http://www.tga.gov.au/ndpsc/record/rr200111.pdf>

<sup>4</sup> [http://www.cognitiveliberty.org/news/salvia\\_australia.htm](http://www.cognitiveliberty.org/news/salvia_australia.htm)

do we have a contact in Australia.  
 need to find out rationale for scheduling

Bring to WHO to see

- Both Europe and US are not listing or placing controls
- many European countries → 21
- other Japan, Australia; Russia
- 22 states in US

peyote cactus.<sup>5</sup>

✓ **Denmark**

In 2003, Denmark added *S. divinorum* and salvinorin A to their list of “category B” controlled substances, a category which also includes psilocybin mushrooms, cocaine, amphetamine, and several others substances that are only legal for medicinal and scientific purposes. Illegal possession carries a penalty of up to two years in prison.

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✓ **Germany**

*S. divinorum* (plant and plant parts) was added to Appendix I of the *Narcotics Act* in Germany on March 1, 2008, making it illegal to produce, traffic, or possess. The law does not specifically mention salvinorin A.

✓ **Italy**

On June 25, 2004, the Italian Ministry of Health issued an ordinance prohibiting the sale of *S. divinorum* and its active constituent salvinorin A. On January 11, 2005, the Ministry of Health made possession of *S. divinorum* and salvinorin A illegal by placing them in “*Tabella I*” of the *Tabelle Sostanze Stupefacenti o Psicotrope*.

**Japan**

On November 9, 2006, the Japanese government added a group of thirty-three drugs to its list of controlled substances, including salvinorin A. The drugs are banned under a revised pharmaceutical law, under which persons involved in their illegal import, production, and sale, i.e., beyond medical treatment or research purposes, will be subject to up to five years imprisonment or a fine of up to five million yen.

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✓ **Spain**

On January 28, 2004, the Spanish Ministry of Health and Consumption issued an order prohibiting the sale of *S. divinorum*. The regulation went into effect on May 6, 2004 and only prohibits activities related to commerce. Possession and/or use are not considered to be criminal offences.

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**Other Countries**

*Salvia divinorum* is illegal to possess or sell in Croatia, Latvia, Lithuania, Poland, Romania, South Korea and Sweden. In Russia it is illegal to grow or sell *S. divinorum*, but it is legal to

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<http://eldd.emcdda.europa.eu/html.cfm/index5176EN.html?pluginMethod=eldd.shownewsdetails&id=20/12/2006BELGIUM:%20New%20substances%20controlled%20include%20mCPP%20and%20khat>

possess it. In Estonia, Finland, Iceland and Norway, *S. divinorum* is treated as a medicinal herb and it is illegal to import it without a relevant prescription from a doctor.

**United States of America**

22 states

*S. divinorum* and salvinorin A are not included in the Schedules to the United States Controlled Substances Act although both *S. divinorum* and salvinorin A have been added to a list of chemicals "of concern" which has no legal implications. In addition, some individual states have implemented laws restricting its use, sale and/or distribution. As of July, 2010, a number of states have enacted legislation placing regulatory controls on *S. divinorum* and/or salvinorin A including Delaware, Georgia, Florida, Hawaii, Illinois, Kansas, Kentucky, Maryland, Mississippi, Missouri, Nebraska, North Dakota, Ohio, Oklahoma, South Dakota, Wisconsin, Virginia, California, Louisiana, Maine, North Carolina, and Tennessee. More details regarding the regulation of *S. divinorum* in these last five states are provided below.

**California**

As of January 1, 2009, the sale or distribution of *S. divinorum* or salvinorin A, or any substance or material containing *S. divinorum* or salvinorin A, to any person under 18 years of age is a misdemeanor punishable by imprisonment in a county jail for not more than six months, a fine of no more than \$1,000, or both.

**Louisiana**

In 2005, Louisiana passed a bill which prohibits the possession, production, manufacture and distribution of a material, compound, mixture, or preparation intended for human consumption and that contains a hallucinogenic plant. A "hallucinogenic plant" is defined as "any part or portion" of a plant on a list of forty plants, which includes *S. divinorum*.

**Maine**

In Maine, *S. divinorum* and salvinorin A are regulated in the same way as tobacco products; adults eighteen years of age or over can legally purchase and use the material, but selling or providing *S. divinorum* or salvinorin A to anyone under the age of eighteen is a criminal offence. Possession by a minor is a civil violation, punishable by a fine, community service, or both.

**North Carolina**

On December 1, 2009, the North Carolina State Legislature brought a new law into force which made *Salvia divinorum* and salvinorin A illegal. The only legal *S. divinorum* activities are the growing for aesthetic, landscaping, or decorative purposes or university-affiliated medical or pharmacological research.

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- Deleted: Schedule I controlled substances in that state. This bill was later amended to make possession of *S. divinorum* an infraction, a minor crime punishable by a maximum \$25 fine. A third possession offence would be charged as a ... [1]
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## Tennessee

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On July 1, 2006, Tennessee classified the deliberate production, manufacture, distribution, or possession of the active chemical ingredient in the hallucinogenic plant *S. divinorum* as a Class A misdemeanor. It is not, however, a criminal offence to possess, plant, cultivate, grow, or harvest *S. divinorum* for aesthetic, landscaping, or decorative purposes. The law also does not apply to any dosage that is legally obtainable from a retail establishment without a prescription when (and if) it is recognized by the Food and Drug Administration as a homeopathic drug.

### 4.2.2 Chemical and/or Pharmacological Similarity to Substances listed in the Schedules to the CDSA

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In addition, the U.S. Department of Justice Drug Enforcement Agency (DEA) has placed *S. divinorum* and salvinorin A on a list of drugs and chemicals "of concern," without legal implications.¶

The psychoactive ingredient in *Salvia divinorum* is salvinorin A. Other plants which contain psychotropic terpenoids are *Artemisia absinthium* (wormwood) and *Cannabis sativa*. Salvinorin A is considered by some as the most potent natural hallucinogen ever isolated.<sup>6</sup>

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Unlike all other hallucinogens, salvinorin A is structurally distinct and does not interact with the serotonin-2A receptor or any other molecular target of classical hallucinogens. It thus affects the brain in a way that is quite unique.<sup>7</sup> Recent pharmacological screenings of receptors have found it to be a highly potent and selective κ-opioid receptor (KOR) agonist.<sup>8</sup>

Deleted: Chemical and Pharmacological Similarity to Other Substances Listed in the CDSA

The use of *S. divinorum* or salvinorin A can lead to a number of effects with variable onset and duration. These effects are generally accepted to be: sensation of becoming an object, visions of various two-dimensional surfaces, films and membranes, revisiting places of the past (particularly childhood), perceived loss of the body and/or identity, various sensations of motion (being pulled or twisted by a force of some kind), uncontrollable hysterical laughter, and overlapping realities (perceptions of being in more than one place).<sup>9</sup> Laughter, happiness, sense of well-being and dissociative effects were deemed the best aspects of *S. divinorum* by users, second only to the "trip" that the drug elicits.<sup>10</sup> Depersonalization, speaking gibberish, widening of consciousness and subjective illusions of rapid movement, flying or hovering have also been

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<sup>6</sup> Ott J. Ethnopharmacognosy and human pharmacology of *Salvia divinorum* and salvinorin A. *Curare*. 1995 18: 103-129. Unofficial transcription available online. URL <http://www.sagewisdom.org/ott2.html>

<sup>7</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>8</sup> Roth BL, Baner K, Westkaemper R, Siebert D, Rice KC, Steinberg S, Ernberger P, Rothman RB. Salvinorin A: a potent naturally occurring nonnitrogenous kappa opioid selective agonist. *Proc Natl Acad Sci U S A*. 2002 Sep 3;99(18):11934-9.

<sup>9</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>10</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

(as potent as LSD)

reported.<sup>11</sup>

The psychomimetic effects of *S. divinorum* closely resemble schizophrenia symptoms induced by lysergic acid diethylamide (LSD) or phencyclidine (PCP).<sup>14</sup> Yet, it is said to have only weak influence on the prevailing mood of the user which differentiates it from other hallucinogens such as LSD and psilocybin.<sup>15</sup> Its strong dissociative effects are often compared to those of ketamine. Users have reported that the psychedelic effects of *S. divinorum* were most similar to those caused by psilocybin mushrooms.<sup>16</sup> However, users familiar with the effects of other hallucinogens agree that despite certain similarities to classical hallucinogens, the visions and overall experience are quite unique.<sup>17</sup>

**Deleted:** Unlike all other hallucinogens, salvinorin A is structurally distinct and does not interact with the serotonin-2A receptor or any other molecular target of classical hallucinogens. It thus affects the brain in a way that is quite unique.<sup>12</sup> Recent pharmacological screenings of receptors have found it to be a highly potent and selective κ-opioid receptor (KOR) agonist.<sup>13</sup>¶

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In addition, the psychedelic effects of *S. divinorum* are similar to those of classical psychedelics regarding changes in perception and somatic sensations. *S. divinorum* causes an unusually high degree of sedation, weakness and fatigue, while the increased de-realization is not commonly reported for classical psychedelics.<sup>18</sup> The combination of these effects seems to correlate with that of other KOR agonists such as pentazocine.<sup>19</sup>

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#### 4.2.3 Legitimate Use of the Substance, including Therapeutic, Scientific, Industrial or Commercial Uses

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*Salvia divinorum* has traditionally been used for spiritual and medicinal purposes by the Mazatec

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<sup>11</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5 and Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

**Deleted:** There are presently no legitimate medical or industrial uses for *S. divinorum* in Canada. ¶

<sup>14</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>15</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>16</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>17</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6 and González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>18</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>19</sup> Arasteh K, Poudevida S, Farre M, Roset PN, Cami J. Response patterns of the Spanish version of the 49-item short form of the Addiction Research Center Inventory after the use of sedatives, stimulants, and opioids. *Drug Alcohol Depend*. 1999 Jun 1;55(1-2):117-25.



such no traditional use in Canada

Oaxaca: Traditional use -> no difference between spiritual and medicinal uses

Treated as one and the same (culture specific).

Indians in Oaxaca, Mexico,<sup>20</sup> where an infusion of the leaves or the leaves themselves are ingested to treat gastrointestinal problems, headaches, rheumatism, anemia and swelling of the stomach.<sup>21</sup> Its main use today is, however, for its psychoactive properties in the aid of producing "mystical" or hallucinogenic experiences as part of spiritual rituals.<sup>22</sup>

Although selective kappa receptor agonists have been shown to produce analgesic effects, adverse effects such as psychotomimesis, dysphoria and diuresis have been observed in studies investigating their therapeutic use.<sup>23</sup> In addition, while it has been speculated that KOR agonists may prove to be useful in the treatment of certain psychiatric disorders including Alzheimer's disease, schizophrenia, dementia and bipolar disorder,<sup>24</sup> much more research is needed in order to substantiate these hypotheses. Similarly, another study has suggested that chemical analogues of salvinorin A may be a useful treatment for those suffering from addiction to other substances.<sup>25</sup> That said, there are presently no legitimate medical uses for *S. divinorum* in Canada.

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Indicence? should we address this

Similarly, there are no known industrial or commercial uses for *S. divinorum* in Canada. The plant is a semi-tropical perennial that can only grow outdoors in a humid climate where it will not encounter frost. Most websites offering *S. divinorum* cuttings and seeds for sale appear to do so in the context of growing the plant in order to utilize its psychoactive properties, rather than out of horticultural interest or for its esthetic appeal.

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NHPD To provide wording as "indicence use" - not a real claim.

4.2.4 Potential for Abuse and/or Addiction Liability of the Substance

Salvinorin A is a potent, selective agonist of the kappa-opioid receptor (KOR), and in contrast to the euphoria produced by mu-opioid receptor (MOR) agonists, KOR agonists are negatively reinforcing and aversive.<sup>26</sup> In addition, KOR agonists have analgesic properties but are not

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<sup>20</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>21</sup> Munro, T. The Chemistry of Salvia divinorum. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

<sup>22</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage Salvia divinorum. Life Sci. 2005 Dec 22;78(5):527-31.

<sup>23</sup> Barker RL, Fawcett J, Barkin SJ. 2002. Chronic pain management with a focus on the role of newer antidepressants and centrally acting agents. In: Pain Management: A Practical Guide for Clinicians, 6th edition, Weiner RS ed. CRC Press, Boca Raton, FL. pp. 415-34 and Tidgewell et al., 2004. A facile method for the preparation of deuterium labelled salvinorin A: Biorganic & Medicinal Chemistry Letters, 14: 5099-5102.

<sup>24</sup> Sheffler DJ & Roth BL. Salvinorin A: the 'magic mint' hallucinogen finds a molecular target in the kappa opioid receptor. Trends Pharmacol Sci. 2003 Mar;24(3):107-109.

<sup>25</sup> Prisinzano TE. Natural products as tools for neuroscience: discovery and development of novel agents to treat drug abuse. J Nat Prod. 2009 Mar 27;72(3):581-7.

<sup>26</sup> Gustein HB & Akil H. Opioid Analgesics. In: Goodman and Gilman's The Pharmacological Basis of Therapeutics 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590, Cooper S. Interactions between endogenous opioids and dopamine: Implications for reward and aversion. In: The Mesolimbic Dopamine System: From Motivation to Action. Willner P and Scheel-Kruger J (editors) Wiley, Chester, England, 1991, pp. 331-366, and Shippenberg TS, Herz A, Spanagel R, Bals-Kubik R, Stein C. Conditioning of opioid reinforcement: neuroanatomical and neurochemical substrates. Ann N Y Acad Sci. 1992 Jun 28;654:347-56.

associated with respiratory depression like MOR agonists. Finally, while MOR agonists increase, the release of dopamine, the activation of KOR decreases dopamine release in the nucleus accumbens.<sup>28</sup>

**Deleted:** Initially, these effects provided hope for the development of an analgesic absent of addiction liability and respiratory depression. However, it was soon discovered that KOR agonists produced dysphoria and psychomimetic effects such as confusion, hallucinations and depersonalization.<sup>27</sup>

The onset and intensity of the effects of *Salvia divinorum* appear to be related to the route of administration.

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Traditional uses generally produce mild effects because the leaves are rolled and chewed or crushed and prepared as a foamy infusion whereby the salvinorin A is degraded in the gastrointestinal system before being absorbed into the bloodstream. Hence, the level of effect relates quite closely to the length of time the material spends in the mouth, with the onset of effect generally taking 5-10 minutes. The effects build over the next hour and last for another hour before they begin to subside.<sup>29</sup>

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Routes of administration that avoid the hepatic first-pass effect (i.e. inhalation, intravenous, intramuscular and sublingual use) are the quickest and most intense.<sup>30</sup> Salvinorin A can be isolated from the plant to make a powder which can be vaporized and inhaled. The onset of effects felt from vaporizing salvinorin A powder occurs in about 30 seconds and effects last for about 5-10 minutes and then subside over the next 30 minutes.<sup>31</sup>

**Deleted:** This method of administration is the most powerful and only requires 200-500 micrograms of salvinorin A powder to produce the same effects as those of fresh leaves.

Smoking is by far the most popular method of administration<sup>32</sup> and this is accomplished by smoking the dried leaves or a concentrated extract using a pipe or bong. Dried leaves may also be fortified with a concentrated extract of salvinorin A. A concentrated extract can also be used sublingually. Neither *S. divinorum* nor salvinorin A can be injected because the powder is insoluble in water.<sup>33</sup>

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<sup>28</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.

<sup>29</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>30</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.

<sup>31</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>32</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62 and Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>33</sup> Valdés LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs.* 1994 Jul-Sep;26(3):277-83.

The aversive effects of previously studied KOR agonists predict that the risk of addiction to *S. divinorum* is negligible. However, very few controlled scientific studies of the physical and psychotropic effects of *S. divinorum* on humans have been carried out. Therefore, it is difficult to predict its potential for addiction and abuse. In studies that have been conducted, there is conflicting information around the addiction liability of *S. divinorum* in both animals and humans. Some users have noted that they require increasing doses of salvinorin A in order to achieve the desired effect and the stimulated cerebral KOR may act as a mechanism of tolerance.<sup>37</sup> Further studies in this area and on the mediated decrease of dopamine as well as the impact of dose on effects are also required.

While concerns for the potential of abuse were once minimal because 1 kg of dried leaves yields only 3 to 6 human doses of salvinorin A, it was discovered that vaporizing and inhaling 200-500 micrograms had profound hallucinogenic effects.<sup>38</sup> The extraction of salvinorin A from the plant is very easy, and with care, approximately 1.5 grams of pure salvinorin A per kilogram of dried leaves (8kg of fresh leaves) can be isolated. This is enough substance to provide for 2000 human doses.<sup>39</sup>

<sup>37</sup> Bucheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>38</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>39</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs*. 1994 Jul-Sep;26(3):277-83.

<sup>44</sup> Turner DM. *Salvinorin - The Psychedelic Essence of Salvia Divinorum*. Panther Press, San Francisco, CA 1996.

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The various modes of administration of *S. divinorum* lead to the variable onset and duration of its effects. These effects are generally accepted to be: sensation of becoming an object, visions of various two-dimensional surfaces, films and membranes, revisiting places of the past (particularly childhood), perceived loss of the body and/or identity, various sensations of motion (being pulled or twisted by a force of some kind), uncontrollable hysterical lau ... [3]

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#### 4.2.5 Evidence of Extent of Actual Abuse of the Substance in Canada and Internationally

In Canada, the extent of actual abuse of *Salvia divinorum* and/or salvinorin A is relatively unknown. There is, however, some data regarding the use of *Salvia divinorum* in Canada, despite the lack of legitimate uses for this plant. Questions about the use of *S. divinorum* were included in the 2008-2009 Youth Smoking Survey, the 2009 Canadian Alcohol and Drug Use Monitoring Survey and the 2009 Ontario Student Drug Use and Health Survey.

The results from the 2009 Ontario Student Drug Use and Health Survey were published on November 18, 2009 and indicate that:

- Among all responding students in Ontario, 4.4% reported using *Salvia divinorum* at least once in the past year. In comparison, 58.2% indicated they had used alcohol, 25.6% indicated they had used cannabis and 5.0% indicated they had used hallucinogens other than LSD and PCP in the past year;
- Males (6.2%) were significantly more likely than females (2.3%) to report using *Salvia divinorum*;
- There is significant grade variation, with *Salvia divinorum* use most likely among 11<sup>th</sup> graders (8.6%) and 12<sup>th</sup> graders (8.4%); and
- There are significant regional variations, with students in Northern Ontario (9.2%) most likely to use *Salvia divinorum*.

The results of the 2008-2009 Youth Smoking Survey were published on May 31, 2010 and indicate that:

- 4.9% of students stated that they had used *S. divinorum* in the last twelve months. In comparison, 53.0% indicated they had used alcohol, 27.3% indicated they had used cannabis and 6.9% indicated they had used other hallucinogens in the last twelve months;
- 2.6% of students in Grades 7-9 and 7.0% of students in Grades 10-12 had used *S. divinorum* in the last twelve months; and
- Males (6.6%) were more likely to have used *S. divinorum* in the past twelve months compared to females (3.2%).

*cannabis*

The scope of the previously mentioned studies did not provide for any explanations regarding differences in usage between ages, genders and regions. In this regard, it is difficult to speculate on the causality of such differences.

The Canadian Alcohol and Drug Use Monitoring Survey specifically examined *Salvia* for the first time in 2009. An estimated 1.6% of Canadians, aged 15 years and older, reported that they had used *salvia* in their lifetime, and 0.2% reported using it in the past-year. In comparison, the prevalence of past-year cannabis use among Canadians 15 years of age and older was 10.6%. 1.2% of respondents reported using cocaine or crack in the past 12 months, 0.9% had used ecstasy and 0.7% used illicit hallucinogens.

Health Canada's Drug Analysis Services (DAS) has identified salvinorin A in a number of

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- As far as law enforcement is concerned, the Department has only received a limited number of communications indicating concern with respect to *S. divinorum* and none of these have advised that the use of *S. divinorum* poses any threat to public safety. Sgt. Doug Culver of the Royal Canadian Mounted Police (RCMP) stated that while *S. divinorum* is readily available, it has not become a popular drug in Canada. Sgt. Culver speculated that this may be due to its aversive effects such as anxiety and introversion. ¶
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samples seized by law enforcement, as shown in the following table.

**NUMBER OF SAMPLES FOUND TO CONTAIN SALVINORIN A**

Year	Count
2006	9
2007	8
2008	4
2009	20
2010 (as of May 7)	8

The National Forensic Laboratory Information System (NFLIS) and the System to Retrieve Information from Drug Evidence (STRIDE) in the United States are Drug Enforcement Agency (DEA) databases that collect scientifically verified data on analyzed samples in state and local forensic labs as well as samples from DEA labs. The following table shows the quantity of *S. divinorum* products that were seized from 2000 through to 2009.

**ANALYZED SALVIA DIVINORUM or SALVINORIN A SEIZURES**

(Number of Items/Exhibits)

Source	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009*
NFLIS-State/Local <sup>1</sup>	0	0	0	0	1	8	12	12	70	34
STRIDE <sup>2</sup>	0	0	1	1	1	0	0	0	N/A	N/A
<b>TOTAL</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>1</b>	<b>2</b>	<b>8</b>	<b>12</b>	<b>12</b>	<b>70</b>	<b>34</b>

Data Source: NFLIS & STRIDE, 2008 data queried 11/24/08, updated 06/10/2010

<sup>1</sup> NFLIS reported seizures of *Salvia divinorum* and/or salvinorin A

<sup>2</sup> STRIDE reported items of *Salvia divinorum*.

\* Includes only January – May data in 2009.

It is difficult to determine the extent of actual abuse of *S. divinorum* in Canada or elsewhere as there appear to be inconsistencies in the literature regarding risk aversion. For example, one author states: "Many who have used salvinorin A find the experience extremely unnerving, frightening and overly intense and most have no desire to repeat the experience."<sup>44</sup> However, another study suggested that this is not the experience of all recreational users of *S. divinorum*.<sup>45</sup> Over eighty percent of users surveyed on a web-based questionnaire about their *S. divinorum* use said that they would probably or definitely use *S. divinorum* again.<sup>46</sup> Users have reported the negative effects of *S. divinorum* as: the short duration of action, lack of control over the

<sup>45</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62, Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5, and Valdés LJ 3rd. Salvia divinorum and the unique diterpene hallucinogen, Salvinorin (divinorin) A. J Psychoactive Drugs. 1994 Jul-Sep;26(3):277-83.

<sup>46</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

**Deleted:** however, as the plant and/or substance is not in the Controlled Drugs and Substances Database (CDS) druglist, it is not possible to have records of any seizures of it in the database. However, there have been a number of samples submitted to DAS for analysis that have been confirmed to contain salvinorin A.

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 A handful of case reports regarding the use of *S. divinorum* have been published in the academic literature. One report was an international case report in which a young man (19 years of age) described his perceptions after inhaling smoke from *S. divinorum*. The peak psychotropic effects, including prickling of the skin, fever-like hot flashes, muscular tremor, and depersonalization, were reached in less than five minutes after inhalation of an unknown amount of smoke from burning dried leaves.<sup>41</sup> Another report involved a 15-year-old male who presented to psychiatric emergency services with acute onset of paranoia, déjà vu, blunted affect, difficulties in thought processing and slowed speech after smoking *Salvia divinorum* over an unknown period of time. During his hospitalization all symptoms improved significantly except the feeling of déjà vu. Based on this case presentation, the author suggested that the feelings of déjà vu may be a long-term effect of *S. divinorum* use.<sup>42</sup> However, given that this is the only case report in which déjà vu was associated with the use of *S. divinorum*, more reports are needed to substantiate this finding.¶

¶ In addition to the above-mentioned reports, in 2006, a case was reported in the U.S. in which a¶ 17-year-old boy committed suicide after smoking *S. divinorum* for an unknown period of time.<sup>43</sup> ¶ ... [7]

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experience, persisting negative effects (most often anxiety),<sup>47</sup> sweating, chills, increased diuresis, impaired vigilance,<sup>48</sup> and negative after-effects including tiredness, feeling head heavy, dizziness, physical exhaustion, and some degree of malaise or 'hangover' as they 'comedown' from the drug.<sup>49</sup>

**Deleted:** However, it is difficult to determine the influence these effects have on the use of *S. divinorum*.

#### 4.2.6 Risk to Personal and Public Health and Safety

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The increase in both the number of enquiries from various municipalities and members of the public and the amount of media interest regarding the availability of *Salvia divinorum* in Canada may be an indication that the recreational use of *S. divinorum* as a hallucinogen is on the rise. However, there are no available statistics that indicate there has been a significant increase in *S. divinorum* use in the Canadian population and, in comparison to the use of other drugs such as alcohol and cannabis, the actual use of *S. divinorum* is quite low.

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The potential for harm to the user and/or other individuals is primarily related to the hallucinogenic properties of the substance. Users may get up and walk around without apparent awareness of their movements, behaviour or surroundings, and distinction between self and surroundings is often lost. At doses greater than 1mg of salvinorin A, out of body experiences are frequent and loss of consciousness has been reported.<sup>50</sup> There is little information regarding the social behaviours of persons under the influence of *S. divinorum* products, and what risks their activities such as operating a motorized vehicle may pose to the general public. There is also very little data regarding the toxicity, teratogenicity or other long-term effects of *S. divinorum* use.<sup>51</sup>

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As far as law enforcement is concerned, the Department has only received a limited number of communications indicating concern with respect to *S. divinorum* and none of these have advised that the use of *S. divinorum* poses any threat to public safety. The Royal Canadian Mounted Police (RCMP) has stated that while *S. divinorum* is readily available, it has not become a popular drug in Canada, probably due to its aversive effects such as anxiety and introversion.

A handful of case reports regarding the use of *S. divinorum* have been published in the academic literature. One report was an international case report in which a young man (19 years of age) described his perceptions after inhaling smoke from *S. divinorum*. The peak psychotropic effects, including prickling of the skin, fever-like hot flashes, muscular tremor, and depersonalization, were reached in less than five minutes after inhalation of an unknown amount of smoke from burning dried leaves.<sup>52</sup> Another report involved a 15-year-old male who presented

<sup>47</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>48</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>49</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>50</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>51</sup> Grundmann O, Phipps SM, Zadezensky I, Butterweck V. *Salvia divinorum* and Salvinorin A: An Update on Pharmacology and Analytical Methodology. *Planta Med* 2007 Jun;73:1039-1046.

to psychiatric emergency services with acute onset of paranoia, déjà vu, blunted affect, difficulties in thought processing and slowed speech after smoking *Salvia divinorum* over an unknown period of time. During his hospitalization all symptoms improved significantly except the feeling of déjà vu. Based on this case presentation, the author suggested that the feelings of déjà vu may be a long-term effect of *S. divinorum* use.<sup>53</sup> However, given that this is the only case report in which déjà vu was associated with the use of *S. divinorum*, more reports are needed to substantiate this finding.

In addition to the above-mentioned reports, in 2006, a case was reported in the U.S. in which a 17-year-old boy committed suicide after smoking *S. divinorum* for an unknown period of time.<sup>54</sup> It should be noted that alcohol and general depression were the main confounders in this case. After this case was reported, the state of Delaware passed a law which classified *S. divinorum* as a Schedule I controlled substance along with other hallucinogenic substances.

Like many drugs of abuse, users are often unaware of the potency and adulterants in the product they purchase. A study by Wolowich *et al.* (2006)<sup>55</sup>, showed that the salvinorin A content in five out of five *S. divinorum* products was falsely indicated on the label and 4 out of 5 products contained unidentified adulterants (i.e. vitamin E, caffeine).

Summarize this

Health Canada has only anecdotal information about the use and abuse of *S. divinorum* in Canada as well as the threat *S. divinorum* may pose to the health and safety of Canadians. Although reports of domestic adverse reactions related to the use of *S. divinorum* as a hallucinogen have been received through the Canada Vigilance database, it is important to note that the number of reports and the nature of reactions reported are not adequate to characterize the risk to the general population.

## 5. ASSESSMENT OF RISKS AND BENEFITS

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**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**



## 9. CONSULTATIONS

The Drug Analysis Services (DAS) was contacted in order to provide any data available regarding the identification of salvinorin A in samples submitted by law enforcement.

The Royal Canadian Mounted Police (RCMP) was contacted in order to establish their views with respect to *S. divinorum* use in Canada. The RCMP advised that though *S. divinorum* is readily available, it does not appear to pose a threat to public safety.

OCS has received a number of correspondences from Canada Border Services Agency (CBSA) officers concerning a lack of information regarding the status of *S. divinorum* and how the plant should be treated at the border. CBSA officers have also expressed concern regarding the plant's hallucinogenic properties. At present, only shipments of *S. divinorum* that are represented as health products that modify organic functions can be refused for import under the NHPR.

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Schedule I controlled substances in that state. This bill was later amended to make possession of <i>S. divinorum</i> an infraction, a minor crime punishable by a maximum \$25 fine. A third possession offence would be charged as a misdemeanor. There are no separate penalties for manufacturing or sales. This bill includes two exemptions. One permits		
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. The new law came into effect on December 1, 2009.		
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The various modes of administration of *S. divinorum* lead to the variable onset and duration of its effects. These effects are generally accepted to be: sensation of becoming an object, visions of various two-dimensional surfaces, films and membranes, revisiting places of the past (particularly childhood), perceived loss of the body and/or identity, various sensations of motion (being pulled or twisted by a force of some kind), uncontrollable hysterical laughter, and overlapping realities (perceptions of being in more than one place).<sup>1</sup> Laughter, happiness, sense of well-being and dissociative effects were deemed the best aspects of *S. divinorum* by users, second only to the "trip" that the drug elicits.<sup>2</sup> Depersonalization, speaking gibberish, widening of consciousness and subjective illusions of rapid movement, flying or hovering have also been reported.<sup>3</sup>

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More controlled systematic research in this area is needed.		
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Another aspect of the <i>S. divinorum</i> abuse potential stems from its availability. As previously mentioned, it is widely available for purchase on the Internet through drug promotional sites and it is also sold in various "head shops" and corner stores. In addition, the potential for high yields and ease of extraction may make buying and selling this substance quite affordable and attractive. Originally, t		
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It is also believed to be easier to obtain salvinorin A than to extract LSD or produce PCP derivatives. <sup>4</sup>		
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<sup>1</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>2</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>3</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5 and Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

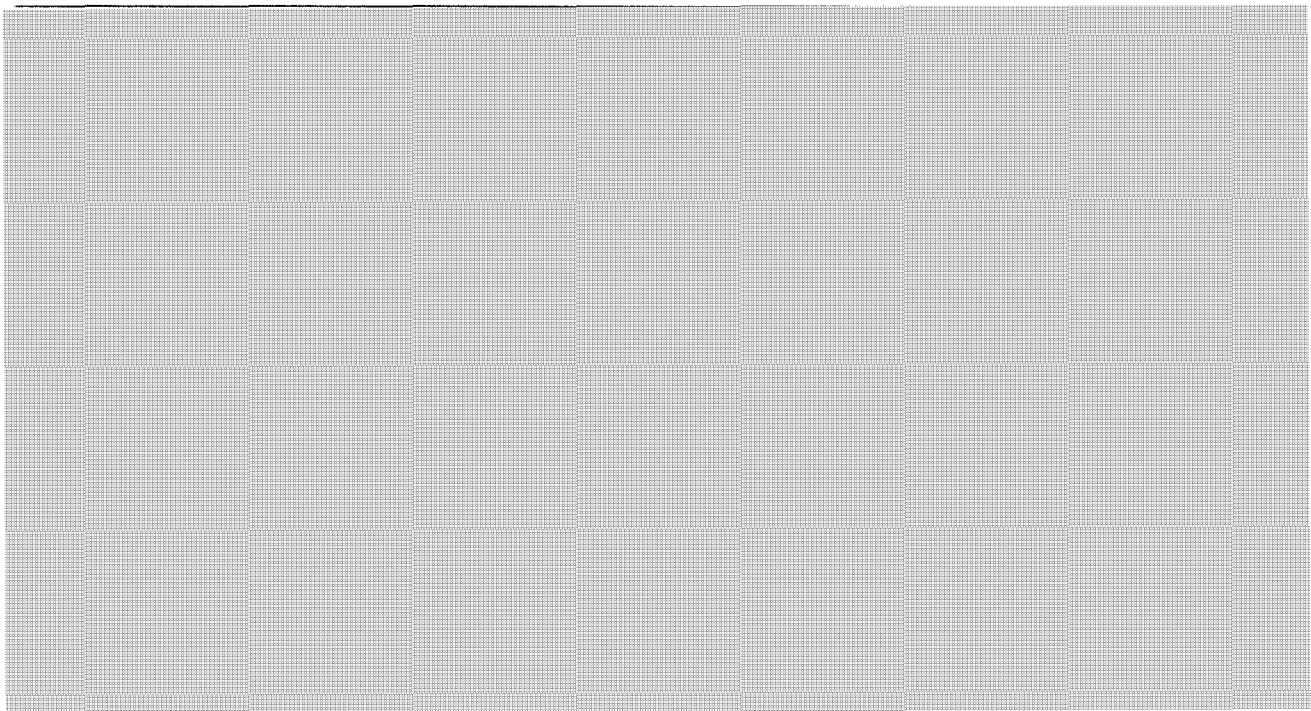
<sup>4</sup> Bucheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5.

A handful of case reports regarding the use of *S. divinorum* have been published in the academic literature. One report was an international case report in which a young man (19 years of age) described his perceptions after inhaling smoke from *S. divinorum*. The peak psychotropic effects, including prickling of the skin, fever-like hot flashes, muscular tremor, and depersonalization, were reached in less than five minutes after inhalation of an unknown amount of smoke from burning dried leaves.<sup>5</sup> Another report involved a 15-year-old male who presented to psychiatric emergency services with acute onset of paranoia, déjà vu, blunted affect, difficulties in thought processing and slowed speech after smoking *Salvia divinorum* over an unknown period of time. During his hospitalization all symptoms improved significantly except the feeling of déjà vu. Based on this case presentation, the author suggested that the feelings of déjà vu may be a long-term effect of *S. divinorum* use.<sup>6</sup> However, given that this is the only case report in which déjà vu was associated with the use of *S. divinorum*, more reports are needed to substantiate this finding.

In addition to the above-mentioned reports, in 2006, a case was reported in the U.S. in which a 17-year-old boy committed suicide after smoking *S. divinorum* for an unknown period of time.<sup>7</sup>

It should be noted that alcohol and general depression were the main confounders in this case.

After this case was reported, the state of Delaware passed a law which classified *S. divinorum* as a Schedule I controlled substance along with other hallucinogenic substances.



<sup>6</sup> Singh S. (2007) Adolescent salvia substance abuse. *Addiction*. 102, 823-824.

<sup>7</sup> <http://www.kvbc.com/Global/story.asp?S=4893692>

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est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**



Tiffany  
Thornton/HC-SC/GC/CA  
2010-08-17 10:01 AM

To Bruna Brands/HC-SC/GC/CA@HWC, Colette Strnad/HC-SC/GC/CA@HWC, Collin Pinto/HC-SC/GC/CA@HWC, Evelyn  
cc Isabel Shanahan/HC-SC/GC/CA@HWC, Laura Cooney/HC-SC/GC/CA@HWC, Valence Nebie/HC-SC/GC/CA@HWC

bcc

Subject CSS-WG Meeting: August 18th

Hi everyone,

Please find attached the draft agenda and ROD for your review in preparation for tomorrow's meeting **Wednesday August 18th 10-11:30am in Rm 405A, 123 Slater**. If you need to participate via teleconference please let me know prior to the meeting ( I will be out of the office from 8am-9:45 so please contact me today).

**Draft Agenda:**

- 1- Members' introduction
- 2- Approval of Agenda
- 3 - Approval of ROD from July 18th
- 4- Discussion on Salvia (Stephanie/Israd/All)
- 5- Next steps i.e next meeting scheduled September 15, 2010 Rm 405A



Draft Salvia Divinorum IAS\_July 12 2010.doc



CSS-WG July 2010 Meeting ROD\_TBinput.doc

Thank you,  
Tiffany

----- Forwarded by Tiffany Thornton/HC-SC/GC/CA on 2010-08-17 09:42 AM -----

Calendar Entry  
**Meeting**



<b>Subject</b>	CSS-WG Meeting
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<b>When</b>	Starts	2010-08-18 Wed	10:00 AM	1 hr 30 mins
	Ends	2010-08-18 Wed	11:30 AM	

<b>Invited</b>	The following invitees have been invited
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<b>Chair</b>	Tiffany Thornton/HC-SC/GC/CA
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<b>Where</b>	Location	123 Slater Rm 405
	<b>Reserved</b>	No rooms or resources have been reserved

<b>Invitees</b>	Required (to)	Bruna Brands/HC-SC/GC/CA@HWC, Colette Strnad/HC-SC/GC/CA@HWC, Collin Pinto/HC-SC/GC/CA@HWC, Evelyn Soo/HC-SC/GC/CA@HWC, Hanan Abramovici/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Robin Marles/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC, Tanja Kalajdzic/HC-SC/GC/CA@HWC, Tiana Branch/HC-SC/GC/CA@HWC
	Optional (cc)	Isabel Shanahan/HC-SC/GC/CA@HWC, Laura Cooney/HC-SC/GC/CA@HWC

<b>Categorize</b>	
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<b>Description</b>	
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In preparation for the next meeting, please find the attached the current draft of the IAS on Salvia for review. The agenda and the ROD from July will be send prior to the meeting. Should you have any further questions, please do not hesitate to contact me.



Draft Salvia Divinorum IAS\_July 12 2010.doc

Thank you,  
Tiffany  
946-3590

<b>Your Notes</b>	
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# Issue Analysis Summary

DRAFT w/ Comments from H.A.

## Scheduling *Salvia Divinorum* and/or Salvinorin A under the CDSA

Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Controlled Substances and Tobacco and Directorate

July 12, 2010

### CONTENTS

1. APPROVALS
2. ISSUE
3. PURPOSE
4. CONTEXT
5. ASSESSMENT OF RISKS AND BENEFITS
6. IDENTIFICATION AND ANALYSIS OF OPTIONS
7. CONSIDERATIONS
8. RECOMMENDATION(S)
9. CONSULTATIONS
10. IMPLEMENTATION AND EVALUATION

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### 1. APPROVALS

This Issue Analysis Summary is approved.

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Diane Allan, Director  
Office of Controlled Substances  
Tobacco and Drugs Directorate

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[DD/MM/2010]

### 2. ISSUE

Health Canada has received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *S. divinorum* and/or its main active ingredient salvinorin A, neither of which are currently regulated under the *Controlled Drugs and Substances Act* (CDSA). These requests are further to reports from scientific and media sources suggesting that *S. divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has also noted an

ongoing media interest regarding the availability of *S. divinorum* in Canada.

### 3. PURPOSE

To assess *Salvia divinorum* and/or salvinorin A against the criteria for the addition of a substance to one of the Schedules to the CDSA, and determine whether one or both should be regulated as controlled substances in Canada.

### 4. CONTEXT

*Salvia divinorum* is a species of sage which belongs to the mint family, and which is found in the form of dried leaves, extract and plant cuttings. Also known as "diviner's sage", the plant is known to induce illusions and hallucinations when chewed or smoked. Salvinorin A, the psychoactive ingredient in *S. divinorum* (also referred to chemically as a neoclerodane diterpene) is found primarily in the leaves, and to a lesser extent in the stems.<sup>1</sup>

*S. divinorum* is widely touted as a "legal" hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs among adolescents and young adults.<sup>2</sup> While very little is known about how and where *S. divinorum* is sold in Canada, it is suspected that it is mainly purchased over the Internet and/or bought at head shops or alternative life style stores, etc.

The use of *S. divinorum* as a psychotropic agent first came to Health Canada's attention in 2002. In 2004, Health Canada received four adverse drug reaction (ADR) reports associated with the use of *S. divinorum* as a hallucinogen, with three being considered non-serious (requiring no medical attention) and the fourth being considered serious (medical intervention was required). The serious ADR report involved the concomitant use of alcohol in a person diagnosed with Attention Deficit Disorder.

Further to the receipt of the aforementioned ADRs, the Marketed Health Products Directorate (MHPD) and the Natural Health Products Directorate (NHPD) of the Health Products and Food Branch (HPFB) prepared an issue analysis summary (IAS), which recommended that *S. divinorum* and its active ingredient salvinorin A be regulated as controlled substances. This recommendation was maintained when the IAS was updated in November 2006.

Later, in December 2005, MHPD and NHPD prepared a Signal Assessment (SA) (updated in June 2007) that eventually led to the preparation of a Health Risk Assessment (HRA), which concluded that *S. divinorum* or salvinorin A-containing health products would constitute a Type II Health Risk according to the Health Hazard Classification of the Recall Policy of the Health

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<sup>1</sup> U.S. Department of Justice Drug Enforcement Administration. 2002. Drugs and Chemicals of Concern: *Salvia Divinorum* (salvinorin A, divinorin A) URL: [http://www.dea/diversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.dea/diversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm) Nov 2008

<sup>2</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.



Products and Food Branch Inspectorate (HBFBI). Such a risk is defined as “a situation in which the use of, or exposure to, a product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote”.

Further to an Assistant Deputy Minister (ADM) discussion in April 2007, the Drug Strategy and Controlled Substances Directorate (DSCSD) organized a meeting with MHPD, NHPD and HPFBI to discuss *S. divinorum*. HPFBI was to determine appropriate compliance activities regarding *S. divinorum* and consult with the Canada Border Services Agency (CBSA) regarding the movement of products containing *S. divinorum* into and out of Canada.

On September 13, 2007, a further meeting between DSCSD, MHPD, NHPD and HPFBI led to the conclusion that DSCSD would conduct a scheduling assessment of *S. divinorum* in order to explore the possibility of scheduling this substance under the CDSA.

In September 2008, the Director Generals of DSCSD, MHPD, TPD and the HPFBI agreed that media lines and an “It’s Your Health” article on *S. divinorum* would be prepared.

#### **4.1 Relevant Legislative Frameworks in Canada**

##### **4.1.1 Food and Drug Regulations (under the Food and Drugs Act)**

The *Food and Drug Regulations* (F&DR) serve to ensure the safety, efficacy, and quality of health products offered for sale in Canada, including drugs and medical devices. Prior to being given market authorization, a manufacturer must present substantive scientific evidence that a product is safe, efficacious and of high quality. For drugs, Health Canada reviews this information carefully and, if the review is satisfactory, a Notice of Compliance (NOC) is issued and appropriate Drug Identification Numbers (DINs) are assigned.

A “drug” is defined under the F&DR as any substance or mixture of substances manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
- (b) restoration, correction or modification of organic functions in human beings or animals, or
- (c) disinfection in premises in which food is manufactured, prepared or kept;

As no products containing *S. divinorum* or its extracts have been reviewed and approved by Health Canada as of July 2010, it is illegal to market *S. divinorum* when it is represented as a drug.

#### **4.1.2 Natural Health Products Regulations (under the Food and Drugs Act)**

The *Natural Health Products Regulations* (NHPR) aim to provide Canadians with ready access to natural health products (NHPs) that are safe, effective, and of high quality, while respecting freedom of choice and philosophical and cultural diversity. The NHPR require that all licensed products display a Natural Product Number (NPN), or, in the case of a homeopathic medicine, Drug Identification Number - Homeopathic Medicine (DIN-HM), on their labels. These numbers are issued once a product is authorized for sale in Canada further to a *natural health product monograph* or submission of other evidence of safety and efficacy. The NHPR also require that all manufacturers, packagers, labelers, and importers be licensed which in turn requires the presence of procedures respecting distribution records, product recalls, product handling, storage and delivery, and manufacturing practices.

The definition of an NHP under the NHPR has both a function and substance component. The function component refers to those substances that are manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
- (b) restoring or correcting organic functions in humans; or
- (c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

The substance component refers to whether the product or medicinal ingredient therein is safe for consideration as an over-the-counter product, can be available for self-care and self-selection, and does not require a prescription to be sold. To be considered a NHP, no direct health claims need to be made regarding the substance. In the case of *S. divinorum*, it is generally marketed for its hallucinogenic properties which are considered a modification of an organic function. Therefore products containing it meet the definition of a NHP.

As of July 2010, no products containing *S. divinorum* have been reviewed and approved by Health Canada and no NPNs or DIN-HMs have been issued. Therefore sales of *S. divinorum* are illegal under the NHPR if it is represented for use as a hallucinogen or if other health claims in regards to modifying organic functions are made.

#### **4.1.3 Controlled Drugs and Substances Act and its Regulations**

The CDSA provides a legislative framework for the control of substances that can alter mental processes and that may produce harm to the health of an individual or to society when diverted or misused. Except as authorized under its regulations, activities such as possession, possession for the purposes of trafficking, trafficking, importation, exportation, possession for the purposes of exportation and production of controlled substances are prohibited under the CDSA.

The substances regulated under the CDSA are grouped into eight Schedules, and each Schedule is associated with particular offences and penalties as described in Part I of the CDSA.

In determining whether a substance should be regulated as a controlled substance, and into which Schedule of the CDSA it should be placed, Health Canada considers the following factors:

- International requirements and trends in the control and/or scheduling of the substance;
- Chemical and/or pharmacological similarity to substances listed in the Schedules to the CDSA;
- Legitimate use of the substance, including therapeutic, scientific, industrial or commercial uses;
- Potential for abuse and/or addiction liability of the substance;
- Evidence of extent of actual abuse of the substance in Canada and internationally; and
- Risk to personal and public health and safety.

## 4.2 Assessment of *Salvia Divinorum* for Scheduling Purposes

### 4.2.1 International Requirements and Trends in the Control and/or Scheduling of the Substance

At the present time, neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and therefore do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

#### *Australia*

In June 2002, Australia became the first country to prohibit the sale, supply, possession and use of *S. divinorum* and salvinorin A. Although both *S. divinorum* and salvinorin A are listed in Schedule 9 of Australia's Standard for the Uniform Scheduling of Drugs and Poisons on the basis of "high potential for abuse and risk to public health and safety", no substantiation of this risk was provided at the time of this scheduling decision.<sup>3</sup> Schedule 9 is Australia's most restrictive drug schedule, and includes "substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities."<sup>4</sup>

#### *Belgium*

A decree was passed in Belgium on October 22, 2006 which added *S. divinorum* to the list of controlled substances. This list includes substances such as psilocybin mushrooms, khat and

<sup>3</sup> <http://www.tga.gov.au/ndpsc/record/rr200111.pdf>

<sup>4</sup> [http://www.cognitiveliberty.org/news/salvia\\_australia.htm](http://www.cognitiveliberty.org/news/salvia_australia.htm)

peyote cactus.<sup>5</sup>

### **Denmark**

In 2003, Denmark added *S. divinorum* and salvinorin A to their list of “category B” controlled substances, a category which also includes psilocybin mushrooms, cocaine, amphetamine, and several others substances that are only legal for medicinal and scientific purposes. Illegal possession carries a penalty of up to two years in prison.

### **Germany**

*S. divinorum* (plant and plant parts) was added to Appendix I of the *Narcotics Act* in Germany on March 1, 2008, making it illegal to produce, traffic, or possess. The law does not specifically mention salvinorin A.

### **Italy**

On June 25, 2004, the Italian Ministry of Health issued an ordinance prohibiting the sale of *S. divinorum* and its active constituent salvinorin A. On January 11, 2005, the Ministry of Health made possession of *S. divinorum* and salvinorin A illegal by placing them in “*Tabella 1*” of the *Tabella Sostanze Stupefacenti o Psicotrope*.

### **Japan**

On November 9, 2006, the Japanese government added a group of thirty-three drugs to its list of controlled substances, including salvinorin A. The drugs are banned under a revised pharmaceutical law, under which persons involved in their illegal import, production, and sale, i.e. beyond medical treatment or research purposes, will be subject to up to five years imprisonment or a fine of up to five million yen.

### **Spain**

On January 28, 2004, the Spanish Ministry of Health and Consumption issued an order prohibiting the sale of *S. divinorum*. The regulation went into effect on May 6, 2004 and only prohibits activities related to commerce. Possession and/or use are not considered to be criminal offences.

### **Other Countries**

*Salvia divinorum* is illegal to possess or sell in Croatia, Latvia, Lithuania, Poland, Romania, South Korea and Sweden. In Russia it is illegal to grow or sell *S. divinorum*, but it is legal to

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<http://eldd.emcdda.europa.eu/html.cfm/index5176EN.html?pluginMethod=eldd.shownewsdetails&id=20/12/2006BELGIUM:%20New%20substances%20controlled%20include%20mCPP%20and%20khat>

possess it. In Estonia, Finland, Iceland and Norway, *S. divinorum* is treated as a medicinal herb and it is illegal to import it without a relevant prescription from a doctor.

### ***United States of America***

*S. divinorum* and salvinorin A are not included in the Schedules to the United States *Controlled Substances Act* although both *S. divinorum* and salvinorin A have been added to a list of chemicals "of concern" which has no legal implications. In addition, some individual states have implemented laws restricting its use, sale and/or distribution. As of July 2010, a number of states have enacted legislation placing regulatory controls on *S. divinorum* and/or salvinorin A including Delaware, Georgia, Florida, Hawaii, Illinois, Kansas, Kentucky, Maryland, Mississippi, Missouri, Nebraska, North Dakota, Ohio, Oklahoma, South Dakota, Wisconsin, Virginia, California, Louisiana, Maine, North Carolina, and Tennessee. More details regarding the regulation of *S. divinorum* in these last five states are provided below.

#### ***California***

As of January 1, 2009, the sale or distribution of *S. divinorum* or salvinorin A, or any substance or material containing *S. divinorum* or salvinorin A, to any person under 18 years of age is a misdemeanor punishable by imprisonment in a county jail for not more than six months, a fine of no more than \$1,000, or both.

#### ***Louisiana***

In 2005, Louisiana passed a bill which prohibits the possession, production, manufacture and distribution of a material, compound, mixture, or preparation intended for human consumption and that contains a hallucinogenic plant. A "hallucinogenic plant" is defined as "any part or portion" of a plant on a list of forty plants, which includes *S. divinorum*.

#### ***Maine***

In Maine, *S. divinorum* and salvinorin A are regulated in the same way as tobacco products; adults eighteen years of age or over can legally purchase and use the material, but selling or providing *S. divinorum* or salvinorin A to anyone under the age of eighteen is a criminal offence. Possession by a minor is a civil violation, punishable by a fine, community service, or both.

#### ***North Carolina***

On December 1, 2009, the North Carolina State Legislature brought a new law into force which made *Salvia divinorum* and salvinorin A illegal. The only legal *S. divinorum* activities are the growing for aesthetic, landscaping, or decorative purposes or university-affiliated medical or pharmacological research.

## Tennessee

On July 1, 2006, Tennessee classified the deliberate production, manufacture, distribution, or possession of the active chemical ingredient in the hallucinogenic plant *S. divinorum* as a Class A misdemeanor. It is not, however, a criminal offence to possess, plant, cultivate, grow, or harvest *S. divinorum* for aesthetic, landscaping, or decorative purposes. The law also does not apply to any dosage that is legally obtainable from a retail establishment without a prescription when (and if) it is recognized by the Food and Drug Administration as a homeopathic drug.

### 4.2.2 Chemical and/or Pharmacological Similarity to Substances Listed in the Schedules to the CDSA

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The psychoactive ingredient in *Salvia divinorum* is the neoclerodane diterpene salvinorin A {need reference}. Other plants which contain psychotropic terpenoids are *Artemisia absinthium* (wormwood) and *Cannabis sativa* {reference needed}. Salvinorin A is considered by some as the most potent natural hallucinogen ever isolated.<sup>6</sup>

Comment [HABR1]: What is the potency relative to other hallucinogens?

Unlike all other hallucinogens, salvinorin A is structurally distinct and does not interact with the serotonin-2A receptor or any other molecular target of classical hallucinogens {reference?}. Instead, the available research suggests the psychotropic effects of salvinorin A are mediated by its agonistic actions at  $\kappa$ -opioid (KOR) receptor {ref}. Its mechanism of action is therefore unique.<sup>7 8</sup>

Deleted: It thus affects the brain in a way that is quite unique

The psychoactive effects of *S. divinorum* vary in onset and duration and include the sensation of becoming an object, visions of various two-dimensional surfaces, films and membranes, revisiting places of the past (particularly childhood), perceived loss of the body and/or identity, various sensations of motion (being pulled or twisted by a force of some kind), uncontrollable hysterical laughter, and overlapping realities (perceptions of being in more than one place).<sup>9</sup> Laughter, happiness, sense of well-being and dissociative effects were deemed the best aspects of

Deleted: Recent pharmacological screenings of receptors have found it to be a highly potent and selective  $\kappa$ -opioid receptor (KOR) agonist.

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Deleted: The use of *S. divinorum* or salvinorin A can lead to a number of effects with variable onset and duration. These effects are generally accepted to

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Comment [HABR2]: Can we qualify that? What does "best" mean in this case?

<sup>6</sup> Ott J. Ethnopharmacognosy and human pharmacology of *Salvia divinorum* and salvinorin A. *Curare*. 1995 18: 103-129. Unofficial transcription available online. URL <http://www.sagewisdom.org/ott2.html>

<sup>7</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>8</sup> Roth BL, Baner K, Westkaemper R, Siebert D, Rice KC, Steinberg S, Ernsberger P, Rothman RB. Salvinorin A: a potent naturally occurring nonnitrogenous kappa opioid selective agonist. *Proc Natl Acad Sci U S A*. 2002 Sep 3;99(18):11934-9.

<sup>9</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

*S. divinorum* by users, second only to the "trip" that the drug elicits.<sup>10</sup> Depersonalization, speaking gibberish, widening of consciousness and subjective illusions of rapid movement, flying or hovering have also been reported.<sup>11</sup>

The psychomimetic (psychotomimetic) effects of *S. divinorum* closely resemble schizophrenia symptoms induced by lysergic acid diethylamide (LSD) or phencyclidine (PCP).<sup>12</sup> Yet, it is said to have only weak influence on the prevailing mood of the user which differentiates it from other hallucinogens such as LSD and psilocybin.<sup>13</sup> Its strong dissociative effects are often compared to those of ketamine {reference needed}. Users have reported that the psychedelic effects of *S. divinorum* were most similar to those caused by psilocybin mushrooms.<sup>14</sup> However, users familiar with the effects of other hallucinogens agree that despite certain similarities to classical hallucinogens, the visions and overall experience are quite unique.<sup>15</sup>

In addition, the psychedelic effects of *S. divinorum* are similar to those of classical psychedelics regarding changes in perception and somatic sensations {reference needed}. *S. divinorum* causes an unusually high degree of sedation, weakness and fatigue, while the increased de-realization is not commonly reported for classical psychedelics.<sup>16</sup> The combination of these effects seems to correlate with that of other KOR agonists such as pentazocine.<sup>17</sup>

#### 4.2.3 Legitimate Use of the Substance, including Therapeutic, Scientific, Industrial or Commercial Uses

*Salvia divinorum* has traditionally been used for spiritual and medicinal purposes by the Mazatec Indians in Oaxaca, Mexico,<sup>18</sup> where an infusion of the leaves or the leaves themselves are

**Comment [HABR3]:** We have too many "psycho" terms. Psychoactive, psychomimetic, psychotropic, psychedelic. Either we use one or we have to define them. Are they different?

**Comment [HABR4]:** I think we should perhaps say "schizoid" not schizophrenia.

**Comment [HABR5]:** Definition ?

**Comment [HABR6]:** Are these psychedelic effects??

**Comment [HABR7]:** Too many ideas in this paragraph. In addition, we say that Salvia's properties are unique, but here we seem to imply that it shares some properties to other KORs such as pentazocine.

<sup>10</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>11</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry.* 2005 Jan;38(1):1-5 and Siebert DJ. *Salvia divinorum* and salvininorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>12</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry.* 2005 Jan;38(1):1-5.

<sup>13</sup> Siebert DJ. *Salvia divinorum* and salvininorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>14</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>15</sup> Siebert DJ. *Salvia divinorum* and salvininorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6 and González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>16</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>17</sup> Arasteh K, Poudevida S, Farre M, Roset PN, Cami J. Response patterns of the Spanish version of the 49-item short form of the Addiction Research Center Inventory after the use of sedatives, stimulants, and opioids. *Drug Alcohol Depend.* 1999 Jun 1;55(1-2):117-25.

<sup>18</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

ingested to treat gastrointestinal problems, headaches, rheumatism, anemia and swelling of the stomach.<sup>19</sup> Its main use today is, however, for its psychoactive properties in the aid of producing “mystical” or hallucinogenic experiences as part of spiritual rituals.<sup>20</sup>

**Comment [HABR8]:** Similar comment as above on the meaning and interchangeability of the terms psychoactive, psychedelic etc... Psychedelic may be more appropriate here since it may refer to transcendental or mystical experiences.

Although selective kappa receptor agonists have been shown to produce analgesic effects, adverse effects such as psychotomimesis, dysphoria and diuresis have been observed in studies investigating their therapeutic use.<sup>21</sup> In addition, while it has been speculated that KOR agonists may be useful in the treatment of certain psychiatric disorders including Alzheimer's disease, schizophrenia, dementia and bipolar disorder,<sup>22</sup> much more research is needed in order to substantiate these hypotheses. Similarly, another study has suggested that chemical analogues of salvinorin A may be a useful treatment for those suffering from addiction to other substances.<sup>23</sup> That said, there are presently no legitimate medical uses for *S. divinorum* in Canada.

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Similarly, there are no known industrial or commercial uses for *S. divinorum* in Canada. The plant is a semi-tropical perennial that can only grow outdoors in a humid climate where it will not encounter frost. Most websites offering *S. divinorum* cuttings and seeds for sale appear to do so in the context of growing the plant for “recreational” purposes, rather than out of horticultural interest or for its esthetic appeal.

**Comment [HABR9]:** So?

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**Deleted:** for its

**Deleted:** to utilize its

**Deleted:** psychoactive properties

#### 4.2.4 Potential for Abuse and/or Addiction Liability of the Substance

Salvinorin A is a potent, selective agonist of the  $\kappa$ -opioid receptor (KOR), and in contrast to the euphoria produced by  $\mu$ -opioid receptor (MOR) agonists such as morphine (?), KOR agonists are negatively reinforcing and aversive.<sup>24</sup> In addition, KOR agonists have analgesic properties but are not associated with respiratory depression like MOR agonists. Finally, while MOR agonists increase the release of dopamine, the activation of KOR decreases dopamine release in the

<sup>19</sup> Munro, T. The Chemistry of Salvia divinorum. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

<sup>20</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage Salvia divinorum. Life Sci. 2005 Dec 22;78(5):527-31.

<sup>21</sup> Barker RL, Fawcett J, Barkin SJ. 2002. Chronic pain management with a focus on the role of newer antidepressants and centrally acting agents. In: Pain Management: A Practical Guide for Clinicians, 6th edition, Weiner RS ed. CRC Press, Boca Raton, FL. pp. 415-34 and Tidgewell et al., 2004. A facile method for the preparation of deuterium labelled salvinorin A: Biorganic & Medicinal Chemistry Letters, 14: 5099-5102.

<sup>22</sup> Sheffler DJ & Roth BL. Salvinorin A: the ‘magic mint’ hallucinogen finds a molecular target in the kappa opioid receptor. Trends Pharmacol Sci. 2003 Mar;24(3):107-109.

<sup>23</sup> Prisinzano TE. Natural products as tools for neuroscience: discovery and development of novel agents to treat drug abuse. J Nat Prod. 2009 Mar 27;72(3):581-7.

<sup>24</sup> Gustein HB & Akil H. Opioid Analgesics. In: Goodman and Gilman's The Pharmacological Basis of Therapeutics 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590, Cooper S. Interactions between endogenous opioids and dopamine: Implications for reward and aversion. In: The Mesolimbic Dopamine System: From Motivation to Action. Willner P and Scheel-Kruger J (editors) Wiley, Chester, England, 1991, pp. 331-366, and Shippenberg TS, Herz A, Spanagel R, Bals-Kubik R, Stein C. Conditioning of opioid reinforcement: neuroanatomical and neurochemical substrates. Ann N Y Acad Sci. 1992 Jun 28;654:347-56.



nucleus accumbens.<sup>25</sup>

The onset and intensity of the effects of *Salvia divinorum* appear to be related to the route of administration.

Traditional uses generally produce mild effects because the leaves are rolled and chewed or crushed and prepared as a foamy infusion whereby the salvinorin A is degraded in the gastrointestinal system before being absorbed into the bloodstream. Hence, the level of effect relates quite closely to the length of time the material spends in the mouth, with the onset of effect generally taking 5-10 minutes. The effects build over the next hour and last for another hour before they begin to subside.<sup>26</sup>

Routes of administration that avoid the hepatic first-pass effect (i.e. inhalation, intravenous, intramuscular and sublingual use) are the quickest and most intense.<sup>27</sup> Salvinorin A can be isolated from the plant to make a powder which can be vaporized and inhaled. The onset of effects felt from vaporizing salvinorin A powder occurs in about 30 seconds and effects last for about 5-10 minutes and then subside over the next 30 minutes.<sup>28</sup>

Smoking is by far the most popular method of administration<sup>29</sup> and this is accomplished by smoking the dried leaves or a concentrated extract using a pipe or bong. Dried leaves may also be fortified with a concentrated extract of salvinorin A. A concentrated extract can also be used sublingually. Neither *S. divinorum* nor salvinorin A can be injected because the powder is insoluble in water.<sup>30</sup>

The aversive effects of KOR agonists suggest that the risk of addiction to *S. divinorum* is negligible. However, very few controlled scientific studies of the physical and psychotropic effects of *S. divinorum* on humans have been carried out. Therefore, it is difficult to predict with certainty its potential for addiction and abuse. In studies that have been conducted, there is conflicting information around the addiction liability of *S. divinorum* in both animals and humans. Some users have noted that they require increasing doses of salvinorin A in order to achieve the desired effect and the stimulated cerebral KOR may act as a mechanism of

**Comment [HABR10]:** This paragraph needs a sentence or two which links these scientific findings to a rationale for why salvia is not addictive. There is much scientific information here but it needs to be explained. For example, why is the decrease in dopamine release in the nucleus accumbens important? What does this have to do with addiction or abuse?

**Comment [HABR11]:** Why is this important?

**Comment [HABR12]:** How does this relate to potential for abuse or addiction liability? This paragraph belongs more in the section on pharmacology.

**Comment [HABR13]:** This para belongs in the pharmacology section.

**Comment [HABR14]:** What does this have to do with potential for abuse or addiction liability?

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<sup>25</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.

<sup>26</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>27</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.

<sup>28</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>29</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62 and Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>30</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs.* 1994 Jul-Sep;26(3):277-83.

tolerance.<sup>31</sup> Further studies in this area and on the mediated decrease of dopamine as well as the impact of dose on effects are also required.

While concerns for the potential of abuse were once minimal because 1 kg of dried leaves yields only 3 to 6 human doses of salvinorin A, it was discovered that vaporizing and inhaling 200-500 micrograms had profound hallucinogenic effects.<sup>32</sup> The extraction of salvinorin A from the plant is simple, and with care, approximately 1.5 grams of pure salvinorin A per kilogram of dried leaves (8kg of fresh leaves) can be isolated. This is enough for 2000 human doses.<sup>33</sup>

**Comment [HABR15]:** Can this sentence be summarized somehow and made more convincing? So what we're trying to say is that the potential for abuse is high because we need very small doses.

**Deleted:** very easy

**Deleted:** substance to provide

#### 4.2.5 Evidence of Extent of Actual Abuse of the Substance in Canada and Internationally

In Canada, the extent of actual abuse of *Salvia divinorum* and/or salvinorin A is relatively unknown. There is, however, some data regarding the prevalence of use of *Salvia divinorum* in Canada, despite the lack of legitimate uses for this plant. Questions about the use of *S. divinorum* were included in the 2008-2009 Youth Smoking Survey, the 2009 Canadian Alcohol and Drug Use Monitoring Survey and the 2009 Ontario Student Drug Use and Health Survey.

**Comment [HABR16]:** Need to re-order these in the order that they are presented below.

The results from the 2009 Ontario Student Drug Use and Health Survey were published on November 18, 2009 and indicate that:

- Among all responding students in Ontario, 4.4% reported using *Salvia divinorum* at least once in the past year. In comparison, 58.2% indicated they had used alcohol, 25.6% indicated they had used cannabis and 5.0% indicated they had used hallucinogens other than LSD and PCP in the past year;
- Males (6.2%) were significantly more likely than females (2.3%) to report using *Salvia divinorum*;
- There is significant grade variation, with *Salvia divinorum* use most likely among 11<sup>th</sup> graders (8.6%) and 12<sup>th</sup> graders (8.4%); and
- There are significant regional variations, with students in Northern Ontario (9.2%) most likely to use *Salvia divinorum*.

<sup>31</sup> Bucheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>32</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>33</sup> Valdés LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs*. 1994 Jul-Sep;26(3):277-83.

The results of the 2008-2009 Youth Smoking Survey were published on May 31, 2010 and indicate that:

- 4.9% of students stated that they had used *S. divinorum* in the last twelve months. In comparison, 53.0% indicated they had used alcohol, 27.3% indicated they had used cannabis and 6.9% indicated they had used other hallucinogens in the last twelve months;
- 2.6% of students in Grades 7-9 and 7.0% of students in Grades 10-12 had used *S. divinorum* in the last twelve months; and
- Males (6.6%) were more likely to have used *S. divinorum* in the past twelve months compared to females (3.2%).

The scope of the previously mentioned studies did not provide for any explanations regarding differences in usage between ages, genders and regions. In this regard, it is difficult to speculate on the causality of such differences.

The Canadian Alcohol and Drug Use Monitoring Survey specifically examined Salvia for the first time in 2009. An estimated 1.6% of Canadians, aged 15 years and older, reported that they had used salvia in their lifetime, and 0.2% reported using it in the past-year. In comparison, the prevalence of past-year cannabis use among Canadians 15 years of age and older was 10.6%. 1.2% of respondents reported using cocaine or crack in the past 12 months, 0.9% had used ecstasy and 0.7% used illicit hallucinogens.

Health Canada's Drug Analysis Services (DAS) has identified salvinorin A in a number of samples seized by law enforcement, as shown in the following table.

**NUMBER OF SAMPLES FOUND TO CONTAIN SALVINORIN A**

Year	Count
2006	9
2007	8
2008	4
2009	20
2010 (as of May 7)	8

**Comment [HABR17]:** Why is this important? What is the message we are trying to convey here?

The National Forensic Laboratory Information System (NFLIS) and the System to Retrieve Information from Drug Evidence (STRIDE) in the United States are Drug Enforcement Agency (DEA) databases that collect scientifically verified data on analyzed samples in state and local forensic labs as well as samples from DEA labs. The following table shows the quantity of *S. divinorum* products that were seized from 2000 through to 2009.

**ANALYZED SALVIA DIVINORUM or SALVINORIN A SEIZURES**

(Number of Items/Exhibits)

Source	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009*
NFLIS-State/Local <sup>1</sup>	0	0	0	0	1	8	12	12	70	34
STRIDE <sup>2</sup>	0	0	1	1	1	0	0	0	N/A	N/A

<b>TOTAL</b>	0	0	1	1	2	8	12	12	70	34
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Data Source: NFLIS & STRIDE, 2008 data queried 11/24/08, updated 06/10/2010

<sup>1</sup> NFLIS reported seizures of *Salvia divinorum* and/or salvinorin A

<sup>2</sup> STRIDE reported items of *Salvia divinorum*.

\* Includes only January – May data in 2009.

It is difficult to determine the extent of actual abuse of *S. divinorum* in Canada or elsewhere as there appear to be inconsistencies in the literature regarding risk aversion. For example, one author states: "Many who have used salvinorin A find the experience extremely unnerving, frightening and overly intense and most have no desire to repeat the experience."<sup>34</sup> However, another study suggested that this is not the experience of all recreational users of *S. divinorum*.<sup>35</sup> Over eighty percent of users surveyed on a web-based questionnaire about their *S. divinorum* use said that they would probably or definitely use *S. divinorum* again.<sup>36</sup> Users have reported the negative effects of *S. divinorum* as: the short duration of action, lack of control over the experience, persisting negative effects (most often anxiety),<sup>37</sup> sweating, chills, increased diuresis, impaired vigilance,<sup>38</sup> and negative after-effects including tiredness, feeling head heavy, dizziness, physical exhaustion, and some degree of malaise or 'hangover' as they 'comedown' from the drug.<sup>39</sup>

**Comment [HABR18]:** Why is this here at the end and what is its connection to seizure data? This should be placed higher up in the section.

#### 4.2.6 Risk to Personal and Public Health and Safety

The increase in both the number of enquiries from various municipalities and members of the public and the amount of media interest regarding the availability of *Salvia divinorum* in Canada may be an indication that the recreational use of *S. divinorum* as a hallucinogen is on the rise. However, there are no available statistics that indicate there has been a significant increase in *S. divinorum* use in the Canadian population and, in comparison to the use of other drugs such as alcohol and cannabis, the actual use of *S. divinorum* is quite low.

The potential for harm to the user and/or other individuals is primarily related to the hallucinogenic properties of the substance. Users may get up and walk around without apparent awareness of their movements, behaviour or surroundings, and distinction between self and surroundings is often lost. At doses greater than 1mg of salvinorin A, out of body experiences

<sup>34</sup> Turner DM. Salvinorin - The Psychedelic Essence of Salvia Divinorum. Panther Press, San Francisco, CA 1996.

<sup>35</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62, Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5, and Valdés LJ 3rd. Salvia divinorum and the unique diterpene hallucinogen, Salvinorin (divinorin) A. J Psychoactive Drugs. 1994 Jul-Sep;26(3):277-83.

<sup>36</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>37</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>38</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5.

<sup>39</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

are frequent and loss of consciousness has been reported.<sup>40</sup> There is little information regarding the social behaviours of persons under the influence of *S. divinorum* products, and what risks their activities such as operating a motorized vehicle may pose to the general public. There is also very little data regarding the toxicity, teratogenicity or other long-term effects of *S. divinorum* use.<sup>41</sup>

As far as law enforcement is concerned, the Department has only received a limited number of communications indicating concern with respect to *S. divinorum* and none of these have advised that the use of *S. divinorum* poses any threat to public safety. The Royal Canadian Mounted Police (RCMP) has stated that while *S. divinorum* is readily available, it has not become a popular drug in Canada, probably due to its aversive effects such as anxiety and introversion.

A handful of case reports regarding the use of *S. divinorum* have been published in the academic literature. An international case report described the perceptions of a 19 year-old man after inhaling *S. divinorum* smoke. The peak psychotropic effects, including prickling of the skin, fever-like hot flashes, muscular tremor, and depersonalization, were reached in less than five minutes after inhalation of an unknown amount of smoke from burning dried leaves.<sup>42</sup> Another report involved a 15-year-old male who presented to psychiatric emergency services with acute onset of paranoia, déjà vu, blunted affect, difficulties in thought processing and slowed speech after smoking *Salvia divinorum* over an unknown period of time. During his hospitalization all symptoms improved significantly except the feeling of déjà vu. Based on this case presentation, the author suggested that the feelings of déjà vu may be a long-term effect of *S. divinorum* use.<sup>43</sup> However, given that this is the only case report in which déjà vu was associated with the use of *S. divinorum*, more reports are needed to substantiate this finding.

**Comment [HABR19]:** The case reports cited below do not relate to use but rather to the physiological and psychotropic effects of *S. divinorum* use.

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**Deleted:** in which a young man (19 years of age) described his perceptions after inhaling smoke from *S. divinorum*.

In addition to the above-mentioned reports, in 2006, a case was reported in the U.S. in which a 17-year-old boy committed suicide after smoking *S. divinorum* for an unknown period of time.<sup>44</sup> It should be noted that alcohol and general depression were the main confounders in this case. After this case was reported, the state of Delaware passed a law which classified *S. divinorum* as a Schedule I controlled substance along with other hallucinogenic substances.

Like many drugs of abuse, users are often unaware of the potency and adulterants in the product they purchase. A study by Wolowich *et al.* (2006)<sup>45</sup>, showed that the salvinorin A content in five out of five *S. divinorum* products was falsely indicated on the label and 4 out of 5 products contained unidentified adulterants (i.e. vitamin E, caffeine).

Health Canada has only anecdotal information about the use and abuse of *S. divinorum* in Canada as well as the threat *S. divinorum* may pose to the health and safety of Canadians. Although

<sup>40</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>41</sup> Grundmann O, Phipps SM, Zadezensky I, Butterweck V. *Salvia divinorum* and Salvinorin A: An Update on Pharmacology and Analytical Methodology. *Planta Med* 2007 Jun;73:1039-1046.

<sup>43</sup> Singh S. (2007) Adolescent salvia substance abuse. *Addiction.* 102, 823-824.

<sup>44</sup> <http://www.kvbc.com/Global/story.asp?S=4893692>

<sup>45</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.

reports of domestic adverse reactions related to the use of *S. divinorum* as a hallucinogen have been received through the Canada Vigilance database, it is important to note that the number of reports and the nature of reactions reported are not adequate to characterize the risk to the general population.

**s.21(1)(a)**  
**s.21(1)(b)**

**5. ASSESSMENT OF RISKS AND BENEFITS**



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**of the Access to Information Act  
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## 7. CONSIDERATIONS

The KOR-mediated aversive and dysphoric effects of *Salvia divinorum* do not appear to be hampering its use as young adults have begun smoking the leaves and leaf extract recreationally.<sup>46</sup> It can be purchased through online botanical companies and other drug promotion sites and is often touted as a legal alternative to substances such as cannabis and mescaline.<sup>47</sup> Interestingly, after being widely available for over a decade, the drug does not appear to have had the same social impact as LSD or ecstasy.<sup>48</sup>

While there has been an increase over the past few years in the number of enquiries from various municipalities and members of the public regarding the availability of *Salvia divinorum* as a hallucinogen, according to available statistics, the reported use of *S. divinorum* by young Canadians is much lower than that of alcohol or cannabis.

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The NHPR are limited in their capacity to control the availability of *S. divinorum* in that *S. divinorum* products are often declared as incense and therefore cannot be considered unapproved natural health products. In addition, compliance and enforcement actions such as voluntary stop-sales, forfeiture, destruction, and administrative seizure, cannot be implemented unless the labeling of the product indicates that it is to be used for human consumption and can modify an organic function.

The previous HPFB recommendation to schedule *S. divinorum* under the CDSA was likely based on a misunderstanding of the (previously-described) criteria upon which scheduling decisions are made within the Healthy Environments and Consumer Safety Branch (HECSB). In particular, it did not consider a number of factors, including potential for abuse and risk to public health and safety. The Office of Controlled Substances (OCS) was also not consulted by HPFB at the time

<sup>46</sup> Hazelden Foundation, 2004. Drug Abuse Trends. June 2004. URL: [www.reserach.hazelden.org](http://www.reserach.hazelden.org).

<sup>47</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

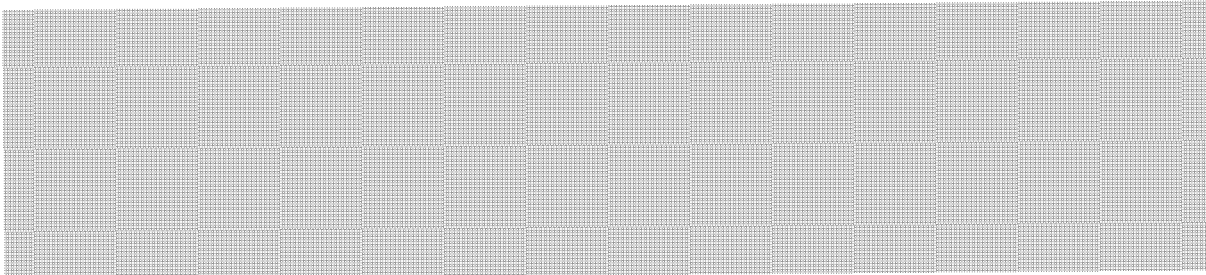
<sup>48</sup> Munro, T. The Chemistry of *Salvia divinorum*. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.



this recommendation was made. In addition, among countries who have decided to control *S. divinorum* in some way, very little or no substantiation of the risks of *S. divinorum* upon which the decision was based are available.

**s.21(1)(a)**  
**s.21(1)(b)**

Neither *Salvia divinorum* nor salvinorin A meet the criteria for scheduling a substance under the CDSA. Despite being regulated in some jurisdictions, neither the plant nor salvinorin A are scheduled under any of the UN Drug Control Conventions. *S. divinorum* and salvinorin A are not structurally or pharmacologically similar to other substances included in the schedules to the CDSA. There are also currently no legitimate therapeutic or industrial uses for *S. divinorum*. The abuse liability and potential for dependence of *S. divinorum* is not known as very few controlled scientific studies of its physical and psychotropic effects have been carried out on humans. The extent of actual abuse of *S. divinorum* is also largely unknown. Evidence of a risk to public health and safety is anecdotal in nature and not quantified in any way as there is a lack of information regarding abuse in Canada.

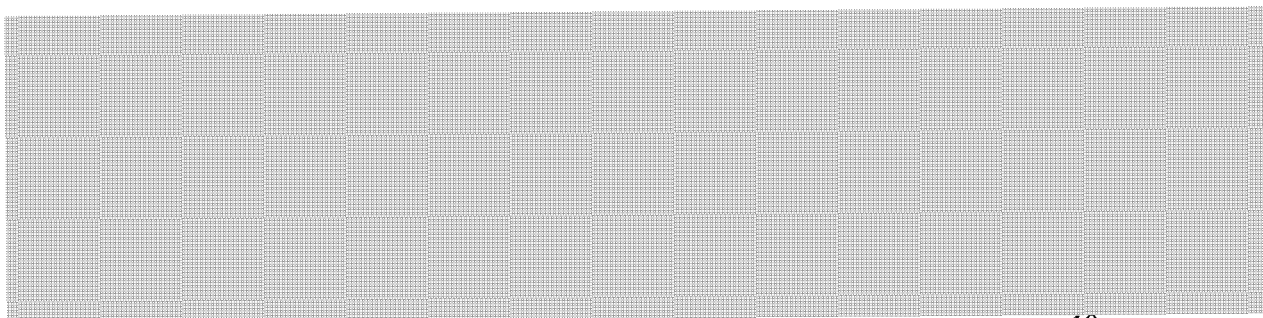


## 9. CONSULTATIONS

The Drug Analysis Services (DAS) was contacted in order to provide any data available regarding the identification of salvinorin A in samples submitted by law enforcement.

The Royal Canadian Mounted Police (RCMP) was contacted in order to establish their views with respect to *S. divinorum* use in Canada. The RCMP advised that though *S. divinorum* is readily available, it does not appear to pose a threat to public safety.

OCS has received a number of correspondences from Canada Border Services Agency (CBSA) officers concerning a lack of information regarding the status of *S. divinorum* and how the plant should be treated at the border. CBSA officers have also expressed concern regarding the plant's hallucinogenic properties. At present, only shipments of *S. divinorum* that are represented as health products that modify organic functions can be refused for import under the NHPR.



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DRAFT  
May 26, 2010

## **Media Lines**

### **Regulatory Control of *Salvia Divinorum***

#### **Issue**

Since 2006, Health Canada has noted ongoing media interest regarding the availability of *Salvia divinorum* in Canada. Health Canada has also received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum*, particularly given reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties.

#### **Key Messages:**

- **Health Canada advises Canadians not to use products containing *S. divinorum* because very little is known about the substance and its potential effects on the brain and/or body.**
- **Because of its hallucinogenic properties, products containing *S. divinorum* meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*.**
- **It is illegal to sell NHPs in Canada unless they have been reviewed and approved by Health Canada and labelled with a Natural Product Number (NPN) or a Drug Identification Number – Homeopathic Medicine (DIN-HM). The illegal sale of products containing *S. divinorum* may be subject to compliance and enforcement action under the *Food and Drug Act*.**
- **Health Canada will continue to collect and study information about *S. divinorum* as it becomes available, and to consult with law enforcement and health officials domestically and internationally in order to determine the best way to manage the risks associated with its availability in Canada.**

#### **Supplementary Messages:**

##### ***On the classification of *Salvia divinorum*:***

- **When products containing *S. divinorum* are manufactured, sold or represented for use in modifying organic functions in humans (where this would include having a hallucinogenic effect), they meet the definition of a Natural Health Product (NHP) in accordance with the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*.**

It is illegal to sell NHPs in Canada unless they have been approved by Health Canada and assigned a Natural Product Number (NPN) or Drug Identification Number - Homeopathic Medicine. As of January 2010, no products containing *S. divinorum* s have however been approved for sale by Health Canada .

- In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA).
- *Salvia divinorum* is not listed under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these Conventions.
- Several countries (Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) have placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Although some individual U.S. states have implemented laws restricting its use, sale and/or distribution, *Salvia divinorum* and salvinorin A are not federally regulated under the *Controlled Substances Act* in the United States.

***If pressed on the lack of statistics on Salvia divinorum use in Canada:***

- Health Canada is taking steps to address this lack of data. Questions about the use of *Salvia divinorum* were included in the 2008-2009 Youth Smoking Survey, and the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS). The results from the Youth Smoking Survey were released on May 31, 2010 and the 2009 CADUMS results are scheduled to be released in late June 2010
- It is anticipated that the data from these surveys will contribute to future decisions that Health Canada may make about how this plant and its active ingredient should be regulated.

***If pressed regarding the results of the 2009 Ontario Student Drug Use and Health Survey:***

- The results from the 2009 Ontario Student Drug Use and Health Survey were published on November 18, 2009 and indicate that among responding students in Ontario, 4.4% reported using *Salvia divinorum* at least once in the past year. Health Canada will consider this data in its ongoing examination of *Salvia divinorum* and salvinorin A.

**Questions and Answers**

**Q1 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why isn't it illegal?**

A1 – Because *S. divinorum* meets the definition of an NHP under the *Natural Health Product Regulations*, it is illegal to manufacture, sell or provide products containing *S. divinorum* without their being approved by Health Canada prior to sale.

With respect to adverse effects, not enough controlled scientific studies looking into the physical and psychotropic effects of *Salvia divinorum* on humans and animals have been carried out. As such, it is difficult to predict the potential for addiction and abuse associated with *Salvia divinorum*, and it is for this reason, that Health Canada is not proceeding to regulate it as a controlled substance at this point in time.

**Q2 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?**

A2 – The *Natural Health Products Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *Salvia divinorum*.

**Q3 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A3 – *Salvia divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. Complaints about the illegal sale of drugs containing *S. divinorum* can be referred to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

**Q4 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum* as a controlled substance. What does that involve and what stage is it at?**

A4 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada has only limited information on some of the above-mentioned factors, and thus there is simply not enough information available to determine whether regulation of *Salvia divinorum* under the CDSA is warranted.

It is anticipated that the data from the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey in addition to the results from the 2009 Ontario Student Drug Use and Health Survey will help address some of the information gaps about this substance. Data from the Youth Smoking Survey has just

been released and data from the 2009 edition of CADUMS will be available in late June 2010.

**Q5 – Didn't an internal report from Health Canada's Marketed Health Products Directorate recommend that *Salvia divinorum* be scheduled under the CDSA? Why has that recommendation not been acted upon?**

A5 – See A4

**Q6 – What is the significance of the adverse reaction reports that Health Canada has received with respect to the use of *Salvia divinorum*?**

A6 – Health Canada has received four domestic adverse reaction reports related to the use of *Salvia divinorum* as a hallucinogen through the Canada Vigilance database. The number of reports and the nature of reactions reported are, however, not adequate to characterize any risk of similar reactions to the general population. In particular, Health Canada does not have any information about the number of individuals in Canada using or who have used *Salvia divinorum*.

***If pressed on whether Health Canada has issued any kind of warning to Canadians about *Salvia divinorum****

A. Health Canada is developing an It's Your Health (IYH) article on *Salvia divinorum* to help inform the general public about the risks associated with the use of this substance.

### **Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for spiritual and medicinal purposes by the Mazatec Indians in Mexico.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

While some users have reported that the psychotropic effects of *Salvia divinorum* resemble those induced by other hallucinogens, such as LSD and phencyclidine, the overall experience appears to be quite unique.

Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that:

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year.
- 5.4% of students (grades 7-12) ever used *S. divinorum*.
- Use of *S. divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

Data from the 2007 report on Alcohol and Other Drugs published by the Addictions Foundation of Manitoba indicate that:

- 3.7% of males vs. 2.2% of females (grades 7-12) used *S. divinorum* during that year.

Data from a 2006 National Survey on Drug Use and Health Report, published by the U.S. Substance Abuse and Mental Health Services Administration estimated that:

- 0.3% of persons aged 12 or older used *S. divinorum* in 2006.
- 0.6% of persons between the ages of 12 and 17 used *S. divinorum* in 2006.
- 1.7% of persons between the ages of 18 to 25 used *S. divinorum* in 2006.
- Young adults (18-25) were nearly three times more likely than youths aged 12-17 to have used *S. divinorum* in 2006.
- Males between the ages of 12-25 were three to four times more likely than females in the same age range to have used *S. divinorum* in 2006.

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Anne Lamar, ADM, PACCB (pending)  
DMO (pending)  
MO (pending)

PCO (pending)



## ***Salvia divinorum***

### **Issue**

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff, incense special, and salvia.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs.

Health Canada recommends that you avoid using this plant because very little is known about the effects it may have on your body and/or brain. There is also no way to predict how it will affect you with each use.

### **Background**

*S. divinorum* is known to have psychotropic effects, which means it can affect the mind and mental processes. The leaves of this plant have been used traditionally by the Mazatec Indians for medicinal purposes (chewing the leaves or using them to make a tea) and spiritual purposes (smoking the leaves to induce a "mystical" or hallucinogenic experience).

Products that claim to contain *S. divinorum* – or its main active ingredient, salvinorin A – are widely available on the Internet and are sold in various "head shops" and natural food stores. The products are sold in a number of forms, including fresh or dried leaves, liquids or seeds and plant cuttings for growing purposes.

### **Risks Associated with the Use of *Salvia divinorum***

The effects of *S. divinorum*, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations;
- dysphoria (feeling unwell, uneasy or unhappy);
- out-of-body experiences;
- uncontrollable laughter;
- loss of consciousness;
- short-term memory loss;
- lack of physical coordination; and
- slurred speech and awkward sentence patterns.

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product;
- how much is used;

- the purity of the product (it may be mixed with other substances);
- how it is taken (e.g., chewed, swallowed or smoked);
- the user's mood and expectations.

While scientists know which brain receptors are targeted by the active ingredient, salvinorin A, very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or permanent damage;
- how it interacts with other substances, including other drugs, natural health products and alcohol.

The potential of *S. divinorum* to produce physical dependence and/or addiction is also not known.

### **Minimizing Your Risk**

Health Canada recommends that you avoid using *S. divinorum*. Just because a drug is plant-based or “natural”, does not mean that it is safe.

Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs and other substances that distort reality. (See the “Need More Info?” section below for links to resources that can help you with this.)

- 

### **Legal Status of *Salvia divinorum***

#### In Canada

When *S. divinorum* is manufactured, sold or represented for use in modifying organic functions in humans, and hallucinogens work by modifying organic functions in the brain, it meets the definition of a Natural Health Product (NHP) in accordance with the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*. It is illegal to sell NHPs in Canada unless they have been reviewed and approved by Health Canada and labelled with one of the following:

- a Natural Product Number (NPN); or
- a Drug Identification Number - Homeopathic Medicine (DIN-HM).

As of January 2010 no products containing *S. divinorum* have been approved by Health Canada. All unauthorized drugs and NHPs are subject to compliance and enforcement actions by the Department.

Neither *S. divinorum* nor salvinorin A are currently regulated under the *Controlled Drugs and Substances Act* (CDSA). This is because there is not enough information available to determine whether regulation as a controlled substance is warranted. In an effort to collect more information about the use of *S. divinorum*, questions on it were included in the 2008-2009 Youth Smoking Survey, the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) and the 2009

Ontario Student Drug Use and Health Survey (OSDUHS). The results from the 2009 OSDUHS were published on November 18, 2009 and indicate that among responding students in Ontario, 4.4% reported using *Salvia divinorum* at least once in the past year. Data from the Youth Smoking Survey was published on May 31, 2010 and indicate that 4.9% of responding students in Grades 7-12 have used *Salvia divinorum* at least once in the past year.

Data Data from these surveys and the 2009 edition of CADUMS (to be released in June 2010) will contribute to future decisions that Health Canada may make regarding the regulation of *S. divinorum* and/or its active ingredient. See the Need More Info? section below for more information on the surveys that are collecting information about *Salvia divinorum* use in Canada and for more detailed findings from the 2009 OSDUHS.

### In Other Countries

Several countries including but not limited to Australia, Belgium, Germany, Italy, Japan, etc., have placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A.

In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on their sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution, e.g., no sales to anyone under the age of 18, etc.

### **Background**

*S. divinorum* is known to have psychotropic effects, which means it affects the mind and mental processes. The leaves of this plant have been used traditionally by the Mazatec Indians for both medicinal purposes (chewing the leaves or using them to make a tea) and spiritual purposes (smoking the leaves to induce a “mystical” or hallucinogenic experience).

Products that claim to contain *S. divinorum* – or its main active ingredient, salvinorin A – are widely available on the Internet and are sold in various “head shops” and natural food stores. The products are sold in a number of forms, including fresh or dried leaves, liquids or seeds and plant cuttings for growing purposes.

### **Health Canada’s Role**

Health Canada continues to collect and consider information regarding *S. divinorum* and will continue to consult with key stakeholders including health officials in other countries and law enforcement officials here at home. This will assist in determining Health Canada’s future approach to decision-making regarding *S. divinorum*.

Complaints about illegal sale of drugs containing *S. divinorum* can be made to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

### **Reporting Adverse Reactions**

You can report any adverse reactions to the Canada Vigilance Program by one of the following three ways:

Report online at the [MedEffect™ Canada Web site](#)

Call toll-free at 1-866-234-2345

Complete a [Canada Vigilance Reporting Form](#) and either:

Fax toll-free to 1-866-678-6789

Mail to: Canada Vigilance Program

Health Canada

AL 0701C

Ottawa, ON K1A 0K9

To have postage pre-paid, download the [postage paid label](#) from the [MedEffect™ Canada Web site](#). The [Canada Vigilance Reporting Form](#) and the adverse reaction reporting guidelines may also be obtained via this Web site.

### Need More Info?

- For information about the Government of Canada's **Anti-Drug Strategy**, go to:

[www.nationalantidrugstrategy.gc.ca/](http://www.nationalantidrugstrategy.gc.ca/)

The Prevention section on this site has a number of helpful resources for parents, including:

- **Tips on Talking to Your Teenager**, at: [www.hc-sc.gc.ca/hc-ps/pubs/adp-apd/talk-aborder/index-eng.php](http://www.hc-sc.gc.ca/hc-ps/pubs/adp-apd/talk-aborder/index-eng.php)

- **What to Do if Your Teen is Using Drugs**, at:

[www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html](http://www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html)

- Information on natural health products and the *Natural Health Products Regulations* can be found at: [www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php)

For more on the surveys that are collecting information about *Salvia divinorum* use in Canada, see:

- **The 2008-2009 Youth Smoking Survey**, at:

[www.yss.uwaterloo.ca/ysssite\\_app/controller/index.cfm](http://www.yss.uwaterloo.ca/ysssite_app/controller/index.cfm) and

- **The 2009 Canadian Alcohol and Drug Use Monitoring Survey**, at: [www.hc-sc.gc.ca/hl-vs/drug-drogues/cadums-escad-eng.php](http://www.hc-sc.gc.ca/hl-vs/drug-drogues/cadums-escad-eng.php)

- **The 2009 Ontario Student Drug Use and Health Survey**, at:

[www.camh.net/Research/osdus.html](http://www.camh.net/Research/osdus.html)

### Additional Resources:

- U.S. Drug Enforcement Administration: Drugs and Chemicals of Concern: *Salvia divinorum* and Salvinorin A at: [www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)

- U.S. Department of Health & Human Services, **National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006** at:

[www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf](http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf)

- For additional articles on health and safety issues go to the ***It's Your Health*** Web section at:  
[www.healthcanada.gc.ca/iyh](http://www.healthcanada.gc.ca/iyh)

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

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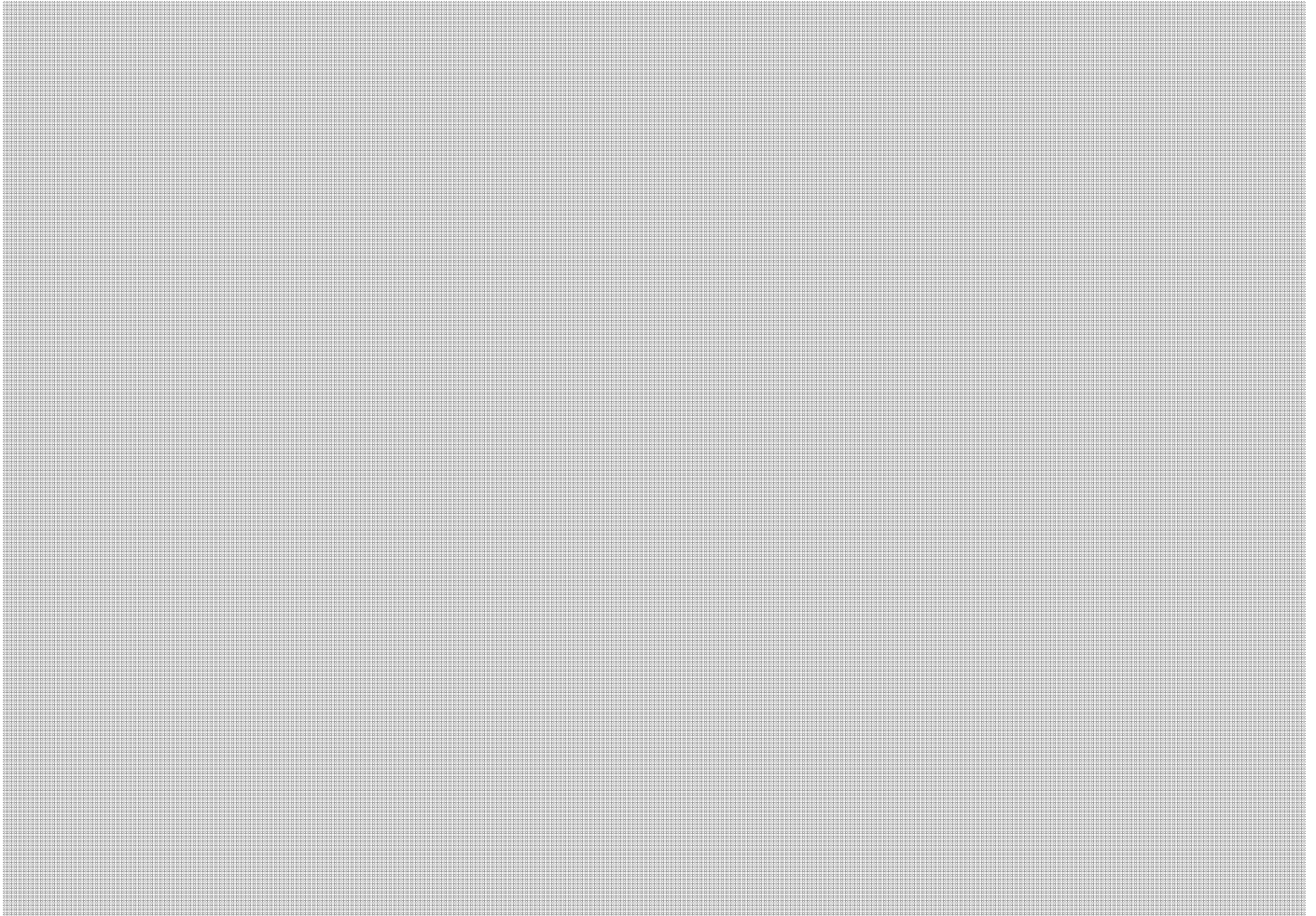
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**s.21(1)(a)**

**s.21(1)(b)**

**Why would we do an *It's Your Health* if we say we have insufficient evidence to regulate it (i.e. why do we have enough information about the health impacts yet aren't acting to regulate)?**

**INPUT 1**



**INPUT 2**

- Why IYH? Instrument choice (enterprise risk) change public behaviour before moving to prohibition; no incidence data outside of Ontario
- there are now recent data on the prevalence of salvia that were just released in the Ontario student drug use survey (6% of students reported having used it at least once, rate higher than for ecstasy) . Bruna is preparing a short article for CMAJ with more details on it .

# NIDA INFOFACTS

www.drugabuse.gov

National Institute on Drug Abuse • National Institutes of Health • U.S. Department of Health & Human Services

## Salvia

Salvia (*salvia divinorum*) is an herb common to southern Mexico and Central and South America. The main active ingredient in salvia, salvinorin A, is a potent activator of kappa opioid receptors in the brain<sup>1,2</sup>. These receptors differ from those activated by the more commonly known opioids, such as heroin and morphine.

Traditionally, *S. divinorum* has been ingested by chewing fresh leaves or by drinking their extracted juices. Recreationally, the dried leaves of *Salvia divinorum* can be smoked as a joint, consumed in water pipes or vaporized and inhaled. Although salvia currently is not a drug regulated by the Controlled Substances Act, several states and countries have passed legislation to regulate its use.<sup>3</sup> The Drug Enforcement Agency has listed salvia as a drug of concern and is considering classifying it as a Schedule I drug, like LSD or marijuana.

### **Health/Behavioral Effects**

People who abuse salvia generally experience hallucinations or psychotomimetic episodes (a transient experience that mimics a psychosis).<sup>4,5</sup> Subjective effects have been described

as intense but short-lived, appearing in less than 1 min and lasting less than 30 min. They include psychedelic-like changes in visual perception, mood and body sensations, emotional swings, feelings of detachment, and importantly, a highly modified perception of external reality and the self, leading to a decreased ability to interact with one's surroundings.<sup>5</sup> This last effect has prompted concern about the dangers of driving under the influence of Salvinorin. The long-term effects of Salvia abuse have not been investigated systematically.

### **Extent of Use**

In 2009, NIDA's Monitoring the Future Survey of 8th, 10th, and 12th graders asked about salvia abuse for the first time 5.7 percent of high school seniors reported past year use (greater than the percent reporting ecstasy use). Although information about this drug is limited, recent salvia-related media reports and Internet traffic suggest the possibility that its abuse is increasing in the US and Europe,<sup>4</sup> likely driven by drug-related videos and information on Internet sites.<sup>3</sup> Because of the nature of the drug's effects its use may be restricted to individual experimentalists, rather than as a social or party drug.<sup>5</sup>



# NIDA INFOFACTS

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For more information on the effects of hallucinogenic drugs, see NIDA's *Research Report on Hallucinogens and Dissociative Drugs* at [www.nida.nih.gov/ResearchReports/hallucinogens/hallucinogens.html](http://www.nida.nih.gov/ResearchReports/hallucinogens/hallucinogens.html).

For more information on *salvia divinorum* and the Controlled Substances Act, visit [www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm).

For **street terms** searchable by drug name, street term, cost and quantities, drug trade, and drug use, visit [www.whitehousedrugpolicy.gov/streetterms/default.asp](http://www.whitehousedrugpolicy.gov/streetterms/default.asp).

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<sup>1</sup> Chavkin, C., Sud, S., Jin, W. et al. (2004) Salvinorin A, an active component of the hallucinogenic sage *salvia divinorum* is a highly efficacious kappa-opioid receptor agonist: structural and functional considerations, *J Pharmacol Exp Ther*, 308, 1197-203.

<sup>2</sup> Harding, W.W., Tidgewell, K., Schmidt, M., Shah, K., Dersch, C.M., Snyder, J., Parrish, D. Deschamps, J.R., Rothman, R.B., and Prisinzano, T.E. Salvinicins A and B, New Neoclerodane Diterpenes from *Salvia Divinorum*. *Organic Letters*, 7, pp. 3017-3020, 2005.

<sup>3</sup> [www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm). Retrieved 09-24-07

<sup>4</sup> Roth, B. L., Baner, K., Westkaemper, R. et al. (2002) Salvinorin A: a potent naturally occurring non-nitrogenous kappa opioid selective agonist, *Proc Natl Acad Sci USA*, 99, 11934-9.

<sup>5</sup> Gonzalez, D., Riba, J., Bouso, J. C., Gomez-Jarabo, G. & Barbanoj, M. J. (2006) Pattern of use and subjective effects of *Salvia divinorum* among recreational users, *Drug Alcohol Depend*, 85, 157-62.

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# SALVIA.CA

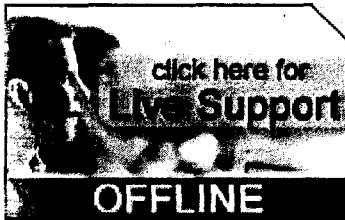


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- Wild Dagga
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We are the exclusive destination of choice for all your salvia divinorum needs. Being a rare sage as salvia is, the demand for our products have never been higher. We offer a broad range of extract including 20x as well as a selection of dried leaves which have proven to be very popular within the salvia community. Our very rare seeds and high quality plants allow for the freshest salvia possible.

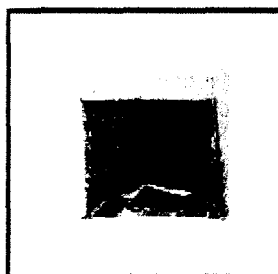
We have taken our time in developing this site for the use of everyone. We hope to make this much more than a place to buy salvia divinorum by offering interesting articles and stories from salvia users. It's our way of helping to increase the awareness of these wonderful

products. If you are new to Salvia and would like to learn more about it, check out this exelent [Salvia Resource](#)

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## **Salvia Divinorum Extract 10x**

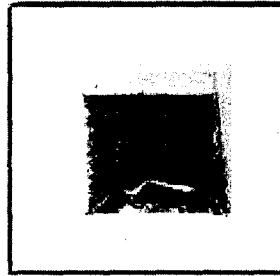


Our 10 x Salvia Divinorum Extract contains 36mg of pure salvinorin-A per gram of extract which is extracted from the plant and then redeposited back onto dried leaves. Our skilled chemists use a standardized method, which costs a little more than non-standardized methods, but means you will find no extra plant matter which can be harmful to your lungs. Salvia Extract is not a liquid. Twice as potent as the 5x salvia extract.

- Salvia Divinorum Extract 10x, 1g \$26.62
- Salvia Divinorum Extract 10x, 3g \$66.55
- Salvia Divinorum Extract 10x, 10g \$181.50
- Salvia Divinorum Extract 10x, 25g \$326.70
- Salvia Divinorum Extract 10x, 50g \$544.50

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## **Salvia Divinorum Extract 15x**

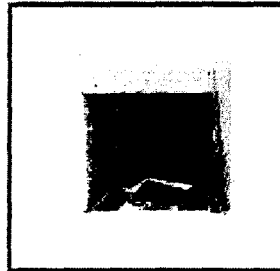


Our 15x salvia extract contains 54mg of pure salvinorin-A per gram of extract which is extracted from the plant and then redeposited back onto dried leaves. Our skilled chemists use a standardized method, which costs a little more than non-standardized methods, but means you will find no extra plant matter which can be harmful to your lungs. Salvia Extract is not a liquid. **This dosage has been described as very potent, and we recommend that you exercise caution when using this product.**

- Salvia Divinorum Extract 15x, 1g \$36.30
- Salvia Divinorum Extract 15x, 3g \$84.70
- Salvia Divinorum Extract 15x, 10g \$235.95
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- Salvia Divinorum Extract 15x, 50g \$707.85

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Our 20x extract is extremely rare and hard to find and contains 72mg of pure salvinorin-A per gram of extract which is extracted from the plant and then redeposited back onto dried leaves. Our skilled chemists use a standardized method, which costs a little more than non-standardized methods, but means you will find no extra plant matter which can be harmful to your lungs. Salvia Extract is not a liquid. **This dosage has been described as very potent, and we recommend that you exercise caution when using this product.**

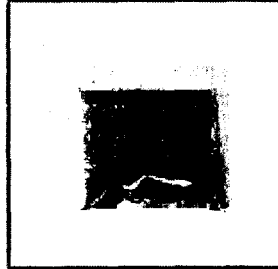
Experienced salvia users only.

**Use with caution**

- Salvia Divinorum Extract 20x, 1g \$48.40
- Salvia Divinorum Extract 20x, 3g \$108.90
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- Salvia Divinorum Extract 20x, 25g \$550.55
- Salvia Divinorum Extract 20x, 50g \$919.60

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## Salvia Divinorum Extract 30x



Our 30 x salvia divinorum extract contains 108mg of pure salvinorin-A per gram of extract which is extracted from the plant and then redeposited back onto dried leaves. Our skilled chemists use a standardized method, which costs a little more than non-standardized methods, but means you will find no extra plant matter which can be harmful to your lungs. Salvia Extract is not a liquid. **This dosage has been described as very potent, and we recommend that you exercise caution when using this product.**

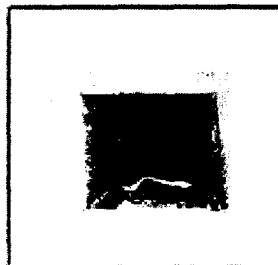
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**Use with caution**

- Salvia Divinorum Extract 30x, 1g \$65.34
- Salvia Divinorum Extract 30x, 3g \$169.40
- Salvia Divinorum Extract 30x, 10g \$435.60
- Salvia Divinorum Extract 30x, 25g \$877.25

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## Salvia Divinorum Extract 5x



Our 5x salvia divinorum extract contains 18mg of salvinorin-a per gram of extract which is extracted from the plant and then redeposited back onto dried leaves. Our skilled chemists use a standardized method, which costs a little more than non-standardized methods, but means you will find no extra plant matter which can be harmful to your lungs. Salvia Extract is not a liquid.

- Salvia Divinorum Extract 5x, 1g \$13.31
- Salvia Divinorum Extract 5x, 3g \$32.67
- Salvia Divinorum Extract 5x, 10g \$93.17
- Salvia Divinorum Extract 5x, 25g \$181.50
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001153

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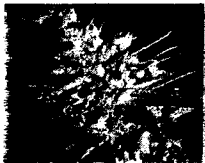
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## Live Salvia Divinorum Cuttings

Salvia divinorum, also known as Diviner's Sage and Sage of the Seers, is a psychoactive herb which can induce strong dissociative effects. It is a member of the Mint family.

Salvia divinorum has a long and continuing tradition of use as an entheogen by indigenous Mazatec shamans, who use it to facilitate visionary states of consciousness during spiritual healing sessions.

The plant is found in isolated, shaded, and moist plots in Oaxaca, Mexico. It grows to well over a meter in height. It has hollow square stems, large green leaves, and occasional white and purple flowers. Salvia Divinorum produces few seeds, and those that do appear seldom germinate.

Salvia prefers indirect sunlight, do not place the plant under intense sunlight. You can begin to harvest leaves when the plant is about three feet tall. The plant will grow quickly under the right conditions.

Salvia divinorum can be chewed, smoked, or taken as a tincture to produce experiences ranging from uncontrollable laughter to much more intense and profoundly altered states. The primary psychoactive constituent is a diterpenoid known as Salvinorin A.

The duration of effects is much shorter than that of other, more well-known psychedelics; the effects of smoked salvia typically last for only a few minutes. The most commonly reported after-effects include an increased feeling of insight, an improved mood, a sense of calmness, and an

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01. Salvia cutting SOLD IN CANADA ONLY

## Reviews



recieved 5 great white shark a month ago, pretty colored see ..  
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increased sense of connection with nature— though, much less often, it may also cause dysphoria (unpleasant or uncomfortable mood).

Salvia divinorum is not generally understood to be toxic or addictive.

Mazatec shamans crush the leaves to extract leaf juices from about 50-200g of fresh leaves (20 to 80 leaves). They usually mix these juices with water to create an infusion or 'tea' which they drink to induce visions in ritual healing ceremonies.



Dry leaves can be smoked in a pipe or water pipe. The temperature required to release salvinorin from the plant material is quite high (about 240°C). A regular flame will work, but the direct application of a butane torch lighter, is often preferred. Many people find that untreated dried salvia leaf produces unnoticeable or only light effects.

The leaves can also be chewed; in this case they should be held in the mouth as long as possible in order to facilitate absorption of the active constituents through the oral mucosa. Chewing consumes more of the plant than smoking, and produces a longer-lasting experience.

Learn more about Salvia Divinorum

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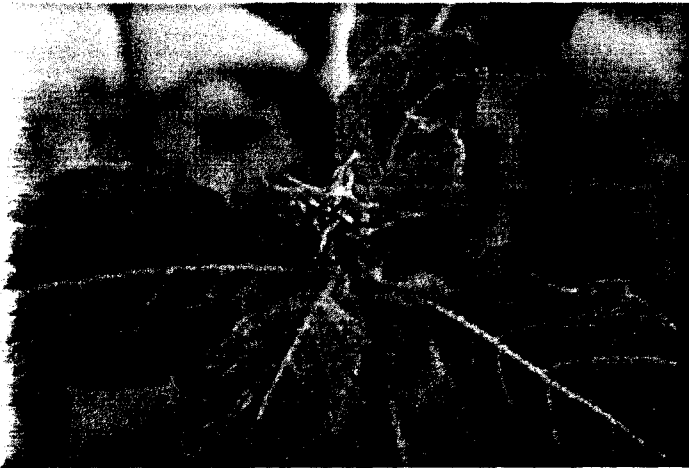
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### Diviners Sage

*Salvia divinorum*

**Uses:** Medicinal

**Duration:** Perennial (*hardy in zones 11+*)

Sacred sage of the Mazateca Indians of Mexico used to induce divinatory visions. To help find lost items, or to solve problems of a material or spiritual nature, the Mazateca Indians would chew the fresh leaves. The leaves are very bitter when chewed but are slightly more palatable taken as a cold infusion of fresh crushed leaves, or smoked. Psychotropic effects similar to mescaline are attributed to compounds called salvivorins. Prefers humid, shaded conditions and humus-rich, moist soil. Rangy plant, reaching 2m/7ft. unless pruned.

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DRAFT 12  
September 1, 2010

## **Media Lines Regulatory Control of *Salvia Divinorum***

### **Issue**

Since 2006, Health Canada has noted ongoing media interest regarding the availability of *Salvia divinorum* in Canada. Health Canada has also received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum*, particularly given reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties.

### **Key Messages:**

- Health Canada advises Canadians not to use products containing *S. divinorum* and/or salvinorin A because very little is known about the substance and its potential effects on the brain and/or body, and its impact on physical and mental functions.
- Because of its hallucinogenic properties, products containing *S. divinorum* and/or salvinorin A meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*.
- It is illegal to sell NHPs in Canada unless they have been reviewed and approved by Health Canada and labelled with a Natural Product Number (NPN) or Exemption Number or a Drug Identification Number – Homeopathic Medicine (DIN-HM). The illegal sale of products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drug Act*.
- Health Canada will continue to collect and study information about *S. divinorum* as it becomes available, and to consult with law enforcement and health officials domestically and internationally in order to determine the best way to manage the risks associated with its availability in Canada.

### **Supplementary Messages:**

#### ***Salvia divinorum as a controlled substance:***

- In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA).
- *Salvia divinorum* is not listed under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these Conventions.

- Several countries (Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) have placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Although some individual U.S. states have implemented laws restricting its use, sale and/or distribution, *Salvia divinorum* and salvinorin A are not federally regulated under the *Controlled Substances Act* in the United States.

***If pressed on the lack of statistics on Salvia divinorum use in Canada:***

- Health Canada is taking steps to address the paucity of data. Questions about the use of *Salvia divinorum* were included in the 2008-2009 Youth Smoking Survey, and the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS). The results from the Youth Smoking Survey were released on May 31, 2010 and the 2009 CADUMS results are scheduled to be released in late June 2010
- It is anticipated that the data from these surveys will contribute to future decisions that Health Canada may make about how this plant and its active ingredient should be regulated.

***If pressed regarding the results of the 2009 Ontario Student Drug Use and Health Survey:***

- The results from the 2009 Ontario Student Drug Use and Health Survey were published on November 18, 2009 and indicate that among responding students in Ontario, 4.4% reported using *Salvia divinorum* at least once in the past year. Health Canada will consider this data in its ongoing examination of *Salvia divinorum* and salvinorin A.

**Questions and Answers:**

**Q1 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why isn't it illegal?**

A1 – Because *S. divinorum* meets the definition of an NHP under the *Natural Health Product Regulations*, it is illegal to manufacture, sell or provide products containing *S. divinorum* and/or salvinorin A without their being authorized by Health Canada prior to sale. With respect to adverse effects, there are insufficient controlled scientific studies looking into the physical and psychotropic effects of *Salvia divinorum* on humans. As such, it is difficult to predict the potential for addiction and abuse associated with *Salvia divinorum*. Based on the available evidence, Health Canada is not proceeding to regulate it as a controlled substance at this point in time.

**Q2 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?**

A2 – The *Natural Health Products Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *Salvia divinorum*.

**Q3 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A3 – *Salvia divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. Complaints about the illegal sale of drugs containing *S. divinorum* and/or **salvinorin A** can be referred to the Health Products and Food Branch Inspectorate at 1-800-267-9675. .

**Q4 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum* as a controlled substance. What does that involve and what stage is it at?**

A4 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada has only limited information on some of the above-mentioned factors, and thus there is simply not enough information available to determine whether regulation of *Salvia divinorum* under the CDSA is warranted.

It is anticipated that the data from the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey in addition to the results from the 2009 Ontario Student Drug Use and Health Survey will help address some of the information gaps about this substance. Data from the Youth Smoking Survey has just been released and data from the 2009 edition of CADUMS will be available in late June 2010. [need to state how these survey information will be used from a regulatory perspective]

**Q5 – Didn't an internal report from Health Canada's Marketed Health Products Directorate recommend that *Salvia divinorum* be scheduled under the CDSA? Why has that recommendation not been acted upon?**

A5 – See A4

**Q6 – What is the significance of the adverse reaction reports that Health Canada has received with respect to the use of *Salvia divinorum*?**

A6 – Health Canada has received four domestic adverse reaction reports related to the use of *Salvia divinorum* as a hallucinogen through the Canada Vigilance database. The number of reports and the nature of reactions reported are, however, not adequate to characterize any risk of similar reactions to the general population. In particular, Health Canada does not have any

information about the number of individuals in Canada using or who have used *Salvia divinorum*. [what about extrapolation from the surveys cited above?]

***If pressed on whether Health Canada has issued any kind of warning to Canadians about Salvia divinorum***

A. Health Canada is developing an It's Your Health (IYH) article on *Salvia divinorum* to help inform the general public about the risks associated with the use of this substance.

**Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec Indians in Mexico.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

While some users have reported that the psychotropic effects of *Salvia divinorum* resemble those induced by other hallucinogens, such as LSD and phencyclidine, the overall experience appears to be quite unique.[this is subjective and does not give information]

Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that;

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year.
- 5.4% of students (grades 7-12) ever used *S. divinorum*.
- Use of *S. divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

Data from the 2007 report on Alcohol and Other Drugs published by the Addictions Foundation of Manitoba indicate that:

- 3.7% of males vs. 2.2% of females (grades 7-12) used *S. divinorum* during that year.

Data from a 2006 National Survey on Drug Use and Health Report, published by the U.S. Substance Abuse and Mental Health Services Administration estimated that:

- 0.3% of persons aged 12 or older used *S. divinorum* in 2006.
- 0.6% of persons between the ages of 12 and 17 used *S. divinorum* in 2006.
- 1.7% of persons between the ages of 18 to 25 used *S. divinorum* in 2006.
- Young adults (18-25) were nearly three times more likely than youths aged 12-17 to have used *S. divinorum* in 2006.

- Males between the ages of 12-25 were three to four times more likely than females in the same age range to have used *S. divinorum* in 2006.

**Prepared by:** Cheryl Tremblay, OCS, CSTD

**Input by:** Lisa Mackay IYH/PACCB, Hanan Abramovici HECSB/ODARS, Jocelyn Kula, HECSB/OCS, Robin Marles HPFB/NHPD, Mano Murty HPFB/MHPD (31/08/10), Robert Leitch HPFB/MHPD, Collin Pinto, HPFB/HPFBI

**Approved by:**

[NAME] Director, Bureau of Policy and Regulatory Affairs, NHPD (pending)  
[NAME] Director, Marketed Biologics, Biotechnology and Natural Health Products  
Bureau,  
MHPD (pending)  
[NAME] Director, HPFBI (pending)  
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Paul Glover, ADM, HECSB (pending)  
Meena Ballantyne, ADM, HPFB (pending)  
Anne Lamar, ADM, PACCB (pending)  
DMO (pending)  
MO (pending)  
PCO (pending)

Draft 16  
Sept 2010

## **Salvia divinorum**

### **Issue**

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff, incense special, and salvia.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs. As of January 2010 no products containing *S. divinorum* have been authorized for use by Health Canada.

Health Canada recommends that you avoid using this plant because very little is known about the effects it may have on your body and/or brain functions. There is also no way to predict how it will affect you with each use.

### **Risks Associated with the Use of *Salvia divinorum***

*S. divinorum* is known to have physical and mental effects. The effects of *S. divinorum*, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations
- dysphoria (feeling unwell, uneasy or unhappy)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product
- how much is used
- the purity of the product (it may be mixed with other substances)
- how it is taken (e.g., chewed, swallowed or smoked)
- the user's mood and expectations

While scientists know which brain receptors are targeted by the active ingredient, salvinorin A, very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or permanent damage



- how it interacts with other substances, including other drugs, natural health products and alcohol
- The potential of *S. divinorum* to produce physical dependence and/or addiction

### **Minimizing Your Risk**

Health Canada recommends that you avoid using *S. divinorum* because very little is known about the effects it may have on your body and/or brain functions. There is also no way to predict how it will affect you with each use. Just because a drug is plant-based or “natural”, does not mean that it is safe.

Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs, such as marijuana, cocaine, ecstasy, LSD and other substances that distort reality. See the “**Need More Info?**” section below for links to resources that can help you with this.

### **Legal Status of *Salvia divinorum***

#### In Canada

When *S. divinorum* is manufactured, sold or represented for use in modifying organic functions in humans, and hallucinogens work by modifying organic functions in the brain, it meets the definition of a Natural Health Product (NHP) in accordance with the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*. It is illegal to sell NHPs in Canada unless they have been reviewed and approved by Health Canada and labelled with one of the following:

- a Natural Product Number (NPN); or
- a Exemption Number; or
- a Drug Identification Number - Homeopathic Medicine (DIN-HM).

As of January 2010 no products containing *S. divinorum* have been authorized by Health Canada. All unauthorized drugs and NHPs are subject to compliance and enforcement actions by the Department.

Neither *S. divinorum* nor salvinorin A are currently regulated under the *Controlled Drugs and Substances Act* (CDSA). This is because there is not enough information available to determine whether regulation as a controlled substance is warranted. In an effort to collect more information about the use of *S. divinorum* in Canada, questions on it were included in the 2008-2009 Youth Smoking Survey, the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) and the 2009 Ontario Student Drug Use and Health Survey (OSDUHS).

Data from these surveys will contribute to future decisions that Health Canada may make regarding the regulation of *S. divinorum* and/or its active ingredient in Canada. See the **Need More Info?** section below for more information on the surveys.

#### In Other Countries

Several countries including but not limited to Australia, Belgium, Germany, Italy, Japan, etc., have placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A.

In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on their sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution, for example, can not sell to anyone under the age of 18.

## Background

The leaves of this plant have been used traditionally by the Mazatec Indians for medicinal uses like chewing the leaves or using them to make a tea, and other purposes like smoking the leaves to induce a “mystical” or hallucinogenic experience.

Products that claim to contain *S. divinorum* – or its main active ingredient, salvinorin A – are widely available on the Internet and are sold in various “head shops” and natural food stores. The products are sold in a number of forms, including fresh or dried leaves, liquids or seeds and plant cuttings for growing purposes.

## Health Canada's Role

Health Canada continues to collect and consider safety information regarding *S. divinorum* and will continue to consult with key stakeholders including health officials in other countries and law enforcement officials here at home. This will assist in determining Health Canada's future approach to decision-making regarding regulation of *S. divinorum* in Canada.

## Need More Info?

- Complaints about illegal sale of drugs containing *S. divinorum* can be made to the **Health Products and Food Branch Inspectorate** at: [http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_44\\_consumer\\_consommateur\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_44_consumer_consommateur_cp-pc-eng.php)  
Tel: 1-800-267-9675.
- You can report any adverse reactions to the Canada Vigilance Program by one of the following three ways:  
Report online at the MedEffect™ Canada website at: <http://www.hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>  
Call toll-free at 1-866-234-2345  
Complete a Canada Vigilance Reporting Form and either:  
Fax toll-free to 1-866-678-6789  
Mail to: Canada Vigilance Program  
Health Canada  
AL 0701C  
Ottawa, ON K1A 0K9

To have postage pre-paid, download the postage paid label from the MedEffect™ Canada website. The Canada Vigilance Reporting Form and the adverse reaction reporting guidelines may also be obtained via this website at : [http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei\\_form-eng.php](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei_form-eng.php)

- For information about the Government of Canada's Anti-Drug Strategy, go to: [www.nationalantidrugstrategy.gc.ca/](http://www.nationalantidrugstrategy.gc.ca/)

The Prevention section on this site has a number of helpful resources for parents, including:

- **Tips on Talking to Your Teenager**, at: [www.hc-sc.gc.ca/hc-ps/pubs/adp-apd/talk-aborder/index-eng.php](http://www.hc-sc.gc.ca/hc-ps/pubs/adp-apd/talk-aborder/index-eng.php)
- **What to Do if Your Teen is Using Drugs**, at: [www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html](http://www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html)
- Health Canada's **Not4Me** youth drug prevention section at: <http://www.hc-sc.gc.ca/hc-ps/drugs-drogues/youth-jeunes/facts-faits/index-eng.php>
- Information on natural health products and the Natural Health Products Regulations can be found at: [www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php)

For more on the surveys that are collecting information about Salvia divinorum use in Canada, see:

- **The 2008-2009 Youth Smoking Survey**, at: [www.yss.uwaterloo.ca/ysssite\\_app/controller/index.cfm](http://www.yss.uwaterloo.ca/ysssite_app/controller/index.cfm)
- **The 2009 Canadian Alcohol and Drug Use Monitoring Survey**, at: [www.hc-sc.gc.ca/hl-vs/drug-drogues/cadums-escad-eng.php](http://www.hc-sc.gc.ca/hl-vs/drug-drogues/cadums-escad-eng.php)
- **The 2009 Ontario Student Drug Use and Health Survey**, at: [http://www.camh.net/Research/Areas\\_of\\_research/Population\\_Life\\_Course\\_Studies/OSDUS/~Detailed\\_DrugReport\\_2009OSDUHS\\_Final.pdf](http://www.camh.net/Research/Areas_of_research/Population_Life_Course_Studies/OSDUS/~Detailed_DrugReport_2009OSDUHS_Final.pdf)

#### **Additional Resources:**

- U.S. Drug Enforcement Administration: **Drugs and Chemicals of Concern: Salvia divinorum and Salvinorin A** at: [www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)
- U.S. Department of Health & Human Services, **National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006** at: [www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf](http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf)
- For additional articles on health and safety issues go to the It's Your Health web section at: [www.healthcanada.gc.ca/iyh](http://www.healthcanada.gc.ca/iyh)

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

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Catalogue#  
ISBN#


Version/date: Draft 16. August 31, 2010.

PACCB IYH - Lisa Mackay: 613-954-0105 – [Lisa.Mackay@hc-sc.gc.ca](mailto:Lisa.Mackay@hc-sc.gc.ca)

Comments from: HECSB - CSTD (OCS&ODARS) & HPFB – NHPD & HPFBI

Contacts: HECSB: Jocelyn Kula, Cheryl Tremblay, Suzanne Desjardin, Denis  
Arsenault, Hanan Abaramovici  
HECSB comms: Christine Roush, Bronwyn Cline  
HPFB-NHPD: Valerie Hurry, Robin Marles  
HPFB-MHPD: Scott Jordan, Robert Leitch, Mano Murty, Shahid Perwaiz  
HPFBI : Collin Pinto  
HPFB comms: Elizabeth Keeping, Blossom Leung

Lisa MacKay/HC-SC/GC/CA  
2010-09-01 04:46 PM

To Robin Marles/HC-SC/GC/CA@HWC  
cc Allison Lui/HC-SC/GC/CA@HWC, Angela Tonary/HC-SC/GC/CA@HWC, Bronwyn Cline/HC-SC/GC/CA@HWC, Bruna  
bcc  
Subject Re: Final review before formal approval - SALVIA 

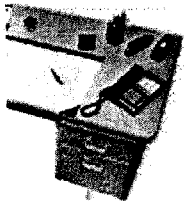
Good point Robin!

I'll put Sept 2010 for now but flag it so that when we are ready to release I'll make sure the proper month is listed.

Thanks


Lisa

Robin Marles/HC-SC/GC/CA



Robin Marles/HC-SC/GC/CA  
2010-09-01 04:43 PM

To Lisa MacKay/HC-SC/GC/CA@HWC  
cc Allison Lui/HC-SC/GC/CA@HWC, Angela Tonary/HC-SC/GC/CA@HWC, Bronwyn Cline/HC-SC/GC/CA@HWC, Bruna Brands/HC-SC/GC/CA@HWC, Christine Roush/HC-SC/GC/CA@HWC, Christine Zaczynski/HC-SC/GC/CA@HWC, Danika Painter/HC-SC/GC/CA@HWC, Darrin Denne/HC-SC/GC/CA@HWC, Dave Stephens/HC-SC/GC/CA@HWC, David Cunningham/HC-SC/GC/CA@HWC, Denis Arsenaault/HC-SC/GC/CA@HWC, Duc Vu/HC-SC/GC/CA@HWC, Elizabeth Keeping/HC-SC/GC/CA@HWC, Hanan Abramovici/HC-SC/GC/CA@HWC, Helene Lacourciere/HC-SC/GC/CA@HWC, Jeff Devine/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Karen Kouassi/HC-SC/GC/CA@HWC, Kathy Howard/HC-SC/GC/CA@HWC, Ken Polk/HC-SC/GC/CA@HWC, Kevan Burrows/HC-SC/GC/CA@HWC, Kevin Bernardo/HC-SC/GC/CA@HWC, Laura Francis-Lamb/HC-SC/GC/CA@HWC, Lindsay Blaney/HC-SC/GC/CA@HWC, Mano Murty/HC-SC/GC/CA@HWC, MBBNHPB Assistants, MBBNHPB Management, Melinda Lee Choon/HC-SC/GC/CA@HWC, Robert Leitch/HC-SC/GC/CA@HWC, Sarah Chippure/HC-SC/GC/CA@HWC, Scott Jordan/HC-SC/GC/CA@HWC, Shahid Perwaiz/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC, Stephanie Jack/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC, Terry LP Smith/HC-SC/GC/CA@HWC, Valerie Hurry/HC-SC/GC/CA@HWC, Zeshan Zakir/HC-SC/GC/CA@HWC

Subject Re: Final review before formal approval - SALVIA   
001169



If you would prefer to say, "As of September, 2010 . . ." I confirm that such a revision is correct. January is already soooo long ago!

Robin

Lisa MacKay/HC-SC/GC/CA


Lisa MacKay/HC-SC/GC/CA

2010-09-01 02:52 PM

To Jocelyn Kula/HC-SC/GC/CA@HWC, Stephanie  
Chandler/HC-SC/GC/CA@HWC, Denis  
Arsenault/HC-SC/GC/CA@HWC, MBBNHPB Assistants,  
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Abramovici/HC-SC/GC/CA@HWC, Suzanne  
Desjardins/HC-SC/GC/CA@HWC, Mano  
Murty/HC-SC/GC/CA@HWC  
cc Kathy Howard/HC-SC/GC/CA@HWC, Ken  
Polk/HC-SC/GC/CA@HWC, Dave  
Stephens/HC-SC/GC/CA@HWC  
Subject Final review before formal approval - SALVIA

Hello all,

I think I have been able to include all requested changes to the media lines and IYH article on Salvia. Here are the final documents for your review. Could you please send any additional comments or requested



changes to me by c.o.b Tuesday September 7.

I have made one additional change to the IYH article. I believe two of the main questions the public has about this substance are "is it safe?" and if not "what is Health Canada doing?" so to that end, I added a sentence (taken from another section of the article) to the Issue section:

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs. As of January 2010 no products containing *S. divinorum* have been authorized for use by Health Canada.

IYH article - mark-up

[attachment "IYH Salvia\_v15 Aug 2010.doc" deleted by Robin Marles/HC-SC/GC/CA]

IYH article - clean version

[attachment "IYH Salvia divinorum\_v16 clean Sept2010.doc" deleted by Robin Marles/HC-SC/GC/CA]

In the media lines comments there was a question regarding the Raw Material Policy:

**Q2 – How can Health Canada regulate a product containing *Salvia divinorum* , but not the sale of *Salvia divinorum* itself?**

A2 – The *Natural Health Products Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *Salvia divinorum*. - **This statement is correct.**

Media Lines - mark-up

[attachment "Salvia MLs + OCS Input SP August 31, 2010.doc" deleted by Robin Marles/HC-SC/GC/CA]

Media Lines - clean version

[attachment "Media Lines\_v12 clean Sept2010.doc" deleted by Robin Marles/HC-SC/GC/CA]

Thank you all for your work so far!

Lisa Mackay

It's Your Health Project Manager/Gestionnaire du projet Votre santé et vous

Strategic Communications and Ministerial Services Division / Division des communications stratégiques et des services ministériels

Public Affairs, Consultation and Communications Branch/ Direction générale des affaires publiques, de la consultation et des communications

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Tel 613.954.0105

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Lisa\_Mackay@hc-sc.gc.ca

Lisa MacKay/HC-SC/GC/CA  
2010-09-02 03:49 PM

To Suzanne Desjardins/HC-SC/GC/CA@HWC  
cc Allison Lui/HC-SC/GC/CA@HWC, Angela  
Tonary/HC-SC/GC/CA@HWC, Bronwyn  
Cline/HC-SC/GC/CA@HWC, Bruna  
bcc

Subject Re: Final review before formal approval - SALVIA 

History:  This message has been replied to.

Thank you Suzanne, Bruna and Hanan

To answer your question about why the background section is so far down in the article - we are trying to change the format of IYH articles somewhat to make them consistent with the style of information on the Consumer Safety Portal. It was suggested that the Background section be moved down in all articles because people generally want to know the Issue first, what are their potential risks second and what can they do to minimize those risks third. Then if they want they can read the rest of the information. Whenever possible we are trying to change to that format.

Lisa Mackay

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et des services ministériels

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Lisa\_Mackay@hc-sc.gc.ca

Suzanne Desjardins/HC-SC/GC/CA



Suzanne  
Desjardins/HC-SC/GC/CA  
2010-09-02 03:35 PM


To Lisa MacKay/HC-SC/GC/CA@HWC

cc Allison Lui/HC-SC/GC/CA@HWC, Angela  
Tonary/HC-SC/GC/CA@HWC, Bronwyn  
Cline/HC-SC/GC/CA@HWC, Bruna  
Brands/HC-SC/GC/CA@HWC, Christine  
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Smith/HC-SC/GC/CA@HWC, Valerie  
Hurry/HC-SC/GC/CA@HWC, Zeshan  
Zakir/HC-SC/GC/CA@HWC

Subject Re: Final review before formal approval - SALVIA 

Hi Lisa,

Bruna Brands, Hanan Abramovici and myself have looked at the article and the media lines. Our comments are included in the attached.

Most of the changes are due to the fact that the results from the surveys are now known and we have started to review the information as part of our drug scheduling process. The decision has not been made yet and can't be communicated, but we can no longer say that at the present time there is not enough information for us to make a decision. Both the article and the Media lines have been amended with that consideration.



IYH Salvia divinorum\_v16 clean Sept2010 ODARS cmts.doc Media Lines\_v12 clean Sept2010ODARS cmts.doc

Thanks

Suzanne

Lisa MacKay/HC-SC/GC/CA

Lisa MacKay/HC-SC/GC/CA

2010-09-01 02:52 PM

To Jocelyn Kula/HC-SC/GC/CA@HWC, Stephanie  
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cc Kathy Howard/HC-SC/GC/CA@HWC, Ken  
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Subject Final review before formal approval - SALVIA

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IYH article - mark-up  
[attachment "IYH Salvia\_v15 Aug 2010.doc" deleted by Suzanne Desjardins/HC-SC/GC/CA]  
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Lisa\_Mackay@hc-sc.gc.ca

ODARS + SC input

DRAFT 12  
September 1, 2010

### Media Lines Regulatory Control of *Salvia Divinorum*

#### **Issue**

Since 2006, Health Canada has noted ongoing media interest regarding the availability of *Salvia divinorum* in Canada. Health Canada has also received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum*, particularly given reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties.

#### **Key Messages:**

- Health Canada advises Canadians not to use products containing *S. divinorum* and/or salvinorin A because very little is known about the substance and its potential effects on the brain and/or body, and its impact on physical and mental functions.
- Because of its hallucinogenic properties, products containing *S. divinorum* and/or salvinorin A meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*.
- It is illegal to sell NHPs in Canada unless they have been reviewed and approved by Health Canada and labelled with a Natural Product Number (NPN) or Exemption Number or a Drug Identification Number – Homeopathic Medicine (DIN-HM). The illegal sale of products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drug Act*.
- Health Canada will continue to collect and study information about *S. divinorum* as it becomes available, and to consult with law enforcement and health officials domestically and internationally in order to determine the best way to manage the risks associated with its availability in Canada.

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#### **Supplementary Messages:**

##### ***Salvia divinorum as a controlled substance:***

- In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA).
- *Salvia divinorum* is not listed under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these Conventions.

- Several countries (Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) have placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Although some individual U.S. states have implemented laws restricting its use, sale and/or distribution, *Salvia divinorum* and salvinorin A are not federally regulated under the *Controlled Substances Act* in the United States.

**Questions and Answers:**

**Q1 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why isn't it illegal?**

A1 – Because *S. divinorum* meets the definition of an NHP under the *Natural Health Product Regulations*, it is illegal to manufacture, sell or provide products containing *S. divinorum* and/or salvinorin A without their being authorized by Health Canada prior to sale. Health Canada is currently reviewing all the available information regarding *Salvia divinorum*, including the prevalence of its use in Canada, to determine whether it should be controlled under the *Controlled Drugs and Substances Act*.

**Q2 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?**

A2 – The *Natural Health Products Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *Salvia divinorum*.

**Q3 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A3 – *Salvia divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. Complaints about the illegal sale of drugs containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

**Q4 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum* as a controlled substance. What does that involve and what stage is it at?**

A4 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and

**Comment [S1]:** Now that we have the results from CADUMS and YSS, I don't think that this will be an issue

**Deleted:** *If pressed on the lack of statistics on *Salvia divinorum* use in Canada:*

¶  
<#>Health Canada is taking steps to address the paucity of data. Questions about the use of *Salvia divinorum* were included in the 2008-2009 Youth Smoking Survey, and the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS). The results from the Youth Smoking Survey were released on May 31, 2010 and the 2009 CADUMS results are scheduled to be released in late June 2010¶

¶  
<#>It is anticipated that the data from these surveys will contribute to future decisions that Health Canada may make about how this plant and its active ingredient should be regulated.¶

¶  
**If pressed regarding the results of the 2009 Ontario Student Drug Use and Health Survey:** ¶

¶  
<#>The results from the 2009 Ontario Student Drug Use and Health Survey were published on November 18, 2009 and indicate that among responding students in Ontario, 4.4% reported using *Salvia divinorum* at least once in the past year. Health Canada will consider this data in its ongoing examination of *Salvia divinorum* and salvinorin A.¶

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**Deleted:** With respect to adverse effects, there are insufficient controlled scientific studies looking into the physical and psychotropic effects of *Salvia divinorum* on humans. As such, it is difficult to predict the potential for addiction and abuse associated with *Salvia divinorum*. Based on the available evidence,

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- Overall risk to public health and safety posed by the substance.

Health Canada is currently reviewing the available information to determine whether regulation of *Salvia divinorum* under the CDSA is warranted.

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**Q5 – Didn't an internal report from Health Canada's Marketed Health Products Directorate recommend that *Salvia divinorum* be scheduled under the CDSA? Why has that recommendation not been acted upon?**

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A5 – See A4

**Q6 – What is the significance of the adverse reaction reports that Health Canada has received with respect to the use of *Salvia divinorum*?**

**Deleted:** It is anticipated that the data from the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey in addition to the results from the 2009 Ontario Student Drug Use and Health Survey will help address some of the information gaps about this substance. Data from the Youth Smoking Survey has just been released and data from the 2009 edition of CADUMS will be available in late June 2010. [need to state how these survey information will be used from a regulatory perspective]¶

A6 – Health Canada has received four domestic adverse reaction reports related to the use of *Salvia divinorum* as a hallucinogen through the Canada Vigilance database. The number of reports and the nature of reactions reported are, however, not adequate to fully characterize the risk of similar reactions to the general population

**If pressed on whether Health Canada has issued any kind of warning to Canadians about *Salvia divinorum***

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A. Health Canada is developing an It's Your Health (IYH) article on *Salvia divinorum* to help inform the general public about the risks associated with the use of this substance.

**Deleted:** In particular, Health Canada does not have any information about the number of individuals in Canada using or who have used *Salvia divinorum*. [what about extrapolation from the surveys cited above?]¶

**Background**

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*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

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The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

While some users have reported that the psychotropic effects of *Salvia divinorum* resemble those induced by other hallucinogens, such as LSD and phencyclidine, the overall experience appears to be quite unique.

**Deleted:** [this is subjective and does not give information]

Data from the 2008-2009 Youth Smoking Survey indicate that:

- 2.6% of students (grades 7-12) reported having used *Salvia divinorum* in the past year.
- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year.

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- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year

Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using *Salvia* in their lifetime (0.2% in the past year).
- The prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that;

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year.
- 5.4% of students (grades 7-12) ever used *S. divinorum*.
- Use of *S. divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

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**Prepared by:** Cheryl Tremblay, OCS, CSTD

**Input by:** Lisa Mackay IYH/PACCB, Hanan Abramovici HECSB/ODARS, Jocelyn Kula, HECSB/OCS, Robin Marles HPFB/NHPD, Mano Murty HPFB/MHPD (31/08/10), Robert Leitch HPFB/MHPD, Collin Pinto, HPFB/HPFBI

**Approved by:**

[NAME] Director, Bureau of Policy and Regulatory Affairs, NHPD (pending)  
[NAME] Director, Marketed Biologics, Biotechnology and Natural Health Products Bureau,  
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Meena Ballantyne, ADM, HPFB (pending)  
Anne Lamar, ADM, PACCB (pending)  
DMO (pending)  
MO (pending)  
PCO (pending)

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Data from the 2007 report on Alcohol and Other Drugs published by the Addictions Foundation of Manitoba indicate that:¶  
<#>3.7% of males vs. 2.2% of females (grades 7-12) used *S. divinorum* during that year.¶  
¶  
Data from a 2006 National Survey on Drug Use and Health Report, published by the U.S. Substance Abuse and Mental Health Services Administration estimated that:¶  
<#>0.3% of persons aged 12 or older used *S. divinorum* in 2006.¶  
<#>0.6% of persons between the ages of 12 and 17 used *S. divinorum* in 2006.¶  
<#>1.7% of persons between the ages of 18 to 25 used *S. divinorum* in 2006.¶  
<#>Young adults (18-25) were nearly three times more likely than youths aged 12-17 to have used *S. divinorum* in 2006.¶  
<#>Males between the ages of 12-25 were three to four times more likely than females in the same age range to have used *S. divinorum* in 2006.¶

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## *Salvia divinorum*

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### Issue

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff, incense special, and salvia.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs. As of September 2010, no products containing *S. divinorum* have been authorized for use by Health Canada.

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Health Canada recommends that you avoid using this plant because very little is known about the effects it may have on your body and/or brain functions. There is also no way to predict how it will affect you with each use.

### Risks Associated with the Use of *Salvia divinorum*

*S. divinorum* is known to have physical and mental effects. The effects of *S. divinorum*, which vary from person to person, are often described as unpleasant and may include the following:

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- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

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There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product
- how much is used
- the purity of the product (it may be mixed with other substances)
- how it is taken (e.g., chewed, swallowed or smoked)
- the user's mood and expectations

While scientists know which brain receptors are targeted by the active ingredient, salvinorin A, very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or permanent damage



- how it interacts with other substances, including other drugs, natural health products and alcohol
- The potential of *S. divinorum* to produce physical dependence and/or addiction

### Minimizing Your Risk

Health Canada recommends that you avoid using *S. divinorum* because very little is known about the effects it may have on your body and/or brain functions. There is also no way to predict how it will affect you with each use. Just because a drug is plant-based or “natural”, does not mean that it is safe.

Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs, such as marijuana, cocaine, ecstasy, LSD and other substances that distort reality. See the “*Need More Info?*” section below for links to resources that can help you with this.

### Legal Status of *Salvia divinorum*

#### In Canada

When *S. divinorum* is manufactured, sold or represented for use in modifying organic functions in humans, and hallucinogens work by modifying functions in the brain, it meets the definition of a Natural Health Product (NHP) in accordance with the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*. It is illegal to sell NHPs in Canada unless they have been reviewed and approved by Health Canada and labelled with one of the following:

- a Natural Product Number (NPN); or
- a Exemption Number; or
- a Drug Identification Number - Homeopathic Medicine (DIN-HM).

As of September 2010 no products containing *S. divinorum* have been authorized by Health Canada. All unauthorized drugs and NHPs are subject to compliance and enforcement actions by the Department.

Neither *S. divinorum* nor salvinorin A are currently regulated under the *Controlled Drugs and Substances Act* (CDSA). Health Canada is currently considering available information to determine whether regulation as a controlled substance is warranted.

#### In Other Countries

Several countries including but not limited to Australia, Belgium, Germany, Italy, Japan, etc., have placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A.

In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on their sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution, for example, can not sell to anyone under the age of 18.

**Comment [S1]:** “organic” should be removed as the “brain” is specified for hallucinogens; there is no such as thing as an “organic” function in the brain

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**Deleted:** In an effort to collect more information about the use of *S. divinorum* in Canada, questions on it were included in the 2008-2009 Youth Smoking Survey, the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) and the 2009 Ontario Student Drug Use and Health Survey (OSDUHS).

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**Deleted:** Data from these surveys will contribute to future decisions that Health Canada may make regarding the regulation of *S. divinorum* and/or its active ingredient in Canada. See the *Need More Info?* section below for more information on the surveys

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## Background

The leaves of this plant have been used traditionally by the Mazatec people for medicinal and mystical purposes.

Products that claim to contain *S. divinorum* or its main active ingredient, salvinorin A, are widely available on the Internet and are sold in various "head shops" and natural food stores. The products are sold in a number of forms, including fresh or dried leaves, liquids or seeds and plant cuttings for growing purposes.

In Canada, results from the Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that, in 2009, less than 2% of Canadians age 15 years and older reported having used *S. divinorum* at least once in their lifetime. Youth 15-24 years of age were, however, much more likely to have ever used it than adults (7.3% vs 0.5%). Similarly, results from the 2008-2009 Youth Smoking Survey show that 5% of 15 year-olds reported using *S. divinorum* in the past year. See the **Need More Info?** section below for more information on these surveys.

**Comment [S2]:** Why is this section here? Would be better placed right after the "Issue" section.

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**Deleted:** uses like chewing the leaves or using them to make a tea, and other

**Deleted:** like smoking the leaves to induce a "mystical" or hallucinogenic experience

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## Health Canada's Role

Health Canada continues to collect and consider safety information regarding *S. divinorum* and will continue to consult with key stakeholders including health officials in other countries and law enforcement officials here at home. This will assist in determining Health Canada's future approach to decision-making regarding regulation of *S. divinorum* in Canada.

## Need More Info?

- Complaints about illegal sale of drugs containing *S. divinorum* can be made to the **Health Products and Food Branch Inspectorate** at: [http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_44\\_consumer\\_consommateur\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_44_consumer_consommateur_cp-pc-eng.php)  
Tel: 1-800-267-9675.
- You can report any adverse reactions to the Canada Vigilance Program by one of the following three ways:  
Report online at the MedEffect™ Canada website at: <http://www.hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>  
Call toll-free at 1-866-234-2345  
Complete a Canada Vigilance Reporting Form and either:  
Fax toll-free to 1-866-678-6789  
Mail to: Canada Vigilance Program  
Health Canada  
AL 0701C  
Ottawa, ON K1A 0K9

To have postage pre-paid, download the postage paid label from the MedEffect™ Canada website. The Canada Vigilance Reporting Form and the adverse reaction reporting guidelines may also be obtained via this website at : [http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei\\_form-eng.php](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei_form-eng.php)

- For information about the Government of Canada's Anti-Drug Strategy, go to: [www.nationalantidrugstrategy.gc.ca/](http://www.nationalantidrugstrategy.gc.ca/)

The Prevention section on this site has a number of helpful resources for parents, including:

- **Tips on Talking to Your Teenager**, at: [www.hc-sc.gc.ca/hc-ps/pubs/adp-apd/talk-aborder/index-eng.php](http://www.hc-sc.gc.ca/hc-ps/pubs/adp-apd/talk-aborder/index-eng.php)
- **What to Do if Your Teen is Using Drugs**, at: [www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html](http://www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html)
- Health Canada's **Not4Me** youth drug prevention section at: <http://www.hc-sc.gc.ca/hc-ps/drugs-drogues/youth-jeunes/facts-faits/index-eng.php>
- Information on natural health products and the Natural Health Products Regulations can be found at: [www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php)

For more on the surveys that are collecting information about Salvia divinorum use in Canada, see:

- **The 2008-2009 Youth Smoking Survey**, at: [www.yss.uwaterloo.ca/ysss/site\\_app/controller/index.cfm](http://www.yss.uwaterloo.ca/ysss/site_app/controller/index.cfm)
- **The 2009 Canadian Alcohol and Drug Use Monitoring Survey**, at: [www.hc-sc.gc.ca/hl-vs/drug-drogues/cadums-escad-eng.php](http://www.hc-sc.gc.ca/hl-vs/drug-drogues/cadums-escad-eng.php)
- **The 2009 Ontario Student Drug Use and Health Survey**, at: [http://www.camh.net/Research/Areas\\_of\\_research/Population\\_Life\\_Course\\_Studies/OSDUS/~Detailed\\_DrugReport\\_2009OSDUHS\\_Final.pdf](http://www.camh.net/Research/Areas_of_research/Population_Life_Course_Studies/OSDUS/~Detailed_DrugReport_2009OSDUHS_Final.pdf)

#### **Additional Resources:**

- U.S. Drug Enforcement Administration: **Drugs and Chemicals of Concern: Salvia divinorum and Salvinorin A** at: [www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)
- U.S. Department of Health & Human Services, **National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006** at: [www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf](http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf)
- For additional articles on health and safety issues go to the It's Your Health web section at: [www.healthcanada.gc.ca/iyh](http://www.healthcanada.gc.ca/iyh)

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

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HECSB comms: Christine Roush, Bronwyn Cline

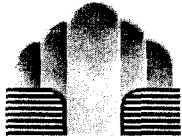
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**Deleted:**

HPFBI : Collin Pinto

HPFB comms: Elizabeth Keeping, Blossom Leung



Jocelyn Kula/HC-SC/GC/CA  
2010-09-06 06:58 PM

To :Stephanie Chandler/HC-SC/GC/CA@HWC  
cc  
bcc

Subject Fw: Final review before formal approval - SALVIA

History:  This message has been forwarded.

Hi there

So here is my input on the IYH and media lines; building on the comments from ODARS, which I largely agree with. I assume you have also reviewed so perhaps you can compare any comments/ thoughts with what I have compiled and edit as required. Then we should send back to Lisa Mackay ASAP as I think she wanted input by COB tomorrow (Tuesday).....

Both docs saved under PRAD/ Salvia in either IYH folder or general folder:



IYH Salvia d\_v16 + ODARS + OCS Sept 2010.doc Media Lines\_v12 ODARS + OCS Sept 2010.doc

Come see me if you have any questions

JK

---

Jocelyn Kula  
Manager/ Gestionnaire  
Regulatory Policy Division/ Division des politiques réglementaires  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0125 Fax: (613) 946-4224  
---- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2010-09-06 06:54 PM ----



Suzanne  
Desjardins/HC-SC/GC/CA  
2010-09-02 03:35 PM

To Lisa MacKay/HC-SC/GC/CA@HWC  
cc Allison Lui/HC-SC/GC/CA@HWC, Angela  
Tonary/HC-SC/GC/CA@HWC, Bronwyn  
Cline/HC-SC/GC/CA@HWC, Bruna  
Brands/HC-SC/GC/CA@HWC, Christine  
Roush/HC-SC/GC/CA@HWC, Christine  
Zaczynski/HC-SC/GC/CA@HWC, Danika  
Painter/HC-SC/GC/CA@HWC, Darrin  
Denne/HC-SC/GC/CA@HWC, Dave  
Stephens/HC-SC/GC/CA@HWC, David  
Cunningham/HC-SC/GC/CA@HWC, Denis  
Arsenault/HC-SC/GC/CA@HWC, Duc  
Vu/HC-SC/GC/CA@HWC, Elizabeth  
Keeping/HC-SC/GC/CA@HWC, Hanan  
Abramovici/HC-SC/GC/CA@HWC, Helene  
Lacourciere/HC-SC/GC/CA@HWC, Jeff  
Devine/HC-SC/GC/CA@HWC, Jocelyn  
Kula/HC-SC/GC/CA@HWC, Karen  
Kouassi/HC-SC/GC/CA@HWC, Kathy  
Howard/HC-SC/GC/CA@HWC, Ken  
Polk/HC-SC/GC/CA@HWC, Kevan

DRAFT 12  
September 1, 2010

### Media Lines Regulatory Control of *Salvia Divinorum*

#### Issue

Since 2006, Health Canada has noted ongoing media interest regarding the availability of *Salvia divinorum* in Canada. Health Canada has also received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum*, particularly given reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties.

#### Key Messages:

- Health Canada advises Canadians not to use products containing *S. divinorum* and/or salvinorin A because very little is known about the substance and its potential effects on the brain and/or body, and its impact on physical and mental functions.
- Because of its hallucinogenic properties, products containing *S. divinorum* and/or salvinorin A meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*.
- It is illegal to sell NHPs in Canada unless they have been reviewed and approved by Health Canada and labelled with a Natural Product Number (NPN) or Exemption Number or a Drug Identification Number – Homeopathic Medicine (DIN-HM). The illegal sale of products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drug Act*.
- Health Canada will continue to collect and study information about *S. divinorum* as it becomes available, and to consult with law enforcement and health officials domestically and internationally in order to determine the best way to manage the risks associated with its availability in Canada.

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#### Supplementary Messages:

##### *Salvia divinorum as a controlled substance:*

- In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA).
- *Salvia divinorum* is not listed under the United Nations Drug Control Conventions and does not have to be regulated as a controlled substance in any of the countries (including Canada) that are signatories to these Conventions.

- Several countries (Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) have placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Although some individual U.S. states have implemented laws restricting its use, sale and/or distribution, *Salvia divinorum* and salvinorin A are not federally regulated under the *Controlled Substances Act* in the United States.

**Questions and Answers:**

**Q1 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why isn't it illegal?**

A1 – Because *S. divinorum* meets the definition of an NHP under the *Natural Health Product Regulations*, it is illegal to manufacture, sell or provide products containing *S. divinorum* and/or salvinorin A without their being authorized by Health Canada prior to sale. Health Canada is currently reviewing all the available information regarding *Salvia divinorum*, including the prevalence of its use in Canada, to determine whether it should be controlled under the *Controlled Drugs and Substances Act*.

HC will be scheduling it now

**Q2 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?**

A2 – The *Natural Health Products Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *Salvia divinorum*.

We did consult as this did we not?

**Q3 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A3 – *Salvia divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. Complaints about the illegal sale of drugs containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

**Q4 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum* as a controlled substance. What does that involve and what stage is it at?**

A4 – Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and

change

**Comment [S1]:** Now that we have the results from CADUMS and YSS, I don't think that this will be an issue

**Deleted:** If pressed on the lack of statistics on *Salvia divinorum* use in Canada:¶

¶<#>Health Canada is taking steps to address the paucity of data. Questions about the use of *Salvia divinorum* were included in the 2008-2009 Youth Smoking Survey, and the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS). The results from the Youth Smoking Survey were released on May 31, 2010 and the 2009 CADUMS results are scheduled to be released in late June 2010¶

¶<#>It is anticipated that the data from these surveys will contribute to future decisions that Health Canada may make about how this plant and its active ingredient should be regulated.¶

¶**If pressed regarding the results of the 2009 Ontario Student Drug Use and Health Survey:** ¶

¶<#>The results from the 2009 Ontario Student Drug Use and Health Survey were published on November 18, 2009 and indicate that among responding students in Ontario, 4.4% reported using *Salvia divinorum* at least once in the past year. Health Canada will consider this data in its ongoing examination of *Salvia divinorum* and salvinorin A.¶

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**Deleted:** With respect to adverse effects, there are insufficient controlled scientific studies looking into the physical and psychotropic effects of *Salvia divinorum* on humans. As such, it is difficult to predict the potential for addiction and abuse associated with *Salvia divinorum*. Based on the available evidence,

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- Overall risk to public health and safety posed by the substance.

moving forward as we do?

Health Canada is currently reviewing the available information to determine whether regulation of *Salvia divinorum* under the CDSA is warranted.

Deleted: has only limited information on some of the above-mentioned factors, and thus there is simply not enough information available to

**Q5 – Didn't an internal report from Health Canada's Marketed Health Products Directorate recommend that *Salvia divinorum* be scheduled under the CDSA? Why has that recommendation not been acted upon?**

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A5 – See A4

**Q6 – What is the significance of the adverse reaction reports that Health Canada has received with respect to the use of *Salvia divinorum*?**

Deleted: It is anticipated that the data from the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey in addition to the results from the 2009 Ontario Student Drug Use and Health Survey will help address some of the information gaps about this substance. Data from the Youth Smoking Survey has just been released and data from the 2009 edition of CADUMS will be available in late June 2010. [need to state how these survey information will be used from a regulatory perspective]¶

A6 – Health Canada has received four domestic adverse reaction reports related to the use of *Salvia divinorum* as a hallucinogen through the Canada Vigilance database. The number of reports and the nature of reactions reported are, however, not adequate to fully characterize the risk of similar reactions to the general population

***If pressed on whether Health Canada has issued any kind of warning to Canadians about *Salvia divinorum****

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A. Health Canada is developing an It's Your Health (IYH) article on *Salvia divinorum* to help inform the general public about the risks associated with the use of this substance.

Deleted: . In particular, Health Canada does not have any information about the number of individuals in Canada using or who have used *Salvia divinorum*. [what about extrapolation from the surveys cited above?]¶

**Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

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The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

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The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

While some users have reported that the psychotropic effects of *Salvia divinorum* resemble those induced by other hallucinogens, such as LSD and phencyclidine, the overall experience appears to be quite unique.

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Data from the 2008-2009 Youth Smoking Survey indicate that:

- 2.6% of students (grades 7-12) reported having used *Salvia divinorum* in the past year.
- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year.

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- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year

Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using *Salvia* in their lifetime (0.2% in the past year).
- The prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that;

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year.
- 5.4% of students (grades 7-12) ever used *S. divinorum*.
- Use of *S. divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

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**Prepared by:** Cheryl Tremblay, OCS, CSTD

**Input by:** Lisa Mackay IYH/PACCB, Hanan Abramovici HECSB/ODARS, Jocelyn Kula, HECSB/OCS, Robin Marles HPFB/NHPD, Mano Murty HPFB/MHPD (31/08/10), Robert Leitch HPFB/MHPD, Collin Pinto, HPFB/HPFBI

**Approved by:**

[NAME] Director, Bureau of Policy and Regulatory Affairs, NHPD (pending)  
[NAME] Director, Marketed Biologics, Biotechnology and Natural Health Products Bureau,  
MHPD (pending)  
[NAME] Director, HPFBI (pending)  
Diane Allan, Director, OCS, CSTD, HECS (pending)  
Suzanne Desjardins, Director, ODARS, CSTD, HECS (pending)  
Cathy Sabiston, DG, CSTD, HECS (pending)  
[NAME], DG, MHPD (pending)  
[NAME], DG, NHPD (pending)  
[NAME] DG, HPFBI (pending)  
Ken Polk, Communications Executive, HPFB (pending)  
Kathleen Malone, Senior Media Relations, PACCB (pending)  
Warren Braun, Director, Strategic Communications, PACCB (pending)  
Peter Yendall, Director, Public Affairs, PACCB (pending)  
HECS Legal (pending)  
HPFB Legal (pending)  
Paul Glover, ADM, HECSB (pending)  
Meena Ballantyne, ADM, HPFB (pending)  
Anne Lamar, ADM, PACCB (pending)  
DMO (pending)  
MO (pending)  
PCO (pending)

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Data from the 2007 report on Alcohol and Other Drugs published by the Addictions Foundation of Manitoba indicate that:¶

<#>3.7% of males vs. 2.2% of females (grades 7-12) used *S. divinorum* during that year.¶

¶

Data from a 2006 National Survey on Drug Use and Health Report, published by the U.S. Substance Abuse and Mental Health Services Administration estimated that:¶

<#>0.3% of persons aged 12 or older used *S. divinorum* in 2006.¶

<#>0.6% of persons between the ages of 12 and 17 used *S. divinorum* in 2006.¶

<#>1.7% of persons between the ages of 18 to 25 used *S. divinorum* in 2006.¶

<#>Young adults (18-25) were nearly three times more likely than youths aged 12-17 to have used *S. divinorum* in 2006.¶

<#>Males between the ages of 12-25 were three to four times more likely than females in the same age range to have used *S. divinorum* in 2006.¶

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It's Your Health

DEPT. OF HEALTH SERVICES

***Salvia divinorum***

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**Issue**

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff, incense special, and salvia.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs. As of September 2010, no products containing *S. divinorum* have been authorized for use by Health Canada.

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Health Canada recommends that you avoid using this plant because very little is known about the effects it may have on your body and/or brain functions. There is also no way to predict how it will affect you with each use.

~~ok [redacted]~~

**Risks Associated with the Use of *Salvia divinorum***

*S. divinorum* is known to have physical and mental effects. The effects of *S. divinorum*, which vary from person to person, are often described as unpleasant and may include the following:

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- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

Deleted: unwell, uneasy or unhappy

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product
- how much is used
- the purity of the product (it may be mixed with other substances)
- how it is taken (e.g., chewed, swallowed or smoked)
- the user's mood and expectations

While scientists know which brain receptors are targeted by the active ingredient, salvinorin A, very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or permanent damage

- how it interacts with other substances, including other drugs, natural health products and alcohol
- The potential of *S. divinorum* to produce physical dependence and/or addiction

### Minimizing Your Risk

Health Canada recommends that you avoid using *S. divinorum* because very little is known about the effects it may have on your body and/or brain functions. There is also no way to predict how it will affect you with each use. Just because a drug is plant-based or “natural”, does not mean that it is safe.

Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs, such as marijuana, cocaine, ecstasy, LSD and other substances that distort reality. See the “*Need More Info?*” section below for links to resources that can help you with this.

### Legal Status of *Salvia divinorum*

#### In Canada

When *S. divinorum* is manufactured, sold or represented for use in modifying organic functions in humans, and hallucinogens work by modifying functions in the brain, it meets the definition of a Natural Health Product (NHP) in accordance with the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*. It is illegal to sell NHPs in Canada unless they have been reviewed and approved by Health Canada and labelled with one of the following:

- a Natural Product Number (NPN); or
- a Exemption Number; or
- a Drug Identification Number - Homeopathic Medicine (DIN-HM).

As of September 2010 no products containing *S. divinorum* have been authorized by Health Canada. All unauthorized drugs and NHPs are subject to compliance and enforcement actions by the Department.

Neither *S. divinorum* nor salvinorin A are currently regulated under the *Controlled Drugs and Substances Act* (CDSA). Health Canada is currently considering available information to determine whether regulation as a controlled substance is warranted.

*moving forward to scheduling*

#### In Other Countries

Several countries including but not limited to Australia, Belgium, Germany, Italy, Japan, etc., have placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A.

In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on their sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution, for example, can not sell to anyone under the age of 18.

**Comment [S1]:** “organic” should be removed as the “brain” is specified for hallucinogens; there is no such as thing as an “organic” function in the brain

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**Deleted:** This is because there is not enough information available to determine

**Deleted:** In an effort to collect more information about the use of *S. divinorum* in Canada, questions on it were included in the 2008-2009 Youth Smoking Survey, the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) and the 2009 Ontario Student Drug Use and Health Survey (OSDUHS).

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**Deleted:** Data from these surveys will contribute to future decisions that Health Canada may make regarding the regulation of *S. divinorum* and/or its active ingredient in Canada. See the *Need More Info?* section below for more information on the surveys

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## Background

The leaves of this plant have been used traditionally by the Mazatec people for medicinal and mystical purposes.

Products that claim to contain *S. divinorum* or its main active ingredient, salvinorin A, are widely available on the Internet and are sold in various "head shops" and natural food stores. The products are sold in a number of forms, including fresh or dried leaves, liquids or seeds and plant cuttings for growing purposes.

In Canada, results from the Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that, in 2009, less than 2% of Canadians age 15 years and older reported having used *S. divinorum* at least once in their lifetime. Youth 15-24 years of age were, however, much more likely to have ever used it than adults (7.3% vs 0.5%). Similarly, results from the 2008-2009 Youth Smoking Survey show that 5% of 15 year-olds reported using *S. divinorum* in the past year. See the **Need More Info?** section below for more information on these surveys.

**Comment [S2]:** Why is this section here? Would be better placed right after the "Issue" section.

**Deleted:** Indians

**Deleted:** uses like chewing the leaves or using them to make a tea, and other

**Deleted:** like smoking the leaves to induce a "mystical" or hallucinogenic experience

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## Health Canada's Role

Health Canada continues to collect and consider safety information regarding *S. divinorum* and will continue to consult with key stakeholders including health officials in other countries and law enforcement officials here at home. This will assist in determining Health Canada's future approach to decision-making regarding regulation of *S. divinorum* in Canada.

*moving forward to scheduling*

## Need More Info?

- Complaints about illegal sale of drugs containing *S. divinorum* can be made to the **Health Products and Food Branch Inspectorate** at: [http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_44\\_consumer\\_consommateur\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_44_consumer_consommateur_cp-pc-eng.php)  
Tel: 1-800-267-9675.
- You can report any adverse reactions to the Canada Vigilance Program by one of the following three ways:  
Report online at the MedEffect™ Canada website at: <http://www.hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>  
Call toll-free at 1-866-234-2345  
Complete a Canada Vigilance Reporting Form and either:  
Fax toll-free to 1-866-678-6789  
Mail to: Canada Vigilance Program  
Health Canada  
AL 0701C  
Ottawa, ON K1A 0K9

To have postage pre-paid, download the postage paid label from the MedEffect™ Canada website. The Canada Vigilance Reporting Form and the adverse reaction reporting guidelines may also be obtained via this website at : [http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei\\_form-eng.php](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei_form-eng.php)

- For information about the Government of Canada's Anti-Drug Strategy, go to: [www.nationalantidrugstrategy.gc.ca/](http://www.nationalantidrugstrategy.gc.ca/)
- The Prevention section on this site has a number of helpful resources for parents, including:
- **Tips on Talking to Your Teenager**, at: [www.hc-sc.gc.ca/hc-ps/pubs/adp-apd/talk-aborder/index-eng.php](http://www.hc-sc.gc.ca/hc-ps/pubs/adp-apd/talk-aborder/index-eng.php)
  - **What to Do if Your Teen is Using Drugs**, at: [www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html](http://www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html)
  - Health Canada's **Not4Me** youth drug prevention section at: <http://www.hc-sc.gc.ca/hc-ps/drugs-drogues/youth-jeunes/facts-faits/index-eng.php>
  - Information on natural health products and the Natural Health Products Regulations can be found at: [www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php)

For more on the surveys that are collecting information about *Salvia divinorum* use in Canada, see:

- **The 2008-2009 Youth Smoking Survey**, at: [www.yss.uwaterloo.ca/ysss/site\\_app/controller/index.cfm](http://www.yss.uwaterloo.ca/ysss/site_app/controller/index.cfm)
- **The 2009 Canadian Alcohol and Drug Use Monitoring Survey**, at: [www.hc-sc.gc.ca/hl-vs/drug-drogues/cadums-escad-eng.php](http://www.hc-sc.gc.ca/hl-vs/drug-drogues/cadums-escad-eng.php)
- **The 2009 Ontario Student Drug Use and Health Survey**, at: [http://www.camh.net/Research/Areas\\_of\\_research/Population\\_Life\\_Course\\_Studies/OSDUS/~Detailed\\_DrugReport\\_2009OSDUHS\\_Final.pdf](http://www.camh.net/Research/Areas_of_research/Population_Life_Course_Studies/OSDUS/~Detailed_DrugReport_2009OSDUHS_Final.pdf)

#### **Additional Resources:**

- U.S. Drug Enforcement Administration: **Drugs and Chemicals of Concern: *Salvia divinorum* and Salvinorin A** at: [www.dea/diversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.dea/diversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)
- U.S. Department of Health & Human Services, **National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006** at: [www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf](http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf)
- For additional articles on health and safety issues go to the *It's Your Health* web section at: [www.healthcanada.gc.ca/iyh](http://www.healthcanada.gc.ca/iyh)

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

Original:

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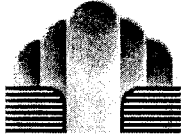
Catalogue#  
ISBN#

Version/date: Draft 16. August 31, 2010.


PACCB IYH - Lisa Mackay: 613-954-0105 – [Lisa.Mackay@hc-sc.gc.ca](mailto:Lisa.Mackay@hc-sc.gc.ca)

Comments from: HECSB - CSTD (OCS&ODARS) & HPFB – NHPD & HPFBI

	Contacts:	HECSB: Jocelyn Kula, <del>Stephanie Chandler</del> , Suzanne Desjardins, Denis	Deleted: Cheryl Tremblay
		Arsenault, Hanan Abramovici	Deleted: a
		HECSB comms: Christine Roush, Bronwyn Cline	
		HPFB-NHPD: Valerie Hurry, Robin Marles	
		HPFB-MHPD: Scott Jordan, Robert Leitch, Mano Murty, <del>Shahid Perwaiz</del>	Deleted:
		HPFBI : Collin Pinto	
		HPFB comms: Elizabeth Keeping, Blossom Leung	



Jocelyn Kula/HC-SC/GC/CA  
2010-09-07 04:02 PM

To Daniel Galarneau/HC-SC/GC/CA@HWC  
cc Stephanie Chandler/HC-SC/GC/CA@HWC  
bcc  
Subject Re: Fw: Final review before formal approval - SALVIA 

I will look at consolidated input tonight but I think the idea was to not be so prescriptive in the IYH just yet. I will also read text of QP as I actually don't think a QP is where we shld be announcing a policy position. If we are truly going to proceed to schedule Salvia, we shld be working on a comms plan to tell the universe as there will be Cdns who are very interested in said decision.

Stephanie, pls let Lisa Mackay know that our input will be delayed until tomorrow.

JK  
Sent by blackberry

Jocelyn Kula  
Manager/ Gestionnaire  
Policy and Regulatory Affairs Division/ Division des politiques et affaires reglementaires  
Daniel Galarneau

----- Original Message -----

**From:** Daniel Galarneau  
**Sent:** 2010-09-07 03:48 PM EDT  
**To:** Jocelyn Kula  
**Cc:** Stephanie Chandler  
**Subject:** Re: Fw: Final review before formal approval - SALVIA

I quickly read both documents. I would suggest that the message from Health Canada should reflect the decision to schedule it under the CDSA. This is how the QP note was re-designed, so both the media lines and IYH should reflect this decision.

*Daniel Galarneau*

Head, Regulatory Affairs Section – Chef, Section de la réglementation  
Office of Controlled Substances -- Bureau des substances contrôlées  
Controlled Substances and Tobacco Directorate – Direction des substances contrôlées et de la lutte au tabagisme  
Healthy Environments and Consumer Safety Branch -- Direction Générale de la Santé Environnementale et de la Sécurité des Consommateurs  
Tel: (613) 946-6521  
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Stephanie Chandler/HC-SC/GC/CA



Stephanie  
Chandler/HC-SC/GC/CA  
2010-09-07 09:45 AM

To Daniel Galarneau/HC-SC/GC/CA@HWC  
cc  
Subject Fw: Final review before formal approval - SALVIA

Hi Daniel,

Please see the revisions for Salvia IYH and ML. This is a combination of the revisions I sent you earlier, as well as those sent to me by Jocelyn yesterday.

[attachment "Media Lines\_v12 ODARS + OCS Sept 2010.doc" deleted by Jocelyn Kula/HC-SC/GC/CA]  
[attachment "IYH Salvia d\_v16 + ODARS + OCS Sept 2010.doc" deleted by Jocelyn Kula/HC-SC/GC/CA]

Please note these must be forwarded to Lisa Mackay by COB today.

Thanks,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca  
----- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2010-09-07 09:43 AM -----



Jocelyn Kula/HC-SC/GC/CA

2010-09-06 06:58 PM

To Stephanie Chandler/HC-SC/GC/CA@HWC

cc

Subject Fw: Final review before formal approval - SALVIA

Hi there

So here is my input on the IYH and media lines; building on the comments from ODARS, which I largely agree with. I assume you have also reviewed so perhaps you can compare any comments/ thoughts with what I have compiled and edit as required. Then we should send back to Lisa Mackay ASAP as I think she wanted input by COB tomorrow (Tuesday).....

Both docs saved under PRAD/ Salvia in either IYH folder or general folder:

[attachment "IYH Salvia d\_v16 + ODARS + OCS Sept 2010.doc" deleted by Stephanie Chandler/HC-SC/GC/CA] [attachment "Media Lines\_v12 ODARS + OCS Sept 2010.doc" deleted by Stephanie Chandler/HC-SC/GC/CA]

Come see me if you have any questions

JK

---

Jocelyn Kula  
Manager/ Gestionnaire  
Regulatory Policy Division/ Division des politiques réglementaires  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0125 Fax: (613) 946-4224





Stephanie  
Chandler/HC-SC/GC/CA  
2010-09-08 01:10 PM

To Lisa MacKay/HC-SC/GC/CA@HWC  
cc Allison Lui/HC-SC/GC/CA@HWC, Angela  
Tonary/HC-SC/GC/CA@HWC, Bronwyn  
Cline/HC-SC/GC/CA@HWC, Bruna  
bcc

Subject Re: Final review before formal approval - SALVIA

Hi Lisa,

Our apologies for the delay. Here are OCS' comments (including the revisions made by ODARS).



Media Lines\_v12 ODARS + OCS Sept 2010.doc IYH Sallvia d\_v16 + ODARS + OCS Sept 2010.doc

Thanks,

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
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Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca  
Lisa MacKay/HC-SC/GC/CA

Lisa MacKay/HC-SC/GC/CA  
2010-09-02 03:49 PM

To Suzanne Desjardins/HC-SC/GC/CA@HWC  
cc Allison Lui/HC-SC/GC/CA@HWC, Angela  
Tonary/HC-SC/GC/CA@HWC, Bronwyn  
Cline/HC-SC/GC/CA@HWC, Bruna  
Brands/HC-SC/GC/CA@HWC, Christine  
Roush/HC-SC/GC/CA@HWC, Christine  
Zaczynski/HC-SC/GC/CA@HWC, Danika  
Painter/HC-SC/GC/CA@HWC, Darrin  
Denne/HC-SC/GC/CA@HWC, Dave  
Stephens/HC-SC/GC/CA@HWC, David  
Cunningham/HC-SC/GC/CA@HWC, Denis  
Arsenault/HC-SC/GC/CA@HWC, Duc  
Vu/HC-SC/GC/CA@HWC, Elizabeth  
Keeping/HC-SC/GC/CA@HWC, Hanan  
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Kouassi/HC-SC/GC/CA@HWC, Kathy  
Howard/HC-SC/GC/CA@HWC, Ken  
Polk/HC-SC/GC/CA@HWC, Kevan  
Burrows/HC-SC/GC/CA@HWC, Kevin  
Bernardo/HC-SC/GC/CA@HWC, Laura  
Francis-Lamb/HC-SC/GC/CA@HWC, Lindsay  
Blaney/HC-SC/GC/CA@HWC, Mano  
Murty/HC-SC/GC/CA@HWC, MBBNHPB Assistants,  
MBBNHPB Management, Melinda Lee  
Choon/HC-SC/GC/CA@HWC, Robert

DRAFT 12  
September 1, 2010

## Media Lines

### Regulation of *Salvia divinorum*

#### Issue

Since 2006, Health Canada has noted ongoing media interest regarding the availability of *Salvia divinorum* in Canada. Health Canada has also received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum*, particularly given reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties.

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#### Key Messages:

- Health Canada advises Canadians not to use products containing *S. divinorum* and/or salvinorin A because very little is known about the substance and its potential effects on the brain and/or body, and its impact on physical and mental functions.
- Because of its hallucinogenic properties, products containing *S. divinorum* and/or salvinorin A meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*.
- It is illegal to sell NHPs in Canada unless they have been reviewed and approved by Health Canada and labelled with a Natural Product Number (NPN) or Exemption Number or a Drug Identification Number – Homeopathic Medicine (DIN-HM). The illegal sale of products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*.
- Health Canada will continue to collect and study information about *S. divinorum* as it becomes available, and to consult with law enforcement and health officials domestically and internationally in order to determine the best way to manage the risks associated with its availability in Canada.

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#### Supplementary Messages:

##### *Salvia divinorum* as a controlled substance:

- In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA).
- Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and thus, do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

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- Several countries (Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) have placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Although some individual U.S. states have implemented laws restricting its use, sale and/or distribution, *Salvia divinorum* and salvinorin A are not regulated under the federal *Controlled Substances Act* in the United States.

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Comment [S1]: Now that we have the results from CADUMS and YSS, I don't think that this will be an issue

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¶<#>Health Canada is taking steps to address the paucity of data. Questions about the use of *Salvia divinorum* were included in the 2008-2009 Youth Smoking Survey, and the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS). The results from the Youth Smoking Survey were released on May 31, 2010 and the 2009 CADUMS results are scheduled to be released in late June 2010¶

¶<#>It is anticipated that the data from these surveys will contribute to future decisions that Health Canada may make about how this plant and its active ingredient should be regulated.¶

¶If pressed regarding the results of the 2009 Ontario Student Drug Use and Health Survey: ¶

¶<#>The results from the 2009 Ontario Student Drug Use and Health Survey were published on November 18, 2009 and indicate that among responding students in Ontario, 4.4% reported using *Salvia divinorum* at least once in the past year. Health Canada will consider this data in its ongoing examination of *Salvia divinorum* and salvinorin A.¶

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Deleted: With respect to adverse effects, there are insufficient controlled scientific studies looking into the physical and psychotropic effects of *Salvia divinorum* on humans. As such, it is difficult to predict the potential for addiction and abuse associated with *Salvia divinorum*. Based on the available evidence,

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#### Questions and Answers:

#### Q1 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why isn't it illegal?

A1 – Because *S. divinorum* meets the definition of an NHP under the *Natural Health Product Regulations*, it is illegal to manufacture, sell or provide products containing *S. divinorum* and/or salvinorin A without their being authorized by Health Canada prior to sale. Health Canada is currently reviewing all the available information regarding *Salvia divinorum*, including the prevalence of its use in Canada, to determine whether it should be regulated under the *Controlled Drugs and Substances Act*.

#### Q2 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?

A2 – The *Natural Health Products Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *Salvia divinorum*.

#### Q3 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?

A3 – *Salvia divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. Complaints about the illegal sale of drugs containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

#### Q4 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum* as a controlled substance. What does that involve and what stage is it at?

A4 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and

- Overall risk to public health and safety posed by the substance.

Health Canada is currently reviewing the available information to determine whether regulation of *Salvia divinorum* under the CDSA is warranted.

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**Q5 – Didn't an internal report from Health Canada's Marketed Health Products Directorate recommend that *Salvia divinorum* be scheduled under the CDSA? Why has that recommendation not been acted upon?**

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A5 – See A4

**Q6 – What is the significance of the adverse reaction reports that Health Canada has received with respect to the use of *Salvia divinorum*?**

**Deleted:** It is anticipated that the data from the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey in addition to the results from the 2009 Ontario Student Drug Use and Health Survey will help address some of the information gaps about this substance. Data from the Youth Smoking Survey has just been released and data from the 2009 edition of CADUMS will be available in late June 2010. [need to state how these survey information will be used from a regulatory perspective]¶

A6 – Health Canada has received four domestic adverse reaction reports related to the use of *Salvia divinorum* as a hallucinogen through the Canada Vigilance database. The number of reports and the nature of reactions reported are, however, not adequate to fully characterize the risk of similar reactions among the general population

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**If pressed on whether Health Canada has issued any kind of warning to Canadians about *Salvia divinorum***

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A - Health Canada is developing an It's Your Health (IYH) article on *Salvia divinorum* to help inform the general public about the risks associated with the use of this substance.

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**Background**

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*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

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The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

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The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

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Some users have reported that the psychotropic effects of *Salvia divinorum* resemble those induced by other hallucinogens, such as LSD and phencyclidine; however this has not been confirmed through scientific study.

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**Deleted:** the overall experience appears to be quite unique. [this is subjective and does not give information]

Data from the 2008-2009 Youth Smoking Survey indicate that:

**Comment [HC2]:** I have suggested some text to respond to the previous comment re the text being subjective and not providing information as I agree that the previous sentence was not helpful. Alternatively, the sentence could just be removed altogether as it really does not add much at this point.....

- 2.6% of students (grades 7-12) reported having used *Salvia divinorum* in the past year.

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- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year; and
- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

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Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using *Salvia* in their lifetime (0.2% in the past year); and
- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

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Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that:

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;
- 5.4% of students (grades 7-12) ever used *S. divinorum*; and
- the use of *S. divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

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**Prepared by:** Cheryl Tremblay and Denis Arsenault, OCS, CSTD

**Input by:** Lisa Mackay IYH/PACCB, Hanan Abramovici HECSB/ODARS, Jocelyn Kula, HECSB/OCS, Robin Marles HPFB/NHPD, Mano Murty HPFB/MHPD, Robert Leitch HPFB/MHPD, Collin Pinto, HPFB/HPFBI

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Meena Ballantyne, ADM, HPFB (pending)  
Anne Lamar, ADM, PACCB (pending)  
DMO (pending)  
MO (pending)

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Data from the 2007 report on Alcohol and Other Drugs published by the Addictions Foundation of Manitoba indicate that:¶  
<#>3.7% of males vs. 2.2% of females (grades 7-12) used *S. divinorum* during that year.¶

¶  
Data from a 2006 National Survey on Drug Use and Health Report, published by the U.S. Substance Abuse and Mental Health Services Administration estimated that:¶  
<#>0.3% of persons aged 12 or older used *S. divinorum* in 2006.¶  
<#>0.6% of persons between the ages of 12 and 17 used *S. divinorum* in 2006.¶  
<#>1.7% of persons between the ages of 18 to 25 used *S. divinorum* in 2006.¶  
<#>Young adults (18-25) were nearly three times more likely than youths aged 12-17 to have used *S. divinorum* in 2006.¶  
<#>Males between the ages of 12-25 were three to four times more likely than females in the same age range to have used *S. divinorum* in 2006.¶

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PCO (pending)

*Salvia divinorum*

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Issue

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff, incense special, and salvia.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs. As of January 2010, no products containing *S. divinorum* have been authorized for sale by Health Canada.

Comment [S1]: September?

Comment [S2]: Is it for "use" or for "sale"?

Comment [HC3]: Agreed by OCS. This definitely should read "for sale", not use.

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Health Canada recommends that you avoid using this plant because very little is known about the effects it may have on your body and/or brain functions. There is also no way to predict how it will affect you with each use.

Risks Associated with the Use of *Salvia divinorum*

*S. divinorum* is known to have both physical and mental effects. The effects of *S. divinorum*, which vary from person to person, are often described as unpleasant and may include the following:

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- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

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There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product
- how much is used
- the purity of the product (products may contain *S. divinorum* mixed with other substances)
- how it is taken, e.g., whether the product is chewed, swallowed or smoked
- the user's mood and expectations

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While scientists know which brain receptors are targeted by the active ingredient, salvinorin A, very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or whether it can cause permanent damage
- how it interacts with other substances, including other drugs, natural health products and alcohol
- the potential of *S. divinorum* to produce physical dependence and/or addiction

### Minimizing Your Risk

Hallucinogens like *S. divinorum* work by modifying functions in the brain. Health Canada recommends that you avoid using *S. divinorum* because very little is known about the effects it may have on your body and/or brain functions. There is also no way to predict how it will affect you with each use. Just because a drug is plant-based or “natural”, does not mean that it is safe.

Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs, such as marijuana, cocaine, ecstasy, LSD and other substances that distort reality. See the “*Need More Info?*” section below for links to resources that can help you with this.

### Legal Status of *Salvia divinorum*

#### In Canada

Because of its hallucinogenic properties, products containing *S. divinorum* or salvinorin A meet the definition of a Natural Health Product (NHP) in accordance with the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*. It is illegal to sell drugs or NHPs in Canada unless they have been reviewed and approved by Health Canada and in the case of NHPs, labelled with one of the following:

- a Natural Product Number (NPN); or
- an Exemption Number; or
- a Drug Identification Number - Homeopathic Medicine (DIN-HM).

As of January 2010, no products containing *S. divinorum* or salvinorin A have been authorized for sale by Health Canada. The sale of unauthorized drugs and NHPs is illegal, and may be subject to compliance and enforcement actions by the Department.

Neither *S. divinorum* nor salvinorin A are currently regulated under the *Controlled Drugs and Substances Act* (CDSA). Health Canada is currently considering available information to determine whether regulation as a controlled substance is warranted.

#### In Other Countries

Several countries including but not limited to Australia, Belgium, Germany, Italy, Japan, etc., have placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on their sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution, e.g., it is illegal for *S. divinorum* to be sold to anyone under the age of 18.

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Comment [HC4]: Just think the whole sentence about “when manufactured..represented for use in modifying organic functions...” sentence is very long and technical, and certainly not at a Great 8 reading level. And since the sentence I have suggested is similar to text in the media lines, I think we can run with it here.

Comment [S5]: “organic” should be removed as the “brain” is specified for hallucinogens; there is no such as thing as an “organic” function in the brain

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Comment [S6]: September?

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Comment [HC7]: Just trying to make this more consistent with media lines....

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## Background

The leaves of this plant have been used traditionally by the Mazatec people for medicinal and mystical purposes.

Products that claim to contain *S. divinorum* or its main active ingredient, salvinorin A, are widely available on the Internet and are sold in various "head shops" and natural food stores. The products are sold in a number of forms, including fresh or dried leaves, liquids or seeds and plant cuttings for growing purposes.

In Canada, results from the Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that, in 2009, less than 2% of Canadians age 15 years and older reported having used *S. divinorum* at least once in their lifetime. Youth 15-24 years of age were however much more likely to have ever used it than adults (7.3% vs 0.5%). Similarly, results from the 2008-2009 Youth Smoking Survey show that 5% of 15 year olds reported using *S. divinorum* in the past year.

See the Need More Info? section below for more information on these surveys.

### Health Canada's Role

Health Canada continues to collect and consider safety information regarding *S. divinorum* and will continue to consult with key stakeholders including health officials in other countries and law enforcement officials here at home. This will assist in determining Health Canada's future approach to decision-making regarding the regulation of *S. divinorum* in Canada.

### Need More Info?

- Complaints about the illegal sale of drugs containing *S. divinorum* can be made to the **Health Products and Food Branch Inspectorate** at: [http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_44\\_consumer\\_consommateur\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_44_consumer_consommateur_cp-pc-eng.php)  
Tel: 1-800-267-9675.
- You can report any adverse reactions to the Canada Vigilance Program by one of the following three ways:  
Report online at the MedEffect™ Canada website at: <http://www.hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>  
Call toll-free at 1-866-234-2345  
Complete a Canada Vigilance Reporting Form and either:  
Fax toll-free to 1-866-678-6789  
Mail to: Canada Vigilance Program  
Health Canada  
AL 0701C  
Ottawa, ON K1A 0K9

**Comment [S8]:** Why is this section here? Would be better placed right after the "Issue" section.

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To have postage pre-paid, download the postage paid label from the MedEffect™ Canada website. The Canada Vigilance Reporting Form and the adverse reaction reporting guidelines may also be obtained via this website at: [http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei\\_form-eng.php](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei_form-eng.php)

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- For information about the Government of Canada's Anti-Drug Strategy, go to: [www.nationalantidrugstrategy.gc.ca/](http://www.nationalantidrugstrategy.gc.ca/)

The Prevention section on this site has a number of helpful resources for parents, including:

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- **Tips on Talking to Your Teenager**, at: [www.hc-sc.gc.ca/hc-ps/pubs/adp-apd/talk-aborder/index-eng.php](http://www.hc-sc.gc.ca/hc-ps/pubs/adp-apd/talk-aborder/index-eng.php)
- **What to Do if Your Teen is Using Drugs**, at: [www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html](http://www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html)
- Health Canada's **Not4Me** youth drug prevention section at: <http://www.hc-sc.gc.ca/hc-ps/drugs-drogues/youth-jeunes/facts-faits/index-eng.php>

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- Information on natural health products and the Natural Health Products Regulations can be found at: [www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php)

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- For more on the surveys that are collecting information about *Salvia divinorum* use in Canada, see:

- **The 2008-2009 Youth Smoking Survey**, at: [www.yss.uwaterloo.ca/ysssite\\_app/controller/index.cfm](http://www.yss.uwaterloo.ca/ysssite_app/controller/index.cfm)
- **The 2009 Canadian Alcohol and Drug Use Monitoring Survey**, at: [www.hc-sc.gc.ca/hl-vs/drug-drogues/cadums-escad-eng.php](http://www.hc-sc.gc.ca/hl-vs/drug-drogues/cadums-escad-eng.php)
- **The 2009 Ontario Student Drug Use and Health Survey**, at: [http://www.camh.net/Research/Areas\\_of\\_research/Population\\_Life\\_Course\\_Studies/OSDUS/~Detailed\\_DrugReport\\_2009OSDUHS\\_Final.pdf](http://www.camh.net/Research/Areas_of_research/Population_Life_Course_Studies/OSDUS/~Detailed_DrugReport_2009OSDUHS_Final.pdf)

Comment [HC9]: Bullet is not the right size

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#### Additional Resources:

- U.S. Drug Enforcement Administration Fact Sheet: Drugs and Chemicals of Concern: *Salvia divinorum* and *Salvinorin A* at: [www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)
- U.S. Department of Health & Human Services, National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006 at: [www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf](http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf)
- For additional articles on health and safety issues go to the It's Your Health web section at: [www.healthcanada.gc.ca/iyh](http://www.healthcanada.gc.ca/iyh)

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

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ODARS Input

## ***Salvia divinorum***

### **Issue**

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff, incense special, and salvia.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs. As of September 2010, no products containing *S. divinorum* have been authorized for use by Health Canada.

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Health Canada recommends that you avoid using this plant because very little is known about the effects it may have on your body and/or brain functions. There is also no way to predict how it will affect you with each use.

### **Background**

*S. divinorum* is known to have physical and mental effects. [see list below]

The leaves of this plant have been used traditionally by the Mazatec Indians for medicinal (chewing the leaves or using them to make a tea) and other purposes (smoking the leaves to induce a "mystical" or hallucinogenic experience).

Products that claim to contain *S. divinorum* – or its main active ingredient, salvinorin A – are widely available on the Internet and are sold in various "head shops" and natural food stores. The products are sold in a number of forms, including fresh or dried leaves, liquids or seeds and plant cuttings for growing purposes.

### **Risks Associated with the Use of *Salvia divinorum***

The effects of *S. divinorum*, which vary from person to person, are often described as unpleasant and may include the following:

Deleted:

- hallucinations;
- dysphoria (feeling unwell, uneasy or unhappy);
- out-of-body experiences;
- uncontrollable laughter;
- loss of consciousness;
- short-term memory loss;
- lack of physical coordination; and
- slurred speech and awkward sentence patterns.

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product;
- how much is used;
- the purity of the product (it may be mixed with other substances);
- how it is taken (e.g., chewed, swallowed or smoked);
- the user's mood and expectations.

While scientists know which brain receptors are targeted by the active ingredient, salvinorin A, very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or permanent damage;
- how it interacts with other substances, including other drugs, natural health products and alcohol;
- The potential of *S. divinorum* to produce physical dependence and/or addiction.

### Minimizing Your Risk

Health Canada recommends that you avoid using *S. divinorum*. Just because a drug is plant-based or "natural", does not mean that it is safe.

Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs and other substances that distort reality. (See the "Need More Info?" section below for links to resources that can help you with this.)

### Legal Status of *Salvia divinorum*

#### In Canada

When *S. divinorum* is manufactured, sold or represented for use in modifying organic functions in humans, and hallucinogens work by modifying organic functions in the brain, it meets the definition of a Natural Health Product (NHP) in accordance with the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*. It is illegal to sell NHPs in Canada unless they have been reviewed and approved by Health Canada and labelled with one of the following:

- a Natural Product Number (NPN); or
- a Exemption Number; or
- a Drug Identification Number - Homeopathic Medicine (DIN-HM).

As of September 2010, no products containing *S. divinorum* have been authorized by Health Canada. All unauthorized drugs and NHPs are subject to compliance and enforcement actions by the Department.

Neither *S. divinorum* nor salvinorin A are currently regulated under the *Controlled Drugs and Substances Act* (CDSA). Health Canada is continuing to analyze information regarding *S. divinorum* as it becomes available in order to determine the most appropriate way of managing the potential risks associated with this substance. In an effort to collect more information about the use of *S. divinorum* in Canada, questions relating to it were included in the 2008-2009 Youth

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<#>international requirements and trends in controlling the substance;¶  
<#>similarity to other substances already regulated under the CDSA;¶  
<#>whether there may be legitimate uses of the substance (e.g., potential health benefits, use in manufacturing, etc.); ¶  
<#>the potential for abuse and the risk of addiction associated with the substance;¶  
<#>the extent of actual abuse of the substance in Canada and elsewhere;¶  
<#>overall risk to public health and safety posed by the substance.¶  
¶  
In the case of *S. divinorum*, there is simply

Deleted: not enough information available to determine whether regulation as a controlled substance

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Smoking Survey, the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) and the 2009 Ontario Student Drug Use and Health Survey (OSDUHS). The results from the 2009 OSDUHS were published on November 18, 2009 and indicate that among responding students in Ontario, 4.4% reported using *Salvia divinorum* at least once in the past year. Data from the Youth Smoking Survey was published on May 31, 2010 and indicate that 4.9% of responding students in Grades 7-12 have used *Salvia divinorum* at least once in the past year.

Data from these surveys and the 2009 edition of CADUMS (released in June 2010) will contribute to future decisions that Health Canada may make regarding the regulation of *S. divinorum* and/or its active ingredient in Canada. See the Need More Info? section below for more information on the surveys that are collecting information about *Salvia divinorum* use in Canada and for more detailed findings from the 2009 OSDUHS.

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### In Other Countries

Several countries including but not limited to Australia, Belgium, Germany, Italy, Japan, etc., have placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A.

In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on their sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution, e.g., no sales to anyone under the age of 18, etc.

### **Background**

*S. divinorum* is known to have psychotropic effects, which means it affects the mind and mental processes. The leaves of this plant have been used traditionally by the Mazatec Indians for both medicinal (chewing the leaves or using them to make a tea) and other purposes (smoking the leaves to induce a "mystical" or hallucinogenic experience).

Products that claim to contain *S. divinorum* – or its main active ingredient, salvinorin A – are widely available on the Internet and are sold in various "head shops" and natural food stores. The products are sold in a number of forms, including fresh or dried leaves, liquids or seeds and plant cuttings for growing purposes.

Comment [S5]: This section also appears at the beginning of the IYH

### **Health Canada's Role**

Health Canada continues to collect and consider safety information regarding *S. divinorum* and will continue to consult with key stakeholders including health officials in other countries and law enforcement officials here at home. This will assist in determining Health Canada's future approach to decision-making regarding regulation of *S. divinorum* in Canada.

Complaints about illegal sale of drugs containing *S. divinorum* can be made to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

### **Reporting Adverse Reactions**

You can report any adverse reactions to the Canada Vigilance Program by one of the following three ways:

Report online at the [MedEffect™ Canada Web site](#)

Call toll-free at 1-866-234-2345

Complete a [Canada Vigilance Reporting Form](#) and either:

Fax toll-free to 1-866-678-6789

Mail to: Canada Vigilance Program  
Health Canada  
AL 0701C  
Ottawa, ON K1A 0K9

To have postage pre-paid, download the [postage paid label](#) from the [MedEffect™ Canada Web site](#). The [Canada Vigilance Reporting Form](#) and the adverse reaction reporting guidelines may also be obtained via this Web site.

### Need More Info?

- For information about the Government of Canada's **Anti-Drug Strategy**, go to:

[www.nationalantidrugstrategy.gc.ca/](http://www.nationalantidrugstrategy.gc.ca/)

The Prevention section on this site has a number of helpful resources for parents, including:

- **Tips on Talking to Your Teenager**, at: [www.hc-sc.gc.ca/hc-ps/pubs/adp-apd/talk-aborder/index-eng.php](http://www.hc-sc.gc.ca/hc-ps/pubs/adp-apd/talk-aborder/index-eng.php)

- **What to Do if Your Teen is Using Drugs**, at:

[www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html](http://www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html)

- Information on natural health products and the **Natural Health Products Regulations** can be found at: [www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php)

For more on the surveys that are collecting information about *Salvia divinorum* use in Canada, see:

- **The 2008-2009 Youth Smoking Survey**, at:

[www.yss.uwaterloo.ca/ysssite\\_app/controller/index.cfm](http://www.yss.uwaterloo.ca/ysssite_app/controller/index.cfm) and

- **The 2009 Canadian Alcohol and Drug Use Monitoring Survey**, at: [www.hc-sc.gc.ca/hl-vs/drug-droques/cadums-esccad-eng.php](http://www.hc-sc.gc.ca/hl-vs/drug-droques/cadums-esccad-eng.php)

- **The 2009 Ontario Student Drug Use and Health Survey**, at:

[www.camh.net/Research/osdus.html](http://www.camh.net/Research/osdus.html)

### Additional Resources:

- U.S. Drug Enforcement Administration: Drugs and Chemicals of Concern: **Salvia divinorum** and Salvinorin A at: [www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)

- U.S. Department of Health & Human Services, **National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006** at:

[www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf](http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf)

- For additional articles on health and safety issues go to the *It's Your Health* Web section at:  
[www.healthcanada.gc.ca/iyh](http://www.healthcanada.gc.ca/iyh)

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

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Lisa Mackay: 613-954-0105 – [Lisa.Mackay@hc-sc.gc.ca](mailto:Lisa.Mackay@hc-sc.gc.ca)

Comments from: HECSB - CSTD (OCS&ODARS) & HPFB – NHPD & HPFBI


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Murty,(31/08/2010) Shahid Perwaiz  
HPFBI : Collin Pinto  
HPFB comms: Elizabeth Keeping, Blossom Leung





Tiffany  
Thornton/HC-SC/GC/CA  
2010-09-09 03:36 PM

To Stephanie Chandler/HC-SC/GC/CA@HWC  
cc  
bcc

Subject Re: CSS-WG re Salvia 

History:  This message has been replied to.

Hi Stephanie,

Sorry for the delay in getting back to you. I was away on holidays. Here is the ROD for the last meeting.



CSS-WG Aug 2010 Meeting RODt.doc

Here is the info from Robin - he sent a detailed email that I have attached below.



Draft Salvia Divinorum IAS\_July 12 2010 ed by NHPD RMarles.doc

Regarding the question of other uses of *Salvia divinorum*, here is what I was able to find:

*Salvia divinorum* has traditional medicinal uses among the native peoples of Mexico, e.g. for the treatment of topical ulcers of the feminine organs (Díaz 1976), to help normalize eliminatory functions (diarrhoea/constipation and urination), anemia, headaches, rheumatism, and alcohol addiction, in addition to its use as a hallucinogen in divination rituals (Valdés et al. 1983). The method of preparation is always an infusion of 4 to 120 pairs (10 to 300 g) of fresh leaves crushed and added to boiling water (a tea) -- low doses of fresh or dried leaves for medicinal purposes and doses of 50+ grams of only fresh leaves for divination/hallucination (Valdés et al. 1983).

There is no record in the scientific literature of a history of use of *Salvia divinorum* as an incense. Burning was not an established method of preparation in traditional uses as a medicine or as a hallucinogenic.

There are a few herbs where burning the leaves produces a very characteristic fragrance (e.g. cured tobacco, *Artemisia*, cedar). However, most aromatic plants lose their characteristic fragrance when burned and simply smell like burned leaves. Gum-resins from trees, e.g. frankincense, myrrh, and copal, are much more common incense ingredients because they gradually release their volatile oils into the smoke (Simpson and Ogorzaly 2001).

Therefore, I believe that the production of "incense" from *Salvia divinorum* leaves or extracts is a recent invention to try to avoid compliance and enforcement actions. Nevertheless, it may be difficult to argue in court that, in the absence of any claims regarding hallucinogenic or other actions in humans, use as incense is not "legitimate" even if there is no history of such use and it just smells like burned leaves.

#### References:

Díaz JL. 1976. Propiedades Terapéuticas Atributas a Plantas Mexicanas, Primera Parte: Nombre Botánico y Usos. Instituto Mexicano para el Estudio de las Plantas Medicinales, Mexico.

Simpson BB and Ogorzaly MC. 2001. Economic Botany: Plants in Our World, third edition. New York, NY: McGraw-Hill Co.

Valdés LJ, Días JL, Paul AG. 1983. Ethnopharmacology of Ska María Pastora (*Salvia divinorum*, Epling

and Játiva-M.). J. Ethnopharmacology 7(3): 287-312.

With respect to the sale of *Salvia divinorum* as a cultivated plant in Canada, yes, it is available from legitimate Canadian garden supply companies, e.g.,

- RICHTERS HERBS, 357 Highway 47, Goodwood, ON L0C 1A0 Canada, Tel. +1.905.640.6677 Fax. +1.905.640.6641, <http://www.richters.com/>. Note the promotional statements explicitly related to its use as a hallucinogen in the attached web site pdf.



Richters Product Listing *Salvia divinorum*.pdf

It is also available from more questionable suppliers, such as:

- Vancouver Seed Bank <http://www.vancouverseedbank.ca/catalog/index.php?cPath=90>



*Salvia divinorum* Vancouver Seed Bank.pdf

and

- <http://www.Salvia.ca>



*Salvia Divinorum* from *Salvia ca*.pdf

Bruna's info from NIDA can be found here:  
<http://drugabuse.gov/infofacts/salvia.html>

International Use? I imputed the CND data in the text from the CADUMS and the OSDUHS but I don't have any other info.

Let me know if there is anything else you need.

Tiffany  
Stephanie Chandler/HC-SC/GC/CA



Stephanie  
Chandler/HC-SC/GC/CA  
2010-08-30 02:43 PM

To Tiffany Thornton/HC-SC/GC/CA@HWC

cc

Subject CSS-WG re *Salvia*

Hi Tiffany,

I was just wondering if you would be sending out a Record of Decision or minutes from the last CSS-WG meeting re: *Salvia divinorum*. There were a few items that members were going to look into, or revisions which they were going to pass along. I wasn't sure if you would be receiving these items and passing them along, or if I should contact the members directly?

According to my notes:

- Robin has revisions re: Natural Health Product Regs

- ODARS may have stats on international use
- Bruna had a NIDA publication re: Salvia and its effects
- Evelyn would provide some info on the status decision of cyclazocine, if available

Thanks,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

# Issue Analysis Summary

DRAFT

## Scheduling *Salvia Divinorum* and/or Salvinorin A under the CDSA

Policy and Regulatory Affairs Division  
Office of Controlled Substances  
Controlled Substances and Tobacco and Directorate

July 12, 2010

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2. ISSUE
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4. CONTEXT
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7. CONSIDERATIONS
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9. CONSULTATIONS
10. IMPLEMENTATION AND EVALUATION

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#### 1. APPROVALS

This Issue Analysis Summary is approved.

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Diane Allan, Director  
Office of Controlled Substances  
Tobacco and Drugs Directorate

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[DD/MM/2010]

#### 2. ISSUE

Health Canada has received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *S. divinorum* and/or its main active ingredient salvinorin A, neither of which are currently regulated under the *Controlled Drugs and Substances Act* (CDSA). These requests are further to reports from scientific and media sources suggesting that *S. divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has also noted an

1

ongoing media interest regarding the availability of *S. divinorum* in Canada.

### 3. PURPOSE

To assess *Salvia divinorum* and/or salvinorin A against the criteria for the addition of a substance to one of the Schedules to the CDSA, and determine whether one or both should be regulated as controlled substances in Canada.

### 4. CONTEXT

*Salvia divinorum* is a species of sage which belongs to the mint family, and which is found in the form of dried leaves, extract and plant cuttings. Also known as "diviner's sage", the plant is known to induce illusions and hallucinations when chewed or smoked. Salvinorin A, the psychoactive ingredient in *S. divinorum* (also referred to chemically as a neoclerodane diterpene) is found primarily in the leaves, and to a lesser extent in the stems.<sup>1</sup>

*S. divinorum* is widely touted as a "legal" hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs among adolescents and young adults.<sup>2</sup> While very little is known about how and where *S. divinorum* is sold in Canada, it is suspected that it is mainly purchased over the Internet and/or bought at head shops or alternative life style stores, etc.

The use of *S. divinorum* as a psychotropic agent first came to Health Canada's attention in 2002. In 2004, Health Canada received four adverse drug reaction (ADR) reports associated with the use of *S. divinorum* as a hallucinogen, with three being considered non-serious (requiring no medical attention) and the fourth being considered serious (medical intervention was required). The serious ADR report involved the concomitant use of alcohol in a person diagnosed with Attention Deficit Disorder.

Further to the receipt of the aforementioned ADRs, the Marketed Health Products Directorate (MHPD) and the Natural Health Products Directorate (NHPD) of the Health Products and Food Branch (HPFB) prepared an issue analysis summary (IAS), which recommended that *S. divinorum* and its active ingredient salvinorin A be regulated as controlled substances. This recommendation was maintained when the IAS was updated in November 2006.

Later, in December 2005, MHPD and NHPD prepared a Signal Assessment (SA) (updated in June 2007) that eventually led to the preparation of a Health Risk Assessment (HRA), which concluded that *S. divinorum* or salvinorin A-containing health products would constitute a Type II Health Risk according to the Health Hazard Classification of the Recall Policy of the Health

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<sup>1</sup> U.S. Department of Justice Drug Enforcement Administration. 2002. Drugs and Chemicals of Concern: Salvia Divinorum (salvinorin A, divinorin A) URL: [http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm) Nov 2008

<sup>2</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.

Products and Food Branch Inspectorate (HBFBI). Such a risk is defined as “a situation in which the use of, or exposure to, a product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote”.

Further to an Assistant Deputy Minister (ADM) discussion in April 2007, the Drug Strategy and Controlled Substances Directorate (DSCSD) organized a meeting with MHPD, NHPD and HPFBI to discuss *S. divinorum*. HPFBI was to determine appropriate compliance activities regarding *S. divinorum* and consult with the Canada Border Services Agency (CBSA) regarding the movement of products containing *S. divinorum* into and out of Canada.

On September 13, 2007, a further meeting between DSCSD, MHPD, NHPD and HPFBI led to the conclusion that DSCSD would conduct a scheduling assessment of *S. divinorum* in order to explore the possibility of scheduling this substance under the CDSA.

In September 2008, the Director Generals of DSCSD, MHPD, TPD and the HPFBI agreed that media lines and an “It’s Your Health” article on *S. divinorum* would be prepared.

#### **4.1 Relevant Legislative Frameworks in Canada**

##### **4.1.1 Food and Drug Regulations (under the Food and Drugs Act)**

The *Food and Drug Regulations* (F&DR) serve to ensure the safety, efficacy, and quality of health products offered for sale in Canada, including drugs and medical devices. Prior to being given market authorization, a manufacturer must present substantive scientific evidence that a product is safe, efficacious and of high quality. For drugs, Health Canada reviews this information carefully and, if the review is satisfactory, a Notice of Compliance (NOC) is issued and appropriate Drug Identification Numbers (DINs) are assigned.

A “drug” is defined under the F&DR as any substance or mixture of substances manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
- (b) restoration, correction or modification of organic functions in human beings or animals, or
- (c) disinfection in premises in which food is manufactured, prepared or kept;

As no products containing *S. divinorum* or its extracts have been reviewed and approved by Health Canada as of July 2010, it is illegal to market *S. divinorum* when it is represented as a drug.

#### 4.1.2 Natural Health Products Regulations (under the Food and Drugs Act)

The *Natural Health Products Regulations* (NHPR) aim to provide Canadians with ready access to natural health products (NHPs) that are safe, effective, and of high quality, while respecting freedom of choice and philosophical and cultural diversity. The NHPR require that all licensed products display a Natural Product Number (NPN), or, in the case of a homeopathic medicine, a Drug Identification Number - Homeopathic Medicine (DIN-HM), on their labels. These numbers are issued once a product is authorized for sale in Canada further to the submission of a product licence application in which the applicant attests to all of the conditions set out in a natural health product monograph prepared and published by the Natural Health Products Directorate or submission of a product licence application that provides sufficient evidence of quality, safety and efficacy that is assessed and approved by NHPD by the non-compendial route. The NHPR also require that all manufacturers, packagers, labelers, and importers be licensed which in turn requires the presence of procedures respecting distribution records, product recalls, product handling, storage and delivery, and all other aspects of Good Manufacturing Practices as set out in the NHPR.

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The definition of an NHP under the NHPR has both a function and substance component. The function component refers to those substances that are manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
- (b) restoring or correcting organic functions in humans; or
- (c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

The substance component refers to the requirement that all of the medicinal ingredients of an NHP must be substances set out in Schedule 1 to the NHPR, which is a list of included substances, substances that are traditional medicines or that are homeopathic medicines, and that none of the ingredients are substances set out on Schedule 2 which is a list of excluded substances, e.g. any substance listed on Schedules I to V of the Controlled Drugs and Substances Act. Section 2(2) of the NHPR excludes those substances (except homeopathic medicines) whose sale is required to be pursuant to a prescription as per Section C.01.043 and thus Schedule F to the F&DR. As per section 93(1)(b)(vi) of the NHPR, every natural health product must be labeled with its authorized recommended use or purpose. In the case of *S. divinorum*, it is generally marketed for its hallucinogenic properties which are considered a modification of an organic function. Therefore products containing it and manufactured, sold or represented for that purpose meet the definition of an NHP.

Deleted: whether the product or medicinal ingredient therein is safe for consideration as an over-the-counter product, can be available for self-care and self-selection, and does not require a prescription to be sold

Deleted: To be considered a NHP, no direct health claims need to be made regarding the substance

As of July 2010, no products containing *S. divinorum* have been reviewed and approved by Health Canada and no NPNs or DIN-HMs have been issued. Therefore sales of *S. divinorum* are

illegal under the NHPR if it is represented for use as a hallucinogen or if other health claims such as with regard to modifying organic functions are made.

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#### 4.1.3 Controlled Drugs and Substances Act and its Regulations

The CDSA provides a legislative framework for the control of substances that can alter mental processes and that may produce harm to the health of an individual or to society when diverted or misused. Except as authorized under its regulations, activities such as possession, possession for the purposes of trafficking, trafficking, importation, exportation, possession for the purposes of exportation and production of controlled substances are prohibited under the CDSA.

The substances regulated under the CDSA are grouped into eight Schedules, and each Schedule is associated with particular offences and penalties as described in Part I of the CDSA.

In determining whether a substance should be regulated as a controlled substance, and into which Schedule of the CDSA it should be placed, Health Canada considers the following factors:

- International requirements and trends in the control and/or scheduling of the substance;
- Chemical and/or pharmacological similarity to substances listed in the Schedules to the CDSA;
- Legitimate use of the substance, including therapeutic, scientific, industrial or commercial uses;
- Potential for abuse and/or addiction liability of the substance;
- Evidence of extent of actual abuse of the substance in Canada and internationally; and
- Risk to personal and public health and safety.

#### 4.2 Assessment of *Salvia Divinorum* for Scheduling Purposes

##### 4.2.1 International Requirements and Trends in the Control and/or Scheduling of the Substance

At the present time, neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and therefore do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

##### *Australia*

In June 2002, Australia became the first country to prohibit the sale, supply, possession and use of *S. divinorum* and salvinorin A. Although both *S. divinorum* and salvinorin A are listed in Schedule 9 of Australia's Standard for the Uniform Scheduling of Drugs and Poisons on the basis of "high potential for abuse and risk to public health and safety", no substantiation of this risk was provided at the time of this scheduling decision.<sup>3</sup> Schedule 9 is Australia's most

<sup>3</sup> <http://www.tga.gov.au/ndpsc/record/tr200111.pdf>



restrictive drug schedule, and includes “substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities.”<sup>4</sup>

### **Belgium**

A decree was passed in Belgium on October 22, 2006 which added *S. divinorum* to the list of controlled substances. This list includes substances such as psilocybin mushrooms, khat and peyote cactus.<sup>5</sup>

### **Denmark**

In 2003, Denmark added *S. divinorum* and salvinorin A to their list of “category B” controlled substances, a category which also includes psilocybin mushrooms, cocaine, amphetamine, and several others substances that are only legal for medicinal and scientific purposes. Illegal possession carries a penalty of up to two years in prison.

### **Germany**

*S. divinorum* (plant and plant parts) was added to Appendix I of the *Narcotics Act* in Germany on March 1, 2008, making it illegal to produce, traffic, or possess. The law does not specifically mention salvinorin A.

### **Italy**

On June 25, 2004, the Italian Ministry of Health issued an ordinance prohibiting the sale of *S. divinorum* and its active constituent salvinorin A. On January 11, 2005, the Ministry of Health made possession of *S. divinorum* and salvinorin A illegal by placing them in “*Tabella I*” of the *Tabelle Sostanze Stupefacenti o Psicotrope*.

### **Japan**

On November 9, 2006, the Japanese government added a group of thirty-three drugs to its list of controlled substances, including salvinorin A. The drugs are banned under a revised pharmaceutical law, under which persons involved in their illegal import, production, and sale, i.e. beyond medical treatment or research purposes, will be subject to up to five years imprisonment or a fine of up to five million yen.

### **Spain**

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<sup>4</sup> [http://www.cognitiveliberty.org/news/salvia\\_australia.htm](http://www.cognitiveliberty.org/news/salvia_australia.htm)

<sup>5</sup> <http://eldd.emcdda.europa.eu/html.cfm/index5176EN.html?pluginMethod=eldd.shownewsdetails&id=20/12/2006BELGIUM:%20New%20substances%20controlled%20include%20mCPP%20and%20khat>

On January 28, 2004, the Spanish Ministry of Health and Consumption issued an order prohibiting the sale of *S. divinorum*. The regulation went into effect on May 6, 2004 and only prohibits activities related to commerce. Possession and/or use are not considered to be criminal offences.

#### ***Other Countries***

*Salvia divinorum* is illegal to possess or sell in Croatia, Latvia, Lithuania, Poland, Romania, South Korea and Sweden. In Russia it is illegal to grow or sell *S. divinorum*, but it is legal to possess it. In Estonia, Finland, Iceland and Norway, *S. divinorum* is treated as a medicinal herb and it is illegal to import it without a relevant prescription from a doctor.

#### ***United States of America***

*S. divinorum* and salvinorin A are not included in the Schedules to the United States *Controlled Substances Act* although both *S. divinorum* and salvinorin A have been added to a list of chemicals "of concern" which has no legal implications. In addition, some individual states have implemented laws restricting its use, sale and/or distribution. As of July 2010, a number of states have enacted legislation placing regulatory controls on *S. divinorum* and/or salvinorin A including Delaware, Georgia, Florida, Hawaii, Illinois, Kansas, Kentucky, Maryland, Mississippi, Missouri, Nebraska, North Dakota, Ohio, Oklahoma, South Dakota, Wisconsin, Virginia, California, Louisiana, Maine, North Carolina, and Tennessee. More details regarding the regulation of *S. divinorum* in these last five states are provided below.

#### ***California***

As of January 1, 2009, the sale or distribution of *S. divinorum* or salvinorin A, or any substance or material containing *S. divinorum* or salvinorin A, to any person under 18 years of age is a misdemeanor punishable by imprisonment in a county jail for not more than six months, a fine of no more than \$1,000, or both.

#### ***Louisiana***

In 2005, Louisiana passed a bill which prohibits the possession, production, manufacture and distribution of a material, compound, mixture, or preparation intended for human consumption and that contains a hallucinogenic plant. A "hallucinogenic plant" is defined as "any part or portion" of a plant on a list of forty plants, which includes *S. divinorum*.

#### ***Maine***

In Maine, *S. divinorum* and salvinorin A are regulated in the same way as tobacco products; adults eighteen years of age or over can legally purchase and use the material,

but selling or providing *S. divinorum* or salvinorin A to anyone under the age of eighteen is a criminal offence. Possession by a minor is a civil violation, punishable by a fine, community service, or both.

### ***North Carolina***

On December 1, 2009, the North Carolina State Legislature brought a new law into force which made *Salvia divinorum* and salvinorin A illegal. The only legal *S. divinorum* activities are the growing for aesthetic, landscaping, or decorative purposes or university-affiliated medical or pharmacological research.

### ***Tennessee***

On July 1, 2006, Tennessee classified the deliberate production, manufacture, distribution, or possession of the active chemical ingredient in the hallucinogenic plant *S. divinorum* as a Class A misdemeanor. It is not, however, a criminal offence to possess, plant, cultivate, grow, or harvest *S. divinorum* for aesthetic, landscaping, or decorative purposes. The law also does not apply to any dosage that is legally obtainable from a retail establishment without a prescription when (and if) it is recognized by the Food and Drug Administration as a homeopathic drug.

#### **4.2.2 Chemical and/or Pharmacological Similarity to Substances listed in the Schedules to the CDSA**

The psychoactive ingredient in *Salvia divinorum* is salvinorin A. Other plants which contain psychotropic terpenoids are *Artemisia absinthium* (wormwood) and *Cannabis sativa*. Salvinorin A is considered by some as the most potent natural hallucinogen ever isolated.<sup>6</sup>

Unlike all other hallucinogens, salvinorin A is structurally distinct and does not interact with the serotonin-2A receptor or any other molecular target of classical hallucinogens. It thus affects the brain in a way that is quite unique.<sup>7</sup> Recent pharmacological screenings of receptors have found it to be a highly potent and selective  $\kappa$ -opioid receptor (KOR) agonist.<sup>8</sup>

The use of *S. divinorum* or salvinorin A can lead to a number of effects with variable onset and duration. These effects are generally accepted to be: sensation of becoming an object, visions of

<sup>6</sup> Ott J. Ethnopharmacognosy and human pharmacology of *Salvia divinorum* and salvinorin A. *Curare*. 1995 18: 103-129. Unofficial transcription available online. URL <http://www.sagewisdom.org/ott2.html>

<sup>7</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>8</sup> Roth BL, Baner K, Westkaemper R, Siebert D, Rice KC, Steinberg S, Ernsberger P, Rothman RB. Salvinorin A: a potent naturally occurring nonnitrogenous kappa opioid selective agonist. *Proc Natl Acad Sci U S A*. 2002 Sep 3;99(18):11934-9.

various two-dimensional surfaces, films and membranes, revisiting places of the past (particularly childhood), perceived loss of the body and/or identity, various sensations of motion (being pulled or twisted by a force of some kind), uncontrollable hysterical laughter, and overlapping realities (perceptions of being in more than one place).<sup>9</sup> Laughter, happiness, sense of well-being and dissociative effects were deemed the best aspects of *S. divinorum* by users, second only to the "trip" that the drug elicits.<sup>10</sup> Depersonalization, speaking gibberish, widening of consciousness and subjective illusions of rapid movement, flying or hovering have also been reported.<sup>11</sup>

The psychomimetic effects of *S. divinorum* closely resemble schizophrenia symptoms induced by lysergic acid diethylamide (LSD) or phencyclidine (PCP).<sup>14</sup> Yet, it is said to have only weak influence on the prevailing mood of the user which differentiates it from other hallucinogens such as LSD and psilocybin.<sup>15</sup> Its strong dissociative effects are often compared to those of ketamine. Users have reported that the psychedelic effects of *S. divinorum* were most similar to those caused by psilocybin mushrooms.<sup>16</sup> However, users familiar with the effects of other hallucinogens agree that despite certain similarities to classical hallucinogens, the visions and overall experience are quite unique.<sup>17</sup>

In addition, the psychedelic effects of *S. divinorum* are similar to those of classical psychedelics regarding changes in perception and somatic sensations. *S. divinorum* causes an unusually high degree of sedation, weakness and fatigue, while the increased de-realization is not commonly reported for classical psychedelics.<sup>18</sup> The combination of these effects seems to correlate with

<sup>9</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>10</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>11</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5 and Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>14</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5.

<sup>15</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>16</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>17</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6 and González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>18</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

that of other KOR agonists such as pentazocine.<sup>19</sup>

#### 4.2.3 Legitimate Use of the Substance, including Therapeutic, Scientific, Industrial or Commercial Uses

*Salvia divinorum* has traditionally been used for spiritual and medicinal purposes by the Mazatec Indians in Oaxaca, Mexico,<sup>20</sup> where an infusion of the leaves or the leaves themselves are ingested to treat gastrointestinal problems, headaches, rheumatism, anemia and swelling of the stomach.<sup>21</sup> Its main use today is, however, for its psychoactive properties in the aid of producing “mystical” or hallucinogenic experiences as part of spiritual rituals.<sup>22</sup>

Although selective kappa receptor agonists have been shown to produce analgesic effects, adverse effects such as psychotomimesis, dysphoria and diuresis have been observed in studies investigating their therapeutic use.<sup>23</sup> In addition, while it has been speculated that KOR agonists may prove to be useful in the treatment of certain psychiatric disorders including Alzheimer’s disease, schizophrenia, dementia and bipolar disorder,<sup>24</sup> much more research is needed in order to substantiate these hypotheses. Similarly, another study has suggested that chemical analogues of salvinorin A may be a useful treatment for those suffering from addiction to other substances.<sup>25</sup> That said, there are presently no legitimate medical uses for *S. divinorum* in Canada.

Similarly, there are no known industrial or commercial uses for *S. divinorum* in Canada. The plant is a semi-tropical perennial that can only grow outdoors in a humid climate where it will not encounter frost. Most websites offering *S. divinorum* cuttings and seeds for sale appear to do so in the context of growing the plant in order to utilize its psychoactive properties, rather than out of horticultural interest or for its esthetic appeal.

#### 4.2.4 Potential for Abuse and/or Addiction Liability of the Substance

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<sup>19</sup> Arasteh K, Poudevida S, Farre M, Roset PN, Cami J. Response patterns of the Spanish version of the 49-item short form of the Addiction Research Center Inventory after the use of sedatives, stimulants, and opioids. *Drug Alcohol Depend.* 1999 Jun 1;55(1-2):117-25.

<sup>20</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>21</sup> Munro, T. The Chemistry of *Salvia divinorum*. PhD dissertation, 2006. Accessed from:

<http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

<sup>22</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage *Salvia divinorum*. *Life Sci.* 2005 Dec 22;78(5):527-31.

<sup>23</sup> Barker RL, Fawcett J, Barkin SJ. 2002. Chronic pain management with a focus on the role of newer antidepressants and centrally acting agents. In: *Pain Management: A Practical Guide for Clinicians*, 6th edition, Weiner RS ed. CRC Press, Boca Raton, FL. pp. 415-34 and Tidgewell et al., 2004. A facile method for the preparation of deuterium labelled salvinorin A: *Biorganic & Medicinal Chemistry Letters*, 14: 5099-5102.

<sup>24</sup> Sheffler DJ & Roth BL. Salvinorin A: the ‘magic mint’ hallucinogen finds a molecular target in the kappa opioid receptor. *Trends Pharmacol Sci.* 2003 Mar;24(3):107-109.

<sup>25</sup> Prisinzano TE. Natural products as tools for neuroscience: discovery and development of novel agents to treat drug abuse. *J Nat Prod.* 2009 Mar 27;72(3):581-7.

Salvinorin A is a potent, selective agonist of the  $\kappa$ -opioid receptor (KOR), and in contrast to the euphoria produced by  $\mu$ -opioid receptor (MOR) agonists, KOR agonists are negatively reinforcing and aversive.<sup>26</sup> In addition, KOR agonists have analgesic properties but are not associated with respiratory depression like MOR agonists. Finally, while MOR agonists increase the release of dopamine, the activation of KOR decreases dopamine release in the nucleus accumbens.<sup>28</sup>

The onset and intensity of the effects of *Salvia divinorum* appear to be related to the route of administration.

Traditional uses generally produce mild effects because the leaves are rolled and chewed or crushed and prepared as a foamy infusion whereby the salvinorin A is degraded in the gastrointestinal system before being absorbed into the bloodstream. Hence, the level of effect relates quite closely to the length of time the material spends in the mouth, with the onset of effect generally taking 5-10 minutes. The effects build over the next hour and last for another hour before they begin to subside.<sup>29</sup>

Routes of administration that avoid the hepatic first-pass effect (i.e. inhalation, intravenous, intramuscular and sublingual use) are the quickest and most intense.<sup>30</sup> Salvinorin A can be isolated from the plant to make a powder which can be vaporized and inhaled. The onset of effects felt from vaporizing salvinorin A powder occurs in about 30 seconds and effects last for about 5-10 minutes and then subside over the next 30 minutes.<sup>31</sup>

Smoking is by far the most popular method of administration<sup>32</sup> and this is accomplished by smoking the dried leaves or a concentrated extract using a pipe or bong. Dried leaves may also

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<sup>26</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590, Cooper S. Interactions between endogenous opioids and dopamine: Implications for reward and aversion. In: *The Mesolimbic Dopamine System: From Motivation to Action*. Willner P and Scheel-Kruger J (editors) Wiley, Chester, England, 1991, pp. 331-366, and Shippenberg TS, Herz A, Spanagel R, Bals-Kubik R, Stein C. Conditioning of opioid reinforcement: neuroanatomical and neurochemical substrates. *Ann N Y Acad Sci.* 1992 Jun 28;654:347-56.

<sup>28</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.

<sup>29</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>30</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.

<sup>31</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>32</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62 and Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

be fortified with a concentrated extract of salvinorin A. A concentrated extract can also be used sublingually. Neither *S. divinorum* nor salvinorin A can be injected because the powder is insoluble in water.<sup>33</sup>

The aversive effects of previously studied KOR agonists predict that the risk of addiction to *S. divinorum* is negligible. However, very few controlled scientific studies of the physical and psychotropic effects of *S. divinorum* on humans have been carried out. Therefore, it is difficult to predict its potential for addiction and abuse. In studies that have been conducted, there is conflicting information around the addiction liability of *S. divinorum* in both animals and humans. Some users have noted that they require increasing doses of salvinorin A in order to achieve the desired effect and the stimulated cerebral KOR may act as a mechanism of tolerance.<sup>37</sup> Further studies in this area and on the mediated decrease of dopamine as well as the impact of dose on effects are also required.

While concerns for the potential of abuse were once minimal because 1 kg of dried leaves yields only 3 to 6 human doses of salvinorin A, it was discovered that vaporizing and inhaling 200-500 micrograms had profound hallucinogenic effects.<sup>38</sup> The extraction of salvinorin A from the plant is very easy, and with care, approximately 1.5 grams of pure salvinorin A per kilogram of dried leaves (8kg of fresh leaves) can be isolated. This is enough substance to provide for 2000 human doses.<sup>39</sup>

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#### 4.2.5 Evidence of Extent of Actual Abuse of the Substance in Canada and Internationally

In Canada, the extent of actual abuse of *Salvia divinorum* and/or salvinorin A is relatively unknown. There is, however, some data regarding the use of *Salvia divinorum* in Canada, despite the lack of legitimate uses for this plant. Questions about the use of *S. divinorum* were

<sup>33</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs*. 1994 Jul-Sep;26(3):277-83.

<sup>37</sup> Bucheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>38</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>39</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs*. 1994 Jul-Sep;26(3):277-83.

<sup>44</sup> Turner DM. *Salvinorin - The Psychedelic Essence of Salvia Divinorum*. Panther Press, San Francisco, CA 1996.

included in the 2008-2009 Youth Smoking Survey, the 2009 Canadian Alcohol and Drug Use Monitoring Survey and the 2009 Ontario Student Drug Use and Health Survey.

The results from the 2009 Ontario Student Drug Use and Health Survey were published on November 18, 2009 and indicate that:

- Among all responding students in Ontario, 4.4% reported using *Salvia divinorum* at least once in the past year. In comparison, 58.2% indicated they had used alcohol, 25.6% indicated they had used cannabis and 5.0% indicated they had used hallucinogens other than LSD and PCP in the past year;
- Males (6.2%) were significantly more likely than females (2.3%) to report using *Salvia divinorum*;
- There is significant grade variation, with *Salvia divinorum* use most likely among 11<sup>th</sup> graders (8.6%) and 12<sup>th</sup> graders (8.4%); and
- There are significant regional variations, with students in Northern Ontario (9.2%) most likely to use *Salvia divinorum*.

The results of the 2008-2009 Youth Smoking Survey were published on May 31, 2010 and indicate that:

- 4.9% of students stated that they had used *S. divinorum* in the last twelve months. In comparison, 53.0% indicated they had used alcohol, 27.3% indicated they had used cannabis and 6.9% indicated they had used other hallucinogens in the last twelve months;
- 2.6% of students in Grades 7-9 and 7.0% of students in Grades 10-12 had used *S. divinorum* in the last twelve months; and
- Males (6.6%) were more likely to have used *S. divinorum* in the past twelve months compared to females (3.2%).

The scope of the previously mentioned studies did not provide for any explanations regarding differences in usage between ages, genders and regions. In this regard, it is difficult to speculate on the causality of such differences.

The Canadian Alcohol and Drug Use Monitoring Survey specifically examined Salvia for the first time in 2009. An estimated 1.6% of Canadians, aged 15 years and older, reported that they had used salvia in their lifetime, and 0.2% reported using it in the past-year. In comparison, the prevalence of past-year cannabis use among Canadians 15 years of age and older was 10.6%. 1.2% of respondents reported using cocaine or crack in the past 12 months, 0.9% had used ecstasy and 0.7% used illicit hallucinogens.

Health Canada's Drug Analysis Services (DAS) has identified salvinorin A in a number of samples seized by law enforcement, as shown in the following table.

**NUMBER OF SAMPLES FOUND TO CONTAIN SALVINORIN A**

Year	Count
2006	9



2007	8
2008	4
2009	20
2010 (as of May 7)	8

The National Forensic Laboratory Information System (NFLIS) and the System to Retrieve Information from Drug Evidence (STRIDE) in the United States are Drug Enforcement Agency (DEA) databases that collect scientifically verified data on analyzed samples in state and local forensic labs as well as samples from DEA labs. The following table shows the quantity of *S. divinorum* products that were seized from 2000 through to 2009.

**ANALYZED SALVIA DIVINORUM or SALVINORIN A SEIZURES**

(Number of Items/Exhibits)

Source	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009*
NFLIS-State/Local <sup>1</sup>	0	0	0	0	1	8	12	12	70	34
STRIDE <sup>2</sup>	0	0	1	1	1	0	0	0	N/A	N/A
<b>TOTAL</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>1</b>	<b>2</b>	<b>8</b>	<b>12</b>	<b>12</b>	<b>70</b>	<b>34</b>

Data Source: NFLIS & STRIDE, 2008 data queried 11/24/08, updated 06/10/2010

<sup>1</sup> NFLIS reported seizures of *Salvia divinorum* and/or salvinorin A

<sup>2</sup> STRIDE reported items of *Salvia divinorum*.

\* Includes only January – May data in 2009.

It is difficult to determine the extent of actual abuse of *S. divinorum* in Canada or elsewhere as there appear to be inconsistencies in the literature regarding risk aversion. For example, one author states: "Many who have used salvinorin A find the experience extremely unnerving, frightening and overly intense and most have no desire to repeat the experience."<sup>44</sup> However, another study suggested that this is not the experience of all recreational users of *S. divinorum*.<sup>45</sup> Over eighty percent of users surveyed on a web-based questionnaire about their *S. divinorum* use said that they would probably or definitely use *S. divinorum* again.<sup>46</sup> Users have reported the negative effects of *S. divinorum* as: the short duration of action, lack of control over the experience, persisting negative effects (most often anxiety),<sup>47</sup> sweating, chills, increased diuresis, impaired vigilance,<sup>48</sup> and negative after-effects including tiredness, feeling head heavy, dizziness, physical exhaustion, and some degree of malaise or 'hangover' as they 'comedown' from the

<sup>45</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62, Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry.* 2005 Jan;38(1):1-5, and Valdés LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs.* 1994 Jul-Sep;26(3):277-83.

<sup>46</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>47</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>48</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry.* 2005 Jan;38(1):1-5.

drug.<sup>49</sup>

#### 4.2.6 Risk to Personal and Public Health and Safety

The increase in both the number of enquiries from various municipalities and members of the public and the amount of media interest regarding the availability of *Salvia divinorum* in Canada may be an indication that the recreational use of *S. divinorum* as a hallucinogen is on the rise. However, there are no available statistics that indicate there has been a significant increase in *S. divinorum* use in the Canadian population and, in comparison to the use of other drugs such as alcohol and cannabis, the actual use of *S. divinorum* is quite low.

The potential for harm to the user and/or other individuals is primarily related to the hallucinogenic properties of the substance. Users may get up and walk around without apparent awareness of their movements, behaviour or surroundings, and distinction between self and surroundings is often lost. At doses greater than 1mg of salvinorin A, out of body experiences are frequent and loss of consciousness has been reported.<sup>50</sup> There is little information regarding the social behaviours of persons under the influence of *S. divinorum* products, and what risks their activities such as operating a motorized vehicle may pose to the general public. There is also very little data regarding the toxicity, teratogenicity or other long-term effects of *S. divinorum* use.<sup>51</sup>

As far as law enforcement is concerned, the Department has only received a limited number of communications indicating concern with respect to *S. divinorum* and none of these have advised that the use of *S. divinorum* poses any threat to public safety. The Royal Canadian Mounted Police (RCMP) has stated that while *S. divinorum* is readily available, it has not become a popular drug in Canada, probably due to its aversive effects such as anxiety and introversion.

A handful of case reports regarding the use of *S. divinorum* have been published in the academic literature. One report was an international case report in which a young man (19 years of age) described his perceptions after inhaling smoke from *S. divinorum*. The peak psychotropic effects, including prickling of the skin, fever-like hot flashes, muscular tremor, and depersonalization, were reached in less than five minutes after inhalation of an unknown amount of smoke from burning dried leaves.<sup>52</sup> Another report involved a 15-year-old male who presented to psychiatric emergency services with acute onset of paranoia, déjà vu, blunted affect, difficulties in thought processing and slowed speech after smoking *Salvia divinorum* over an unknown period of time. During his hospitalization all symptoms improved significantly except the feeling of déjà vu. Based on this case presentation, the author suggested that the feelings of déjà vu may be a long-term effect of *S. divinorum* use.<sup>53</sup> However, given that this is the only case report in which déjà vu was associated with the use of *S. divinorum*, more reports are needed to

<sup>49</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>50</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>51</sup> Grundmann O, Phipps SM, Zadezensky I, Butterweck V. *Salvia divinorum* and Salvinorin A: An Update on Pharmacology and Analytical Methodology. *Planta Med* 2007 Jun;73:1039-1046.

<sup>53</sup> Singh S. (2007) Adolescent salvia substance abuse. *Addiction.* 102, 823-824.

substantiate this finding.

s.21(1)(a)  
s.21(1)(b)

In addition to the above-mentioned reports, in 2006, a case was reported in the U.S. in which a 17-year-old boy committed suicide after smoking *S. divinorum* for an unknown period of time.<sup>54</sup> It should be noted that alcohol and general depression were the main confounders in this case. After this case was reported, the state of Delaware passed a law which classified *S. divinorum* as a Schedule I controlled substance along with other hallucinogenic substances.

Like many drugs of abuse, users are often unaware of the potency and adulterants in the product they purchase. A study by Wolowich *et al.* (2006)<sup>55</sup>, showed that the salvinorin A content in five out of five *S. divinorum* products was falsely indicated on the label and 4 out of 5 products contained unidentified adulterants (i.e. vitamin E, caffeine).

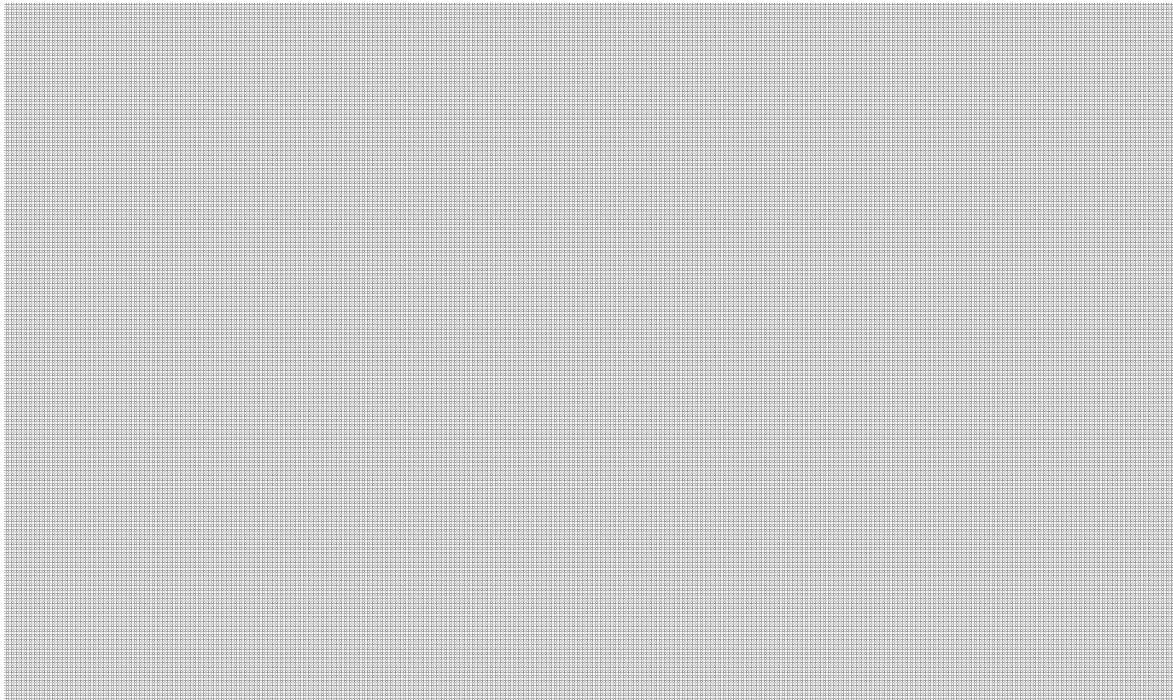
Health Canada has only anecdotal information about the use and abuse of *S. divinorum* in Canada as well as the threat *S. divinorum* may pose to the health and safety of Canadians. There are several reports of domestic adverse reactions related to the use of *S. divinorum* that have been received through the Canada Vigilance database. However, this does not reflect true incidence due to under-reporting. Considering also the limited population exposure information, it is not possible to adequately characterize the risk to the general population.

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## 5. ASSESSMENT OF RISKS AND BENEFITS



<sup>54</sup> <http://www.kvbc.com/Global/story.asp?S=4893692>

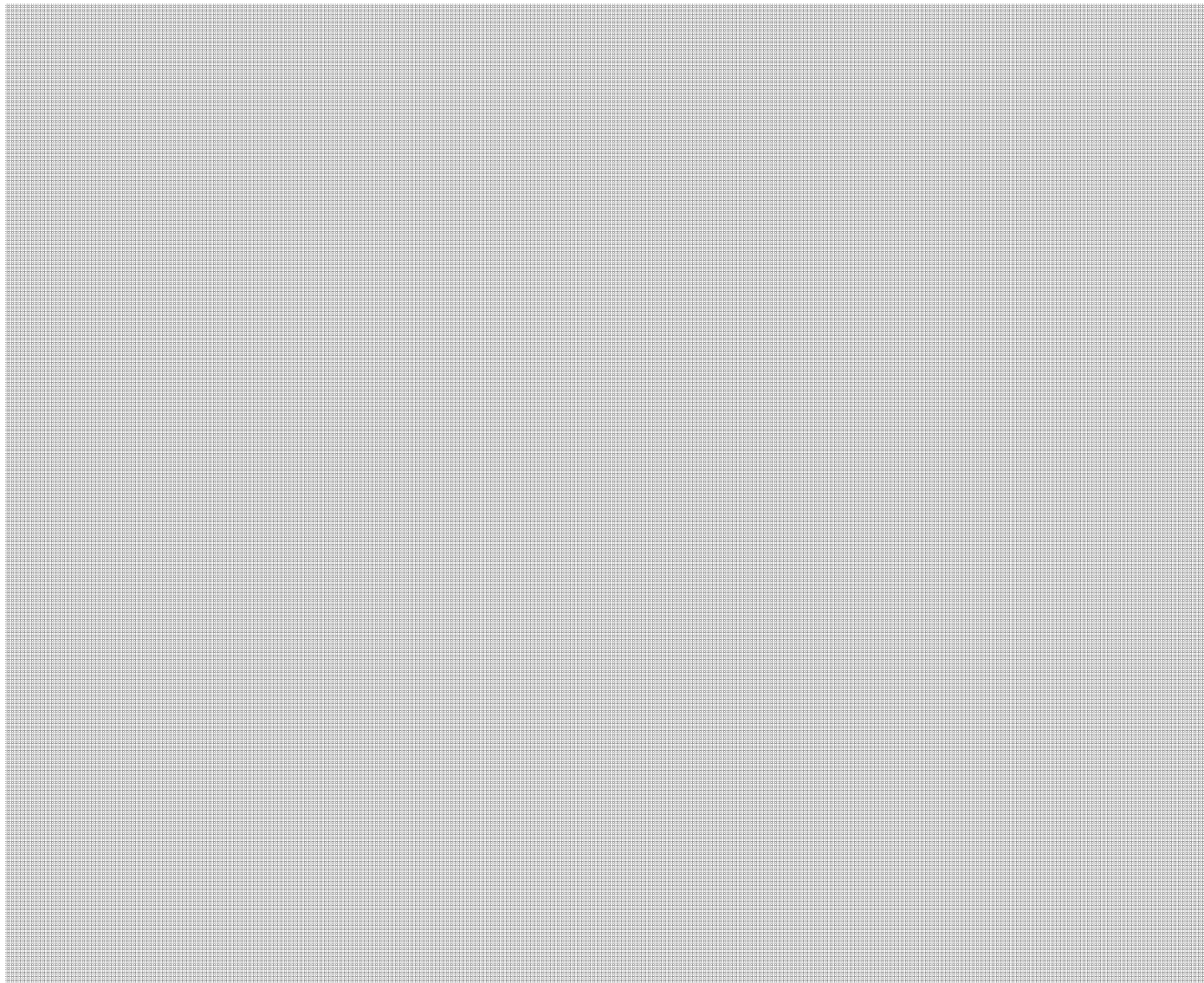
<sup>55</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

**Page(s) 001232 to\à 001232**

**Is(Are) exempted pursuant to section(s)  
est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**



## 7. CONSIDERATIONS

The KOR-mediated aversive and dysphoric effects of *Salvia divinorum* do not appear to be hampering its use as young adults have begun smoking the leaves and leaf extract recreationally.<sup>56</sup> It can be purchased through online botanical companies and other drug promotion sites and is often touted as a legal alternative to substances such as cannabis and mescaline.<sup>57</sup> Interestingly, after being

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<sup>56</sup> Hazelden Foundation, 2004. Drug Abuse Trends. June 2004. URL: [www.research.hazelden.org](http://www.research.hazelden.org).

<sup>57</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

**s.21(1)(a)**  
**s.21(1)(b)**

widely available for over a decade, the drug does not appear to have had the same social impact as LSD or ecstasy.<sup>58</sup>

While there has been an increase over the past few years in the number of enquiries from various municipalities and members of the public regarding the availability of *Salvia divinorum* as a hallucinogen, the reported use of *S. divinorum* by young Canadians is much lower than that of alcohol or cannabis, according to available statistics.

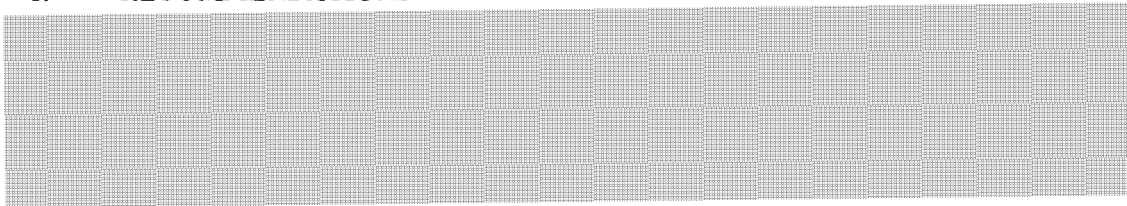
The NHPR are limited in their capacity to control the availability of *S. divinorum* in that *S. divinorum* products are often declared as incense and therefore cannot be considered unapproved natural health products. In addition, compliance and enforcement actions such as voluntary stop-sales, forfeiture, destruction, and administrative seizure, cannot be implemented unless the labeling of the product indicates that it is to be used for human consumption and can modify an organic function.

The previous HPFB recommendation to schedule *S. divinorum* under the CDSA was likely based on a misunderstanding of the (previously-described) criteria upon which scheduling decisions are made within the Healthy Environments and Consumer Safety Branch (HECSB). In particular, it did not consider a number of factors, including potential for abuse and risk to public health and safety. The Office of Controlled Substances (OCS) was also not consulted by HPFB at the time this recommendation was made. In addition, among countries who have decided to control *S. divinorum* in some way, very little or no substantiation of the risks of *S. divinorum* upon which the decision was based are available,

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Neither *Salvia divinorum* nor salvinorin A meet the criteria for scheduling a substance under the CDSA. Despite being regulated in some jurisdictions, neither the plant nor salvinorin A are scheduled under any of the UN Drug Control Conventions. *S. divinorum* and salvinorin A are not structurally or pharmacologically similar to other substances included in the schedules to the CDSA. There are also currently no legitimate therapeutic or industrial uses for *S. divinorum*. The abuse liability and potential for dependence of *S. divinorum* is not known as very few controlled scientific studies of its physical and psychotropic effects have been carried out on humans. The extent of actual abuse of *S. divinorum* is also largely unknown. Evidence of a risk to public health and safety is anecdotal in nature and not quantified in any way as there is a lack of information regarding abuse in Canada.

## 8. RECOMMENDATIONS



s.21(1)(a)  
s.21(1)(b)

## 9. CONSULTATIONS

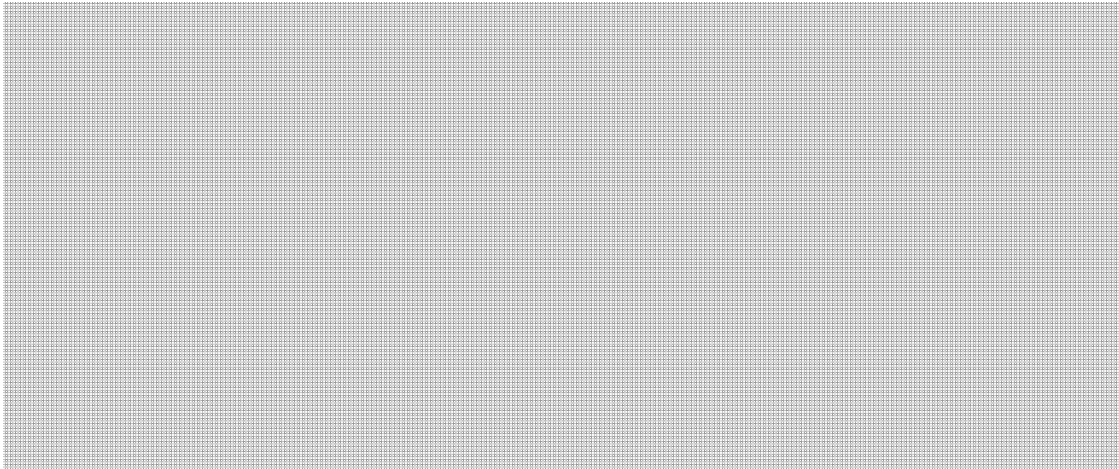
<sup>58</sup> Munro, T. The Chemistry of *Salvia divinorum*. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

The Drug Analysis Services (DAS) was contacted in order to provide any data available regarding the identification of salvinorin A in samples submitted by law enforcement.

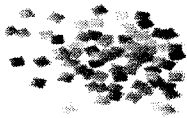
The Royal Canadian Mounted Police (RCMP) was contacted in order to establish their views with respect to *S. divinorum* use in Canada. The RCMP advised that though *S. divinorum* is readily available, it does not appear to pose a threat to public safety.

OCS has received a number of correspondences from Canada Border Services Agency (CBSA) officers concerning a lack of information regarding the status of *S. divinorum* and how the plant should be treated at the border. CBSA officers have also expressed concern regarding the plant's hallucinogenic properties. At present, only shipments of *S. divinorum* that are represented as health products that modify organic functions can be refused for import under the NHPR.


#### 10. IMPLEMENTATION AND EVALUATION



s.21(1)(a)  
s.21(1)(b)



Tiffany  
Thornton/HC-SC/GC/CA  
2010-09-09 04:02 PM

To Colette Strnad/HC-SC/GC/CA@HWC, Collin  
Pinto/HC-SC/GC/CA@HWC, Evelyn  
Soo/HC-SC/GC/CA@HWC, Hanan  
cc Isabel Shanahan/HC-SC/GC/CA@HWC, Laura  
Cooney/HC-SC/GC/CA@HWC, Valence  
Nebie/HC-SC/GC/CA@HWC, Bruna  
bcc  
Subject CSS-WG Meeting Agenda & ROD 

Hi everyone,

Please find attached the draft agenda for the CSS-WG meeting on **Wednesday September 15th from 10-11:30 in Rm 405A, 123 Slater Street.**

I have also attached the ROD from the meeting in August and supporting documentation for your review. Thanks very much to Robin for providing the revisions for the IAS and the background information on Salvia - much appreciated!

Should you wish to participate in the meeting via teleconference please give me advance notice (1 day) so that I can make arrangements..

Thanks,  
Tiffany  
946-3590

**Draft Agenda - September 15th:**

- 1- Members' introduction
- 2- Approval of Agenda
- 3 - Approval of ROD from August 2010
  - recommendation on scheduling Salvia
- 4- Update on CDSA Scheduling Process
  - ADM briefing scheduled? (Jocelyn)
- 5- Update
  - updates on any emerging issues relevant to the WG's activities
- 6- Next steps i.e next meeting scheduled for October 13th

**August 2010 ROD:**



CSS-WG Aug 2010 Meeting RODt.doc



Media Monitoring.doc

Media Monitoring Attachment (Item #5 on ROD)

**Comments from Robin regarding Salvia IAS & other background info:**



Draft Salvia Divinorum IAS\_July 12 2010 ed by NHPD RMarles.doc



Background info Salvia.doc



Richters Product Listing Salvia divinorum.pdf



Salvia divinorum Vancouver Seed Bank.pdf



# Issue Analysis Summary

DRAFT

Scheduling *Salvia Divinorum* and/or Salvinorin A under the CDSA

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Policy and Regulatory Affairs Division  
Office of Controlled Substances

Controlled Substances and Tobacco and Directorate

July 12, 2010

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1. APPROVALS
2. ISSUE
3. PURPOSE
4. CONTEXT
5. ASSESSMENT OF RISKS AND BENEFITS
6. IDENTIFICATION AND ANALYSIS OF OPTIONS
7. CONSIDERATIONS
8. RECOMMENDATION(S)
9. CONSULTATIONS
10. IMPLEMENTATION AND EVALUATION

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### 1. APPROVALS

This Issue Analysis Summary is approved.

\_\_\_\_\_  
Diane Allan, Director  
Office of Controlled Substances  
Tobacco and Drugs Directorate

\_\_\_\_\_  
[DD/MM/2010]

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2. PURPOSE¶
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6. CONSULTATIONS¶
7. CONSIDERATIONS¶
8. SELECTED STRATEGY¶
9. IMPLEMENTATION AND EVALUATION¶
10. OUTCOME EVALUATION¶

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### 2. ISSUE

Health Canada has received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *S. divinorum*, and/or its main active ingredient salvinorin A, neither of which are currently regulated under the *Controlled Drugs and Substances Act* (CDSA). These requests are further to reports from scientific and media sources suggesting that *S. divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has also noted an

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ongoing media interest regarding the availability of *S. divinorum* in Canada.

3. PURPOSE

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To assess *Salvia divinorum* and/or salvinorin A against the criteria for the addition of a substance to one of the Schedules to the CDSA, and determine whether one or both should be regulated as controlled substances in Canada.

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4. CONTEXT

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*Salvia divinorum* is a species of sage which belongs to the mint family, and which is found in the form of dried leaves, extract and plant cuttings. Also known as "diviner's sage", the plant is known to induce illusions and hallucinations when chewed or smoked. Salvinorin A, the psychoactive ingredient in *S. divinorum* (also referred to chemically as a neoclerodane diterpene) is found primarily in the leaves, and to a lesser extent in the stems.<sup>1</sup>

*S. divinorum* is widely touted as a "legal" hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs among adolescents and young adults.<sup>2</sup> While very little is known about how and where *S. divinorum* is sold in Canada, it is suspected that it is mainly purchased over the Internet and/or bought at head shops or alternative life style stores, etc.

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The use of *S. divinorum* as a psychotropic agent first came to Health Canada's attention in 2002. In 2004, Health Canada received four adverse drug reaction (ADR) reports associated with the use of *S. divinorum* as a hallucinogen, with three being considered non-serious (requiring no medical attention) and the fourth being considered serious (medical intervention was required) The serious ADR report involved the concomitant use of alcohol in a person diagnosed with Attention Deficit Disorder.

Further to the receipt of the aforementioned ADRs, the Marketed Health Products Directorate (MHPD) and the Natural Health Products Directorate (NHPD) of the Health Products and Food Branch (HPFB) prepared an issue analysis summary (IAS), which recommended that *S. divinorum* and its active ingredient salvinorin A be regulated as controlled substances. This recommendation was maintained when the IAS was updated in November 2006.

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Later, in December 2005, MHPD and NHPD prepared a Signal Assessment (SA) (updated in June 2007) that eventually led to the preparation of a Health Risk Assessment (HRA), which concluded that *S. divinorum* or salvinorin A-containing health products would constitute a Type II Health Risk according to the Health Hazard Classification of the Recall Policy of the Health

Deleted: should be restricted from over-the-counter use. Should any such unauthorized health products be found on the Canadian market, they should be removed from sale. Such products

<sup>1</sup> U.S. Department of Justice Drug Enforcement Administration. 2002. Drugs and Chemicals of Concern: Salvia Divinorum (salvinorin A, divinorin A) URL:

[http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm) Nov 2008

<sup>2</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.

Products and Food Branch Inspectorate (HBFBI). Such a risk is defined as “a situation in which the use of, or exposure to, a product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote”.

Further to an Assistant Deputy Minister (ADM) discussion in April 2007, the Drug Strategy and Controlled Substances Directorate (DSCSD) organized a meeting with MHPD, NHPD and HPFBI to discuss *S. divinorum*. HPFBI was to determine appropriate compliance activities regarding *S. divinorum* and consult with the Canada Border Services Agency (CBSA) regarding the movement of products containing *S. divinorum* into and out of Canada.

On September 13, 2007, a further meeting between DSCSD, MHPD, NHPD and HPFBI led to the conclusion that DSCSD would conduct a scheduling assessment of *S. divinorum* in order to explore the possibility of scheduling this substance under the CDSA.

In September 2008, the Director Generals of DSCSD, MHPD, TPD and the HPFBI agreed that media lines and an “It’s Your Health” article on *S. divinorum* would be prepared.

#### 4.1 Relevant Legislative Frameworks in Canada

##### 4.1.1 Food and Drug Regulations (under the Food and Drugs Act)

The *Food and Drug Regulations* (F&DR) serve to ensure the safety, efficacy, and quality of health products offered for sale in Canada, including drugs and medical devices. Prior to being given market authorization, a manufacturer must present substantive scientific evidence that a product is safe, efficacious and of high quality. For drugs, Health Canada reviews this information carefully and, if the review is satisfactory, a Notice of Compliance (NOC) is issued and appropriate Drug Identification Numbers (DINs) are assigned.

A “drug” is defined under the F&DR as any substance or mixture of substances manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
- (b) restoration, correction or modification of organic functions in human beings or animals, or
- (c) disinfection in premises in which food is manufactured, prepared or kept;

As no products containing *S. divinorum* or its extracts have been reviewed and approved by Health Canada as of July 2010, it is illegal to market *S. divinorum* when it is represented as a drug.

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4.1.2 Natural Health Products Regulations (under the Food and Drugs Act)

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The Natural Health Products Regulations (NHPR) aim to provide Canadians with ready access to natural health products (NHPs) that are safe, effective, and of high quality, while respecting freedom of choice and philosophical and cultural diversity. The NHPR require that all licensed products display a Natural Product Number (NPN), or, in the case of a homeopathic medicine, a Drug Identification Number - Homeopathic Medicine (DIN-HM), on their labels. These numbers are issued once a product is authorized for sale in Canada, further to the submission of a product licence application in which the applicant attests to all of the conditions set out in a natural health product monograph prepared and published by the Natural Health Products Directorate or submission of a product licence application that provides sufficient evidence of quality, safety and efficacy that is assessed and approved by NHPD by the non-compendial route. The NHPR also require that all manufacturers, packagers, labelers, and importers be licensed which in turn requires the presence of procedures respecting distribution records, product recalls, product handling, storage and delivery, and all other aspects of Good Manufacturing Practices as set out in the NHPR.

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The definition of an NHP under the NHPR has both a function and substance component. The function component refers to those substances that are manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
- (b) restoring or correcting organic functions in humans; or
- (c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

Deleted: To be considered a NHP, no direct health claims need to be made regarding the substance

The substance component refers to the requirement that all of the medicinal ingredients of an NHP must be substances set out in Schedule 1 to the NHPR, which is a list of included substances, substances that are traditional medicines or that are homeopathic medicines, and that none of the ingredients are substances set out on Schedule 2 which is a list of excluded substances, e.g. any substance listed on Schedules I to V of the Controlled Drugs and Substances Act. Section 2(2) of the NHPR excludes those substances (except homeopathic medicines) whose sale is required to be pursuant to a prescription as per Section C.01.043 and thus Schedule F to the F&DR. As per section 93(1)(b)(vi) of the NHPR, every natural health product must be labeled with its authorized recommended use or purpose. In the case of *S. divinorum*, it is generally marketed for its hallucinogenic properties which are considered a modification of an organic function. Therefore, products containing it and manufactured, sold or represented for that purpose meet the definition of an NHP.

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As of July 2010, no products containing *S. divinorum* have been reviewed and approved by Health Canada and no NPNs or DIN-HMs have been issued. Therefore sales of *S. divinorum* are

illegal under the NHPR if it is represented for use as a hallucinogen or if other health claims such as with regard to modifying organic functions are made.

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#### 4.1.3 Controlled Drugs and Substances Act and its Regulations

The CDSA provides a legislative framework for the control of substances that can alter mental processes and that may produce harm to the health of an individual or to society when diverted or misused. Except as authorized under its regulations, activities such as possession, possession for the purposes of trafficking, trafficking, importation, exportation, possession for the purposes of exportation and production of controlled substances are prohibited under the CDSA.

The substances regulated under the CDSA are grouped into eight Schedules, and each Schedule is associated with particular offences and penalties as described in Part I of the CDSA.

In determining whether a substance should be regulated as a controlled substance, and into which Schedule of the CDSA it should be placed, Health Canada considers the following factors:

- International requirements and trends in the control and/or scheduling of the substance;
- Chemical and/or pharmacological similarity to substances listed in the Schedules to the CDSA;
- Legitimate use of the substance, including therapeutic, scientific, industrial or commercial uses;
- Potential for abuse and/or addiction liability of the substance;
- Evidence of extent of actual abuse of the substance in Canada and internationally; and
- Risk to personal and public health and safety.

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#### 4.2 Assessment of *Salvia Divinorum* for Scheduling Purposes

##### 4.2.1 International Requirements and Trends in the Control and/or Scheduling of the Substance

At the present time, neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and therefore do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

##### *Australia*

In June 2002, Australia became the first country to prohibit the sale, supply, possession and use of *S. divinorum* and salvinorin A. Although both *S. divinorum* and salvinorin A are listed in Schedule 9 of Australia's Standard for the Uniform Scheduling of Drugs and Poisons on the basis of "high potential for abuse and risk to public health and safety", no substantiation of this risk was provided at the time of this scheduling decision.<sup>3</sup> Schedule 9 is Australia's most

- Deleted: International requirements and trends in control/scheduling;¶
- Chemical and pharmacological similarity to other substances already scheduled under the CDSA;¶
- Legitimate uses of the substance (i.e. therapeutic, industrial or commercial);¶
- Potential for abuse and/or addiction liability of the substance;¶
- Extent of actual abuse in Canada and internationally; and¶
- Overall risk to public health and safety of Canadians.
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<sup>3</sup> <http://www.tga.gov.au/ndpsc/record/rr200111.pdf>

restrictive drug schedule, and includes “substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities.”<sup>4</sup>

### Belgium

A decree was passed in Belgium on October 22, 2006 which added *S. divinorum* to the list of controlled substances. This list includes substances such as psilocybin mushrooms, khat and peyote cactus.<sup>5</sup>

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### Denmark

In 2003, Denmark added *S. divinorum* and salvinorin A to their list of “category B” controlled substances, a category which also includes psilocybin mushrooms, cocaine, amphetamine, and several others substances that are only legal for medicinal and scientific purposes. Illegal possession carries a penalty of up to two years in prison.

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### Germany

*S. divinorum* (plant and plant parts) was added to Appendix I of the *Narcotics Act* in Germany on March 1, 2008, making it illegal to produce, traffic, or possess. The law does not specifically mention salvinorin A.

### Italy

On June 25, 2004, the Italian Ministry of Health issued an ordinance prohibiting the sale of *S. divinorum* and its active constituent salvinorin A. On January 11, 2005, the Ministry of Health made possession of *S. divinorum* and salvinorin A illegal by placing them in “*Tabella 1*” of the *Tabelle Sostanze Stupefacenti o Psicotrope*.

### Japan

On November 9, 2006, the Japanese government added a group of thirty-three drugs to its list of controlled substances, including salvinorin A. The drugs are banned under a revised pharmaceutical law, under which persons involved in their illegal import, production, and sale, i.e., beyond medical treatment or research purposes, will be subject to up to five years imprisonment or a fine of up to five million yen.

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### Spain

<sup>4</sup> [http://www.cognitiveliberty.org/news/salvia\\_australia.htm](http://www.cognitiveliberty.org/news/salvia_australia.htm)

<sup>5</sup> <http://eldd.emcdda.europa.eu/html.cfm/index5176EN.html?pluginMethod=eldd.shownewsdetails&id=20/12/2006BELGIUM:%20New%20substances%20controlled%20include%20mCPP%20and%20khat>

On January 28, 2004, the Spanish Ministry of Health and Consumption issued an order prohibiting the sale of *S. divinorum*. The regulation went into effect on May 6, 2004 and only prohibits activities related to commerce. Possession and/or use are not considered to be criminal offences.

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**Other Countries**

*Salvia divinorum* is illegal to possess or sell in Croatia, Latvia, Lithuania, Poland, Romania, South Korea and Sweden. In Russia it is illegal to grow or sell *S. divinorum*, but it is legal to possess it. In Estonia, Finland, Iceland and Norway, *S. divinorum* is treated as a medicinal herb and it is illegal to import it without a relevant prescription from a doctor.

**United States of America**

*S. divinorum* and salvinorin A are not included in the Schedules to the United States Controlled Substances Act although both *S. divinorum* and salvinorin A have been added to a list of chemicals "of concern" which has no legal implications. In addition, some individual states have implemented laws restricting its use, sale and/or distribution. As of July 2010, a number of states have enacted legislation placing regulatory controls on *S. divinorum* and/or salvinorin A including Delaware, Georgia, Florida, Hawaii, Illinois, Kansas, Kentucky, Maryland, Mississippi, Missouri, Nebraska, North Dakota, Ohio, Oklahoma, South Dakota, Wisconsin, Virginia, California, Louisiana, Maine, North Carolina, and Tennessee. More details regarding the regulation of *S. divinorum* in these last five states are provided below.

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¶

**California**

As of January 1, 2009, the sale or distribution of *S. divinorum* or salvinorin A, or any substance or material containing *S. divinorum* or salvinorin A, to any person under 18 years of age is a misdemeanor punishable by imprisonment in a county jail for not more than six months, a fine of no more than \$1,000, or both.

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**Louisiana**

In 2005, Louisiana passed a bill which prohibits the possession, production, manufacture and distribution of a material, compound, mixture, or preparation intended for human consumption and that contains a hallucinogenic plant. A "hallucinogenic plant" is defined as "any part or portion" of a plant on a list of forty plants, which includes *S. divinorum*.

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**Maine**

In Maine, *S. divinorum* and salvinorin A are regulated in the same way as tobacco products; adults eighteen years of age or over can legally purchase and use the material,

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but selling or providing *S. divinorum* or salvinorin A to anyone under the age of eighteen is a criminal offence. Possession by a minor is a civil violation, punishable by a fine, community service, or both.

### North Carolina

On December 1, 2009, the North Carolina State Legislature brought a new law into force which made *Salvia divinorum* and salvinorin A illegal. The only legal *S. divinorum* activities are the growing for aesthetic, landscaping, or decorative purposes or university-affiliated medical or pharmacological research.

### Tennessee

On July 1, 2006, Tennessee classified the deliberate production, manufacture, distribution, or possession of the active chemical ingredient in the hallucinogenic plant *S. divinorum* as a Class A misdemeanor. It is not, however, a criminal offence to possess, plant, cultivate, grow, or harvest *S. divinorum* for aesthetic, landscaping, or decorative purposes. The law also does not apply to any dosage that is legally obtainable from a retail establishment without a prescription when (and if) it is recognized by the Food and Drug Administration as a homeopathic drug.

#### 4.2.2 Chemical and/or Pharmacological Similarity to Substances listed in the Schedules to the CDSA

The psychoactive ingredient in *Salvia divinorum* is salvinorin A. Other plants which contain psychotropic terpenoids are *Artemisia absinthium* (wormwood) and *Cannabis sativa*. Salvinorin A is considered by some as the most potent natural hallucinogen ever isolated.<sup>6</sup>

Unlike all other hallucinogens, salvinorin A is structurally distinct and does not interact with the serotonin-2A receptor or any other molecular target of classical hallucinogens. It thus affects the brain in a way that is quite unique.<sup>7</sup> Recent pharmacological screenings of receptors have found it to be a highly potent and selective  $\kappa$ -opioid receptor (KOR) agonist.<sup>8</sup>

The use of *S. divinorum* or salvinorin A can lead to a number of effects with variable onset and duration. These effects are generally accepted to be: sensation of becoming an object, visions of

<sup>6</sup> Ott J. Ethnopharmacognosy and human pharmacology of *Salvia divinorum* and salvinorin A. *Curare*. 1995 18: 103-129. Unofficial transcription available online. URL <http://www.sagewisdom.org/ott2.html>

<sup>7</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>8</sup> Roth BL, Baner K, Westkaemper R, Siebert D, Rice KC, Steinberg S, Ernsberger P, Rothman RB. Salvinorin A: a potent naturally occurring nonnitrogenous kappa opioid selective agonist. *Proc Natl Acad Sci U S A*. 2002 Sep 3;99(18):11934-9.

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Deleted: Schedule I controlled substances in that state. This bill was later amended to make possession of *S. divinorum* an infraction, a minor crime punishable by a maximum \$25 fine. A third possession offence would be charged as a misdemeanor. There are no separate penalties for manufacturing or sales. This bill includes two exemptions. One permits

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various two-dimensional surfaces, films and membranes, revisiting places of the past (particularly childhood), perceived loss of the body and/or identity, various sensations of motion (being pulled or twisted by a force of some kind), uncontrollable hysterical laughter, and overlapping realities (perceptions of being in more than one place).<sup>9</sup> Laughter, happiness, sense of well-being and dissociative effects were deemed the best aspects of *S. divinorum* by users, second only to the "trip" that the drug elicits.<sup>10</sup> Depersonalization, speaking gibberish, widening of consciousness and subjective illusions of rapid movement, flying or hovering have also been reported.<sup>11</sup>

The psychomimetic effects of *S. divinorum* closely resemble schizophrenia symptoms induced by lysergic acid diethylamide (LSD) or phencyclidine (PCP).<sup>14</sup> Yet, it is said to have only weak influence on the prevailing mood of the user which differentiates it from other hallucinogens such as LSD and psilocybin.<sup>15</sup> Its strong dissociative effects are often compared to those of ketamine. Users have reported that the psychedelic effects of *S. divinorum* were most similar to those caused by psilocybin mushrooms.<sup>16</sup> However, users familiar with the effects of other hallucinogens agree that despite certain similarities to classical hallucinogens, the visions and overall experience are quite unique.<sup>17</sup>

**Deleted:** Unlike all other hallucinogens, salvinorin A is structurally distinct and does not interact with the serotonin-2A receptor or any other molecular target of classical hallucinogens. It thus affects the brain in a way that is quite unique.<sup>12</sup> Recent pharmacological screenings of receptors have found it to be a highly potent and selective κ-opioid receptor (KOR) agonist.<sup>13</sup>

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In addition, the psychedelic effects of *S. divinorum* are similar to those of classical psychedelics regarding changes in perception and somatic sensations. *S. divinorum* causes an unusually high degree of sedation, weakness and fatigue, while the increased de-realization is not commonly reported for classical psychedelics.<sup>18</sup> The combination of these effects seems to correlate with

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<sup>9</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>10</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>11</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5 and Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>14</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5.

<sup>15</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>16</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>17</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6 and González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>18</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

that of other KOR agonists such as pentazocine.<sup>19</sup>

**4.2.3 Legitimate Use of the Substance, including Therapeutic, Scientific, Industrial or Commercial Uses**

*Salvia divinorum* has traditionally been used for spiritual and medicinal purposes by the Mazatec Indians in Oaxaca, Mexico,<sup>20</sup> where an infusion of the leaves or the leaves themselves are ingested to treat gastrointestinal problems, headaches, rheumatism, anemia and swelling of the stomach.<sup>21</sup> Its main use today is, however, for its psychoactive properties in the aid of producing "mystical" or hallucinogenic experiences as part of spiritual rituals.<sup>22</sup>

Although selective kappa receptor agonists have been shown to produce analgesic effects, adverse effects such as psychotomimesis, dysphoria and diuresis have been observed in studies investigating their therapeutic use.<sup>23</sup> In addition, while it has been speculated that KOR agonists may prove to be useful in the treatment of certain psychiatric disorders including Alzheimer's disease, schizophrenia, dementia and bipolar disorder,<sup>24</sup> much more research is needed in order to substantiate these hypotheses. Similarly, another study has suggested that chemical analogues of salvinorin A may be a useful treatment for those suffering from addiction to other substances.<sup>25</sup> That said, there are presently no legitimate medical uses for *S. divinorum* in Canada.

Similarly, there are no known industrial or commercial uses for *S. divinorum* in Canada. The plant is a semi-tropical perennial that can only grow outdoors in a humid climate where it will not encounter frost. Most websites offering *S. divinorum* cuttings and seeds for sale appear to do so in the context of growing the plant in order to utilize its psychoactive properties, rather than out of horticultural interest or for its esthetic appeal.

**4.2.4 Potential for Abuse and/or Addiction Liability of the Substance**

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<sup>19</sup> Arasteh K, Poudevida S, Farre M, Roset PN, Cami J. Response patterns of the Spanish version of the 49-item short form of the Addiction Research Center Inventory after the use of sedatives, stimulants, and opioids. *Drug Alcohol Depend.* 1999 Jun 1;55(1-2):117-25.

<sup>20</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>21</sup> Munro, T. The Chemistry of *Salvia divinorum*. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

<sup>22</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage *Salvia divinorum*. *Life Sci.* 2005 Dec 22;78(5):527-31.

<sup>23</sup> Barker RL, Fawcett J, Barkin SJ. 2002. Chronic pain management with a focus on the role of newer antidepressants and centrally acting agents. In: *Pain Management: A Practical Guide for Clinicians*, 6th edition, Weiner RS ed. CRC Press, Boca Raton, FL. pp. 415-34 and Tidgewell et al., 2004. A facile method for the preparation of deuterium labelled salvinorin A: *Biorganic & Medicinal Chemistry Letters*, 14: 5099-5102.

<sup>24</sup> Sheffler DJ & Roth BL. Salvinorin A: the 'magic mint' hallucinogen finds a molecular target in the kappa opioid receptor. *Trends Pharmacol Sci.* 2003 Mar;24(3):107-109.

<sup>25</sup> Prisinzano TE. Natural products as tools for neuroscience: discovery and development of novel agents to treat drug abuse. *J Nat Prod.* 2009 Mar 27;72(3):581-7.

Salvinorin A is a potent, selective agonist of the  $\kappa$ -opioid receptor (KOR), and in contrast to the euphoria produced by  $\mu$ -opioid receptor (MOR) agonists, KOR agonists are negatively reinforcing and aversive.<sup>26</sup> In addition, KOR agonists have analgesic properties but are not associated with respiratory depression like MOR agonists. Finally, while MOR agonists increase the release of dopamine, the activation of KOR decreases dopamine release in the nucleus accumbens.<sup>28</sup>

The onset and intensity of the effects of *Salvia divinorum* appear to be related to the route of administration.

Traditional uses generally produce mild effects because the leaves are rolled and chewed or crushed and prepared as a foamy infusion whereby the salvinorin A is degraded in the gastrointestinal system before being absorbed into the bloodstream. Hence, the level of effect relates quite closely to the length of time the material spends in the mouth, with the onset of effect generally taking 5-10 minutes. The effects build over the next hour and last for another hour before they begin to subside.<sup>29</sup>

Routes of administration that avoid the hepatic first-pass effect (i.e. inhalation, intravenous, intramuscular and sublingual use) are the quickest and most intense.<sup>30</sup> Salvinorin A can be isolated from the plant to make a powder which can be vaporized and inhaled. The onset of effects felt from vaporizing salvinorin A powder occurs in about 30 seconds and effects last for about 5-10 minutes and then subside over the next 30 minutes.<sup>31</sup>

Smoking is by far the most popular method of administration<sup>32</sup> and this is accomplished by smoking the dried leaves or a concentrated extract using a pipe or bong. Dried leaves may also

**Deleted:** Most clinically used opioid analgesics (e.g. codeine, oxycodone, morphine) are selective for the  $\mu$ -opioid receptor (MOR) and can be habit-forming because activation of the MORs causes euphoria, which makes the user want to take them again. As previously mentioned, s

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<sup>26</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590, Cooper S. Interactions between endogenous opioids and dopamine: Implications for reward and aversion. In: *The Mesolimbic Dopamine System: From Motivation to Action*. Willner P and Scheel-Kruger J (editors) Wiley, Chester, England, 1991, pp. 331-366, and Shippenberg TS, Herz A, Spanagel R, Bals-Kubik R, Stein C. Conditioning of opioid reinforcement: neuroanatomical and neurochemical substrates. *Ann N Y Acad Sci*. 1992 Jun 28;654:347-56.

<sup>28</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.

<sup>29</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>30</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

<sup>31</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>32</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62 and Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

be fortified with a concentrated extract of salvinorin A. A concentrated extract can also be used sublingually. Neither *S. divinorum* nor salvinorin A can be injected because the powder is insoluble in water.<sup>33</sup>

The aversive effects of previously studied KOR agonists predict that the risk of addiction to *S. divinorum* is negligible. However, very few controlled scientific studies of the physical and psychotropic effects of *S. divinorum* on humans have been carried out. Therefore, it is difficult to predict its potential for addiction and abuse. In studies that have been conducted, there is conflicting information around the addiction liability of *S. divinorum* in both animals and humans. Some users have noted that they require increasing doses of salvinorin A in order to achieve the desired effect and the stimulated cerebral KOR may act as a mechanism of tolerance.<sup>37</sup> Further studies in this area and on the mediated decrease of dopamine as well as the impact of dose on effects are also required.

While concerns for the potential of abuse were once minimal because 1 kg of dried leaves yields only 3 to 6 human doses of salvinorin A, it was discovered that vaporizing and inhaling 200-500 micrograms had profound hallucinogenic effects.<sup>38</sup> The extraction of salvinorin A from the plant is very easy, and with care, approximately 1.5 grams of pure salvinorin A per kilogram of dried leaves (8kg of fresh leaves) can be isolated. This is enough substance to provide for 2000 human doses.<sup>39</sup>

#### 4.2.5 Evidence of Extent of Actual Abuse of the Substance in Canada and Internationally

In Canada, the extent of actual abuse of *Salvia divinorum* and/or salvinorin A is relatively unknown. There is, however, some data regarding the use of *Salvia divinorum* in Canada, despite the lack of legitimate uses for this plant. Questions about the use of *S. divinorum* were

<sup>33</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs*. 1994 Jul-Sep;26(3):277-83.

<sup>37</sup> Bucheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>38</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>39</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs*. 1994 Jul-Sep;26(3):277-83.

<sup>44</sup> Turner DM. *Salvinorin - The Psychedelic Essence of Salvia Divinorum*. Panther Press, San Francisco, CA 1996.

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The various modes of administration of *S. divinorum* lead to the variable onset and duration of its effects. These effects are generally accepted to be: sensation of becoming an object, visions of various two-dimensional surfaces, films and membranes, revisiting places of the past (particularly childhood), perceived loss of the body and/or identity, various sensations of motion (being pulled or twisted by a force of some kind), uncontrollable hysterical laughter, and overlapping realities ... [1]

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included in the 2008-2009 Youth Smoking Survey, the 2009 Canadian Alcohol and Drug Use Monitoring Survey and the 2009 Ontario Student Drug Use and Health Survey.

The results from the 2009 Ontario Student Drug Use and Health Survey were published on November 18, 2009 and indicate that:

- Among all responding students in Ontario, 4.4% reported using *Salvia divinorum* at least once in the past year. In comparison, 58.2% indicated they had used alcohol, 25.6% indicated they had used cannabis and 5.0% indicated they had used hallucinogens other than LSD and PCP in the past year;
- Males (6.2%) were significantly more likely than females (2.3%) to report using *Salvia divinorum*;
- There is significant grade variation, with *Salvia divinorum* use most likely among 11<sup>th</sup> graders (8.6%) and 12<sup>th</sup> graders (8.4%); and
- There are significant regional variations, with students in Northern Ontario (9.2%) most likely to use *Salvia divinorum*.

The results of the 2008-2009 Youth Smoking Survey were published on May 31, 2010 and indicate that:

- 4.9% of students stated that they had used *S. divinorum* in the last twelve months. In comparison, 53.0% indicated they had used alcohol, 27.3% indicated they had used cannabis and 6.9% indicated they had used other hallucinogens in the last twelve months;
- 2.6% of students in Grades 7-9 and 7.0% of students in Grades 10-12 had used *S. divinorum* in the last twelve months; and
- Males (6.6%) were more likely to have used *S. divinorum* in the past twelve months compared to females (3.2%).

The scope of the previously mentioned studies did not provide for any explanations regarding differences in usage between ages, genders and regions. In this regard, it is difficult to speculate on the causality of such differences.

The Canadian Alcohol and Drug Use Monitoring Survey specifically examined *Salvia* for the first time in 2009. An estimated 1.6% of Canadians, aged 15 years and older, reported that they had used salvia in their lifetime, and 0.2% reported using it in the past-year. In comparison, the prevalence of past-year cannabis use among Canadians 15 years of age and older was 10.6%. 1.2% of respondents reported using cocaine or crack in the past 12 months, 0.9% had used ecstasy and 0.7% used illicit hallucinogens.

Health Canada's Drug Analysis Services (DAS) has identified salvinorin A in a number of samples seized by law enforcement, as shown in the following table.

**NUMBER OF SAMPLES FOUND TO CONTAIN SALVINORIN A**

Year,	Count
2006	2

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¶ As far as law enforcement is concerned, the Department has only received a limited number of communications indicating concern with respect to *S. divinorum* and none of these have advised that the use of *S. divinorum* poses any threat to public safety. Sgt. Doug Culver of the Royal Canadian Mounted Police (RCMP) stated that while *S. divinorum* is readily available, it has not become a popular drug in Canada. Sgt. Culver speculated that this may be due to its aversive effects such as anxiety and introversion.¶

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2007	8
2008	4
2009	20
2010 (as of May 7)	8

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The National Forensic Laboratory Information System (NFLIS) and the System to Retrieve Information from Drug Evidence (STRIDE) in the United States are Drug Enforcement Agency (DEA) databases that collect scientifically verified data on analyzed samples in state and local forensic labs as well as samples from DEA labs. The following table shows the quantity of *S. divinorum* products that were seized from 2000 through to 2009.

**ANALYZED SALVIA DIVINORUM or SALVINORIN A SEIZURES**

(Number of Items/Exhibits)

Source	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009*
NFLIS-State/Local <sup>1</sup>	0	0	0	0	1	8	12	12	70	34
STRIDE <sup>2</sup>	0	0	1	1	1	0	0	0	N/A	N/A
<b>TOTAL</b>	0	0	1	1	2	8	12	12	70	34

Data Source: NFLIS & STRIDE, 2008 data queried 11/24/08, updated 06/10/2010

<sup>1</sup> NFLIS reported seizures of *Salvia divinorum* and/or salvinorin A

<sup>2</sup> STRIDE reported items of *Salvia divinorum*.

\* Includes only January – May data in 2009.

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 A handful of case reports regarding the use of *S. divinorum* have been published in the academic literature. One report was an international case report in which a young man (19 years of age) described his perceptions after inhaling smoke from *S. divinorum*. The peak psychotropic effects, including pricking of the skin, fever-like hot flashes, muscular tremor, and depersonalization, were reached in less than five minutes after inhalation of an unknown amount of smoke from burning dried leaves.<sup>41</sup> Another report involved a 15-year-old male who presented to psychiatric emergency services with acute onset of paranoia, déjà vu, blunted affect, difficulties in thought processing and slowed speech after smoking *Salvia divinorum* over an unknown period of time. During his hospitalization all symptoms improved significantly except the feeling of déjà vu. Based on this case presentation, the author suggested that the feelings of déjà vu may be a long-term effect of *S. divinorum* use.<sup>42</sup> However, given that this is the only case report in which déjà vu was associated with the use of *S. divinorum*, more reports are needed to substantiate this finding.¶  
 ¶  
 In addition to the above-mentioned reports, in 2006, a case was reported in the U.S. in which a 17-year-old boy committed suicide after smoking *S. divinorum* for an unknown period of time.<sup>43</sup> ¶  
 It should be noted that alcohol and general depression were the main confounders in this case. ¶  
 After this case was reported, the state of Delaware passed a law which classified *S. divinorum* as ¶ a Schedule I controlled substance along with other hallucinogenic substances.¶

It is difficult to determine the extent of actual abuse of *S. divinorum* in Canada or elsewhere as there appear to be inconsistencies in the literature regarding risk aversion. For example, one author states: "Many who have used salvinorin A find the experience extremely unnerving, frightening and overly intense and most have no desire to repeat the experience."<sup>44</sup> However, another study suggested that this is not the experience of all recreational users of *S. divinorum*.<sup>45</sup> Over eighty percent of users surveyed on a web-based questionnaire about their *S. divinorum* use said that they would probably or definitely use *S. divinorum* again.<sup>46</sup> Users have reported the negative effects of *S. divinorum* as: the short duration of action, lack of control over the experience, persisting negative effects (most often anxiety),<sup>47</sup> sweating, chills, increased diuresis, impaired vigilance,<sup>48</sup> and negative after-effects including tiredness, feeling head heavy, dizziness, physical exhaustion, and some degree of malaise or 'hangover' as they 'comedown' from the

<sup>45</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62, Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry.* 2005 Jan;38(1):1-5, and Valdés LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs.* 1994 Jul-Sep;26(3):277-83.

<sup>46</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>47</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>48</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry.* 2005 Jan;38(1):1-5.

drug.<sup>49</sup>

#### 4.2.6 Risk to Personal and Public Health and Safety

The increase in both the number of enquiries from various municipalities and members of the public and the amount of media interest regarding the availability of *Salvia divinorum* in Canada may be an indication that the recreational use of *S. divinorum* as a hallucinogen is on the rise. However, there are no available statistics that indicate there has been a significant increase in *S. divinorum* use in the Canadian population and, in comparison to the use of other drugs such as alcohol and cannabis, the actual use of *S. divinorum* is quite low.

The potential for harm to the user and/or other individuals is primarily related to the hallucinogenic properties of the substance. Users may get up and walk around without apparent awareness of their movements, behaviour or surroundings, and distinction between self and surroundings is often lost. At doses greater than 1mg of salvinorin A, out of body experiences are frequent and loss of consciousness has been reported.<sup>50</sup> There is little information regarding the social behaviours of persons under the influence of *S. divinorum* products, and what risks their activities such as operating a motorized vehicle may pose to the general public. There is also very little data regarding the toxicity, teratogenicity or other long-term effects of *S. divinorum* use.<sup>51</sup>

As far as law enforcement is concerned, the Department has only received a limited number of communications indicating concern with respect to *S. divinorum* and none of these have advised that the use of *S. divinorum* poses any threat to public safety. The Royal Canadian Mounted Police (RCMP) has stated that while *S. divinorum* is readily available, it has not become a popular drug in Canada, probably due to its aversive effects such as anxiety and introversion.

A handful of case reports regarding the use of *S. divinorum* have been published in the academic literature. One report was an international case report in which a young man (19 years of age) described his perceptions after inhaling smoke from *S. divinorum*. The peak psychotropic effects, including prickling of the skin, fever-like hot flashes, muscular tremor, and depersonalization, were reached in less than five minutes after inhalation of an unknown amount of smoke from burning dried leaves.<sup>52</sup> Another report involved a 15-year-old male who presented to psychiatric emergency services with acute onset of paranoia, déjà vu, blunted affect, difficulties in thought processing and slowed speech after smoking *Salvia divinorum* over an unknown period of time. During his hospitalization all symptoms improved significantly except the feeling of déjà vu. Based on this case presentation, the author suggested that the feelings of déjà vu may be a long-term effect of *S. divinorum* use.<sup>53</sup> However, given that this is the only case report in which déjà vu was associated with the use of *S. divinorum*, more reports are needed to

<sup>49</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>50</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>51</sup> Grundmann O, Phipps SM, Zadezensky I, Butterweck V. *Salvia divinorum* and Salvinorin A: An Update on Pharmacology and Analytical Methodology. *Planta Med.* 2007 Jun;73:1039-1046.

<sup>53</sup> Singh S. (2007) Adolescent salvia substance abuse. *Addiction.* 102, 823-824.

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substantiate this finding.

In addition to the above-mentioned reports, in 2006, a case was reported in the U.S. in which a 17-year-old boy committed suicide after smoking *S. divinorum* for an unknown period of time.<sup>54</sup> It should be noted that alcohol and general depression were the main confounders in this case. After this case was reported, the state of Delaware passed a law which classified *S. divinorum* as a Schedule I controlled substance along with other hallucinogenic substances.

Like many drugs of abuse, users are often unaware of the potency and adulterants in the product they purchase. A study by Wolowich *et al.* (2006)<sup>55</sup>, showed that the salvinorin A content in five out of five *S. divinorum* products was falsely indicated on the label and 4 out of 5 products contained unidentified adulterants (i.e. vitamin E, caffeine).

Health Canada has only anecdotal information about the use and abuse of *S. divinorum* in Canada as well as the threat *S. divinorum* may pose to the health and safety of Canadians. There are several reports of domestic adverse reactions related to the use of *S. divinorum* that have been received through the Canada Vigilance database. However, this does not reflect true incidence due to under-reporting. Considering also the limited population exposure information, it is not possible to adequately characterize the risk to the general population.

## 5. ASSESSMENT OF RISKS AND BENEFITS

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**Deleted:** As stated earlier, there are no approved medical uses for *S. divinorum* in Canada. Health Canada has also neither received nor approved any submissions for natural health products for sale in Canada. Therefore, products that claim to contain this substance have not been extensively reviewed by Health Canada and as such, may be counterfeit or may contain other ingredients that may pose health risks.

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de la Loi sur l'accès à l'information**

## 9. CONSULTATIONS

<sup>58</sup> Munro, T. The Chemistry of Salvia divinorum. PhD dissertation, 2006. Accessed from:  
<http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

The Drug Analysis Services (DAS) was contacted in order to provide any data available regarding the identification of salvinorin A in samples submitted by law enforcement.

The Royal Canadian Mounted Police (RCMP) was contacted in order to establish their views with respect to *S. divinorum* use in Canada. The RCMP advised that though *S. divinorum* is readily available, it does not appear to pose a threat to public safety.

OCS has received a number of correspondences from Canada Border Services Agency (CBSA) officers concerning a lack of information regarding the status of *S. divinorum* and how the plant should be treated at the border. CBSA officers have also expressed concern regarding the plant's hallucinogenic properties. At present, only shipments of *S. divinorum* that are represented as health products that modify organic functions can be refused for import under the NHPR.

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## 10. IMPLEMENTATION AND EVALUATION

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The various modes of administration of *S. divinorum* lead to the variable onset and duration of its effects. These effects are generally accepted to be: sensation of becoming an object, visions of various two-dimensional surfaces, films and membranes, revisiting places of the past (particularly childhood), perceived loss of the body and/or identity, various sensations of motion (being pulled or twisted by a force of some kind), uncontrollable hysterical laughter, and overlapping realities (perceptions of being in more than one place).<sup>1</sup> Laughter, happiness, sense of well-being and dissociative effects were deemed the best aspects of *S. divinorum* by users, second only to the "trip" that the drug elicits.<sup>2</sup> Depersonalization, speaking gibberish, widening of consciousness and subjective illusions of rapid movement, flying or hovering have also been reported.<sup>3</sup>

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More controlled systematic research in this area is needed.

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the rewarding and aversive

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Another aspect of the *S. divinorum* abuse potential stems from its availability. As previously mentioned, it is widely available for purchase on the Internet through drug promotional sites and it is also sold in various "head shops" and corner stores. In addition, the potential for high yields and ease of extraction may make buying and selling this substance quite affordable and attractive. Originally, t

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Therefore, a gram of salvinorin A is enough

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It is also believed to be easier to obtain salvinorin A than to extract LSD or produce PCP derivatives.<sup>4</sup>

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Extent of Actual Abuse in Canada and Internationally

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<sup>1</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>2</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>3</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry.* 2005 Jan;38(1):1-5 and Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>4</sup> Bucheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry.* 2005 Jan;38(1):1-5.

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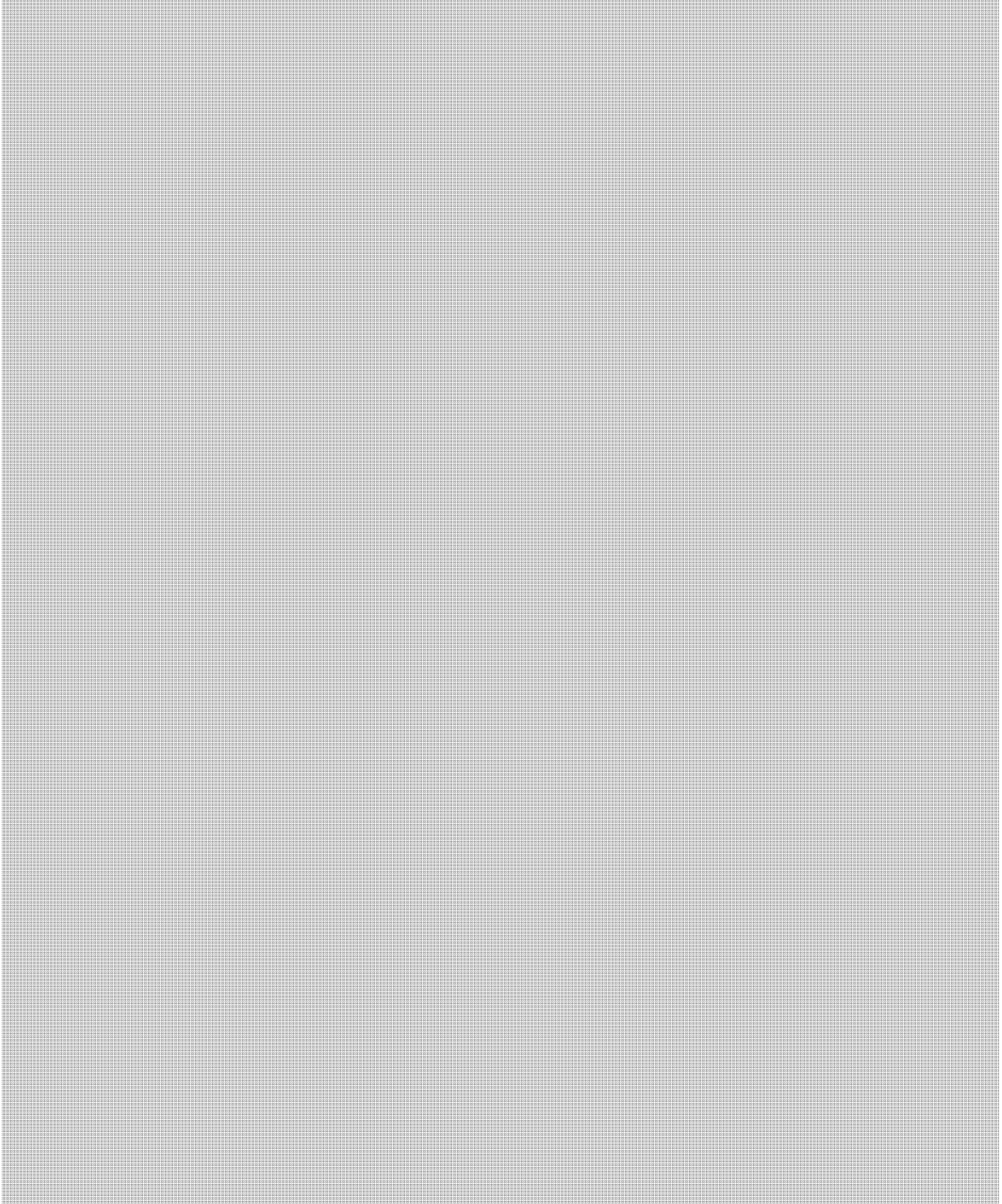
across the Canadian population

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# Protected B Draft

**Record of Discussion (ROD)**  
**Controlled Substances Scheduling (CSS) Working Group Meeting**  
**Wednesday August 18<sup>th</sup>, 2010, 10-12:00am**  
**123 Slater Street, Rm 405A**

***Present:***

- Suzanne Desjardins, Office of Drugs and Alcohol Research and Surveillance (ODARS), Controlled Substances and Tobacco Directorate (CSTD), Healthy Environments Consumer Safety Branch (HECSB) (Chair)
- Bruna Brands, ODARS, CSTD, HECSB via phone
- Colette Strnad, Office of Science, Therapeutic Products Directorate (TPD), HPFB via phone
- Robin Marles, Bureau of Clinical Trials and Health Sciences, Natural Health Products Directorate (NHPD), HPFB
- Evelyn Soo, OCS, CSTD, HECSB
- Stephanie Chandler, OCS, CSTD, HECSB
- Daniel Garlameau, OCS, CSTD, HECSB
- Ishrad Mulla for Colin Pinto, Drug Compliance and Investigations Unit, Health Products and Food Branch Inspectorate, HPFB. via phone
- Hanan Abramovici, ODARS, CSTD, HECSB
- Tiffany Thornton, (Secretariat) ODARS, CSTD, HECSB

***Regrets:***

- Jocelyn Kula, OCS, CSTD, HECSB
- Tanja Kalajdzic, Marketed Pharmaceuticals & Medical Devices Division, Marketed Health Products Directorate, Health Products and Food Branch (HPFB)
- Tiana Branch, OCS, CSTD, HECSB

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**1. Welcome & Introductions**

Suzanne welcomed the working group members and invited guests Stephanie Chandler and Daniel Galarneau from OCS.

**2. Approval of Agenda Items**

Agenda approved with the additional update items added by Bruna [REDACTED] and Robin [REDACTED]

**3. Approval of ROD from June, 2010**

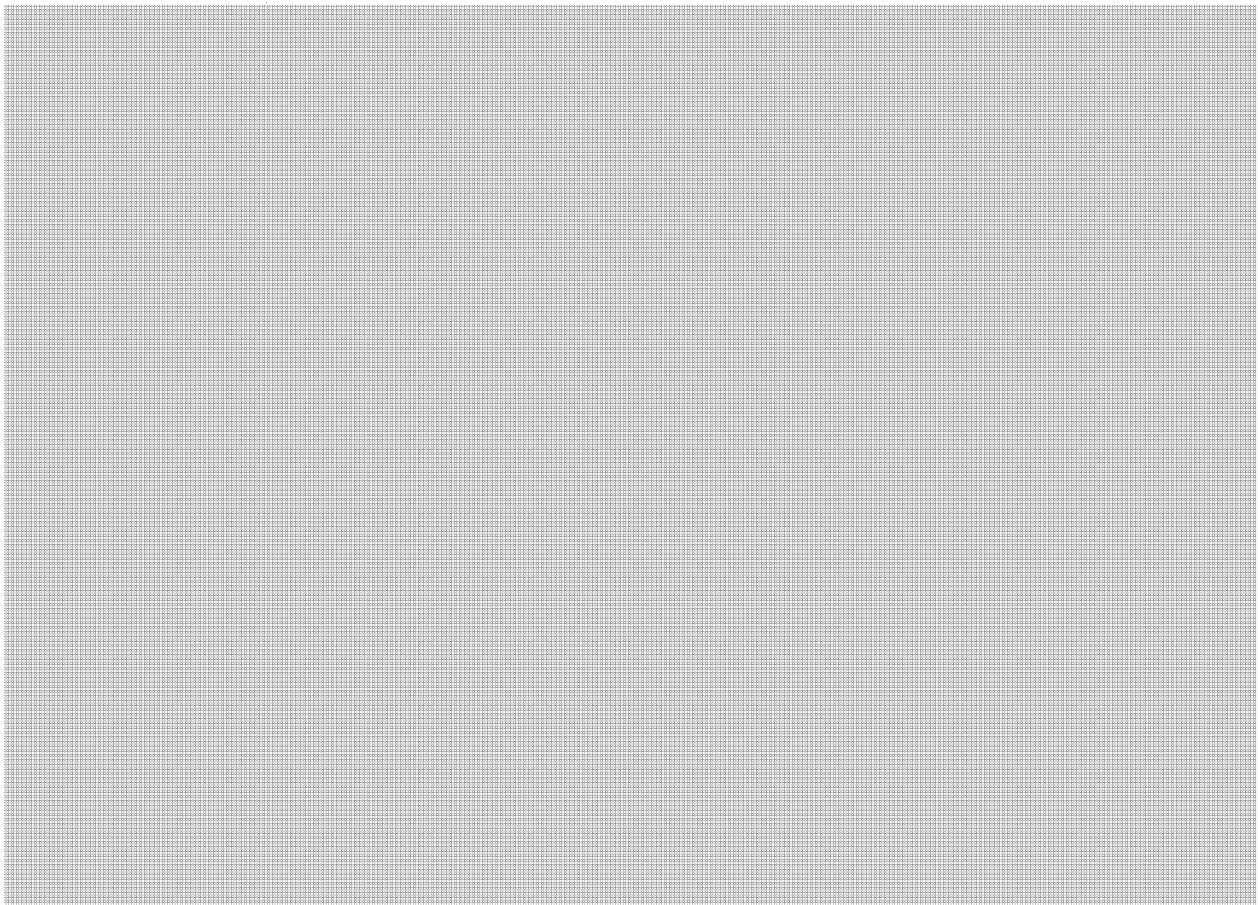
The ROD for Wednesday, July 18<sup>th</sup> meeting was approved.

**4. Issue Analysis Summary: Salvia**

Stephanie noted that this was the most recent version of the IAS on Salvia produced by OCS with input from various groups/branches. Robin noted some inaccuracies within the IAS that needed to be revised.

**Actions:**

- Robin to send revisions to sections 4.1 and 4.2 as well as other comments to Tiffany



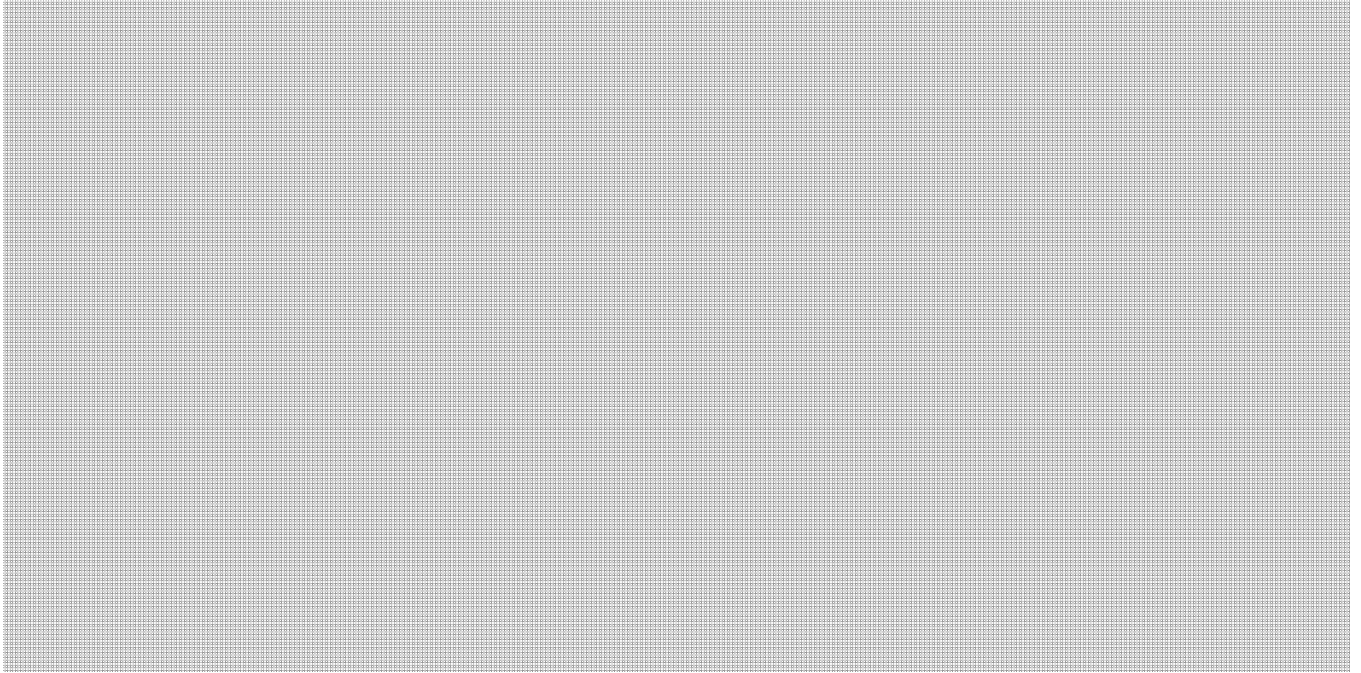


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## **6. Next Steps**

The next meeting scheduled for Wednesday, September 15<sup>th</sup> from 10-11:30am in Room 405A.

### **Actions:**

- Tiffany to circulate the invitation, agenda and ROD for the next meeting.

**PUBLICATION:** Le Soleil  
**DATE:** 2010.08.18  
**SECTION:** Actualités  
**PAGE:** 2 / FRONT  
**BYLINE:** Fortin, Pierre-Olivier  
**WORD COUNT:** 342  
**CIRCULATION:** 81820

## Attention à l'ecstasy "légale"

On l'appelle "miaow miaow" ou "m-cat" parce qu'elle provient du khat, une plante africaine. En dépit de son surnom sympathique, des personnes sont mortes en Europe après avoir consommé de la méphédronne. Une femme qui s'en serait procuré en vente libre à Québec et qui a été sévèrement intoxiquée, un premier cas au Québec, a incité la santé publique à faire une mise en garde. La substance est consommée pour ses effets euphorisants semblables à ceux de l'ecstasy, "pour être de bonne humeur, pour passer la nuit debout", explique le Dr Pierre Auger, **médecin-conseil** à la Direction de **santé** publi- que. Cette drogue est toutefois considérée comme "très dangereuse" par l'organisme, qui conseille de l'éviter.

"C'est considéré comme une substance moins puissante que l'ecstasy ou les amphétamines. Certains n'ont presque pas d'effets secondaires; pour d'autres, ils sont importants : nausée, paranoïa, convulsions, coma, atteinte musculaire avec insuffisance rénale", cite le Dr Auger.

Les effets à long terme sont méconnus parce que la substance est sur le marché depuis trop peu de temps. Il est toutefois possible que cette drogue entraîne des dépressions majeures chez certains, des hallucinations, et provoque de la dépendance. Des personnes qui en ont consommé sont décédées en Suède et en Grande-Bretagne.

A Québec, une jeune femme a été hospitalisée aux soins intensifs après avoir consommé de la méphédronne. Il s'agit du premier cas rapporté au Québec. "Cette substance est faussement vendue comme étant un produit naturel et légal, utilisé notamment comme engrais, selon les commerçants", stipule le communiqué de presse publié par la santé publique. La méphédronne est illégale dans plusieurs pays, alors qu'il s'agit d'une substance contrôlée au Canada.

Il a été impossible de savoir, hier, où la jeune femme s'était procuré la drogue, pas plus que le nom de la boutique où elle est prétendument vendue au public. L'agence précise qu'elle est aussi vendue sur le Web. Effectivement, il semble assez facile d'en commander sur les sites qu'a consultés Le Soleil.

La santé publique a contacté la police de Québec, qui a ouvert une enquête.

pofortin@lesoleil.com

*Salvia divinorum* has traditional medicinal uses among the native peoples of Mexico, e.g. for the treatment of topical ulcers of the feminine organs (Díaz 1976), to help normalize eliminatory functions (diarrhoea/ constipation and urination), anemia, headaches, rheumatism, and alcohol addiction, in addition to its use as a hallucinogen in divination rituals (Valdés et al. 1983). The method of preparation is always an infusion of 4 to 120 pairs (10 to 300 g) of fresh leaves crushed and added to boiling water (a tea) -- low doses of fresh or dried leaves for medicinal purposes and doses of 50+ grams of only fresh leaves for divination/hallucination (Valdés et al. 1983).

There is no record in the scientific literature of a history of use of *Salvia divinorum* as an incense. Burning was not an established method of preparation in traditional uses as a medicine or as a hallucinogenic.

There are a few herbs where burning the leaves produces a very characteristic fragrance (e.g. cured tobacco, *Artemisia*, cedar). However, most aromatic plants lose their characteristic fragrance when burned and simply smell like burned leaves. Gum-resins from trees, e.g. frankincense, myrrh, and copal, are much more common incense ingredients because they gradually release their volatile oils into the smoke (Simpson and Ogorzaly 2001).

Therefore, I believe that the production of "incense" from *Salvia divinorum* leaves or extracts is a recent invention to try to avoid compliance and enforcement actions. Nevertheless, it may be difficult to argue in court that, in the absence of any claims regarding hallucinogenic or other actions in humans, use as incense is not "legitimate" even if there is no history of such use and it just smells like burned leaves.

#### **References:**

Díaz JL. 1976. *Propiedades Terapéuticas Atributas a Plantas Mexicanas, Primera Parte: Nombre Botánico y Usos*. Instituto Mexicano para el Estudio de las Plantas Medicinales, Mexico.

Simpson BB and Ogorzaly MC. 2001. *Economic Botany: Plants in Our World*, third edition. New York, NY: McGraw-Hill Co.

Valdés LJ, Díaz JL, Paul AG. 1983. Ethnopharmacology of Ska María Pastora (*Salvia divinorum*, Epling and Játiva-M.). *J. Ethnopharmacology* 7(3): 287-312.

With respect to the sale of *Salvia divinorum* as a cultivated plant in Canada, yes, it is available from legitimate Canadian garden supply companies, e.g.,

- RICHTERS HERBS, 357 Highway 47, Goodwood, ON L0C 1A0 Canada, Tel. +1.905.640.6677 Fax. +1.905.640.6641, <http://www.richters.com/>. Note the promotional statements explicitly related to its use as a hallucinogen in the attached web site pdf.



**Diviners Sage**  
*Salvia divinorum*  
**Uses:** Medicinal

**Duration:** Perennial (*hardy in zones 11+*)

Sacred sage of the Mazateca Indians of Mexico used to induce divinatory visions. To help find lost items, or to solve problems of a material or spiritual nature, the Mazateca Indians would chew the fresh leaves. The leaves are very bitter when chewed but are slightly more palatable taken as a cold infusion of fresh crushed leaves, or smoked. Psychotropic effects similar to mescaline are attributed to compounds called salvivorins. Prefers humid, shaded conditions and humus-rich, moist soil. Rangy plant, reaching 2m/7ft. unless pruned.

<input type="checkbox"/>	P5164-500	Plants	\$15.00/ea
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Currency: Canadian Dollar

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# SALVIA.CA

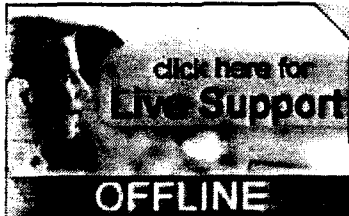


Salvia products



## Our Products

- Salvia Extract
- Salvia Leaves
- Wild Dagga
- Kratom
- Amanita Muscaria



## Buy salvia divinorum for sale.



Welcome to Salvia.ca!

We are the exclusive destination of choice for all your salvia divinorum needs. Being a rare sage as salvia is, the demand for our products have never been higher. We offer a broad range of extract including 20x as well as a selection of dried leaves which have proven to be very popular within the salvia community. Our very rare seeds and high quality plants allow for the freshest salvia possible.

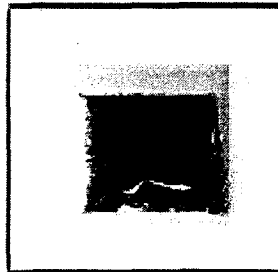
We have taken our time in developing this site for the use of everyone. We hope to make this much more than a place to buy salvia divinorum by offering interesting articles and stories from salvia users. It's our way of helping to increase the awareness of

products. If you are  
new to Salvia and  
would like to learn  
more about it, check  
out this exelent  
[Salvia Resource](#)

**To order or with questions call toll free: 1-800-920-1847**

**All prices quoted are in United States Dollars (USD)**

## **Salvia Divinorum Extract 10x**

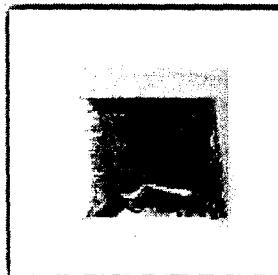


Our 10 x Salvia Divinorum Extract contains 36mg of pure salvinorin-A per gram of extract which is extracted from the plant and then redeposited back onto dried leaves. Our skilled chemists use a standardized method, which costs a little more than non-standardized methods, but means you will find no extra plant matter which can be harmful to your lungs. Salvia Extract is not a liquid. Twice as potent as the 5x salvia extract.

- Salvia Divinorum Extract 10x, 1g \$26.62
- Salvia Divinorum Extract 10x, 3g \$66.55
- Salvia Divinorum Extract 10x, 10g \$181.50
- Salvia Divinorum Extract 10x, 25g \$326.70
- Salvia Divinorum Extract 10x, 50g \$544.50

**Buy Now**

## **Salvia Divinorum Extract 15x**

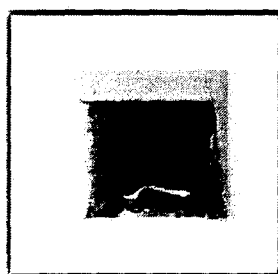


Our 15x salvia extract contains 54mg of pure salvinorin-A per gram of extract which is extracted from the plant and then redeposited back onto dried leaves. Our skilled chemists use a standardized method, which costs a little more than non-standardized methods, but means you will find no extra plant matter which can be harmful to your lungs. Salvia Extract is not a liquid. **This dosage has been described as very potent, and we recommend that you exercise caution when using this product.**

- Salvia Divinorum Extract 15x, 1g \$36.30
- Salvia Divinorum Extract 15x, 3g \$84.70
- Salvia Divinorum Extract 15x, 10g \$235.95
- Salvia Divinorum Extract 15x, 25g \$424.71
- Salvia Divinorum Extract 15x, 50g \$707.85

**Buy Now**

## Salvia Divinorum Extract 20x



Our 20x extract is extremely rare and hard to find and contains 72mg of pure salvinorin-A per gram of extract which is extracted from the plant and then redeposited back onto dried leaves. Our skilled chemists use a standardized method, which costs a little more than non-standardized methods, but means you will find no extra plant matter which can be harmful to your lungs. Salvia Extract is not a liquid. **This dosage has been described as very potent, and we recommend that you exercise caution when using this product.**

Experienced salvia users only.

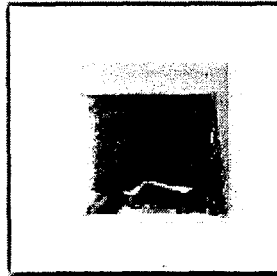
**Use with caution**

- Salvia Divinorum Extract 20x, 1g \$48.40
- Salvia Divinorum Extract 20x, 3g \$108.90
- Salvia Divinorum Extract 20x, 10g \$302.50
- Salvia Divinorum Extract 20x, 25g \$550.55
- Salvia Divinorum Extract 20x, 50g \$919.60



**Buy Now**

## Salvia Divinorum Extract 30x



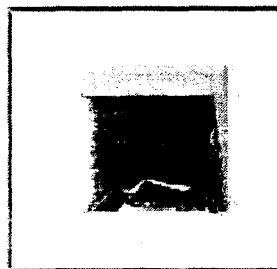
Our 30 x salvia divinorum extract contains 108mg of pure salvinorin-A per gram of extract which is extracted from the plant and then redeposited back onto dried leaves. Our skilled chemists use a standardized method, which costs a little more than non-standardized methods, but means you will find no extra plant matter which can be harmful to your lungs. Salvia Extract is not a liquid. **This dosage has been described as very potent, and we recommend that you exercise caution when using this product.**

Experienced salvia users only.  
**Use with caution**

- Salvia Divinorum Extract 30x, 1g \$65.34
- Salvia Divinorum Extract 30x, 3g \$169.40
- Salvia Divinorum Extract 30x, 10g \$435.60
- Salvia Divinorum Extract 30x, 25g \$877.25

**Buy Now**

## Salvia Divinorum Extract 5x



Our 5x salvia divinorum extract contains 18mg of salvinorin-a per gram of extract which is extracted from the plant and then redeposited back onto dried leaves. Our skilled chemists use a standardized method, which costs a little more than non-standardized methods, but means you will find no extra plant matter which can be harmful to your lungs. Salvia Extract is not a liquid.

- Salvia Divinorum Extract 5x, 1g \$13.31
- Salvia Divinorum Extract 5x, 3g \$32.67
- Salvia Divinorum Extract 5x, 10g \$93.17
- Salvia Divinorum Extract 5x, 25g \$181.50
- Salvia Divinorum Extract 5x, 50g \$326.70

**BEST AVAILABLE COPY**

## **Salvia divinorum**

### **Issue**

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff, incense special, and salvia.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs. As of [REDACTED] 2010 Health Canada has not authorized for sale any products containing *S. divinorum*.

Health Canada recommends that you avoid using this plant because very little is known about the effects it may have on your body and/or brain functions. There is also no way to predict how it will affect you with each use.

### **Risks Associated with the Use of *Salvia divinorum***

*S. divinorum* is known to have both physical and mental effects. The effects of *S. divinorum*, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product
- how much is used
- the purity of the product (products that contain *S. divinorum* may be mixed with other substances)
- how it is taken, for example, whether the product is chewed, swallowed or smoked
- the user's mood and expectations

While scientists know which brain receptors are targeted by the active ingredient, salvinorin A, very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or if it can cause permanent damage
- how it interacts with other substances, including other drugs, natural health products and alcohol
- the potential of *S. divinorum* to produce physical dependence and/or addiction

### **Minimizing Your Risk**

Hallucinogens like *S. divinorum* work by modifying functions in the brain. Health Canada recommends that you avoid using *S. divinorum* because very little is known about the effects it may have on your body and/or brain functions. There is also no way to predict how it will affect you with each use. Just because a drug is plant-based or “natural”, does not mean that it is safe.

Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs, such as marijuana, cocaine, ecstasy, LSD and other substances that distort reality. See the “*Need More Info?*” section below for links to resources that can help you with this.

### **Legal Status of *Salvia divinorum***

#### In Canada

Because of its hallucinogenic properties, products containing *S. divinorum* or salvinorin A meet the definition of a Natural Health Product (NHP) in accordance with the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*. It is illegal to sell drugs or NHPs in Canada, unless they have been reviewed and authorized for sale by Health Canada. In the case of NHPs, they need to be labelled with one of the following:

- a Natural Product Number (NPN); or
- an Exemption Number (EN); or
- a Drug Identification Number - Homeopathic Medicine Number (DIN-HM).

As of **DATE** 2010 no products containing *S. divinorum* or salvinorin A have been authorized by Health Canada for sale. The sale of unauthorized drugs and NHPs is illegal, and may be subject to compliance and enforcement actions by the Department.

Neither *S. divinorum* nor salvinorin A are currently regulated under the *Controlled Drugs and Substances Act* (CDSA). Health Canada is currently considering the available information to determine whether regulation as a controlled substance is warranted.

#### In Other Countries

Several countries including but not limited to Australia, Belgium, Germany, Italy, Japan, etc., have placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on their sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution, for example, it is illegal for *S. divinorum* to be sold to anyone under the age of 18.

#### **Background**

The leaves of this plant have been used traditionally by the Mazatec people for medicinal and mystical purposes.

Products that claim to contain *S. divinorum* or its main active ingredient, salvinorin A are widely available on the Internet and are sold in various “head shops” and natural food stores. The products are sold in a number of forms, including fresh or dried leaves, liquids or seeds and plant cuttings for growing purposes.

Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, less than 2% of Canadians age 15 and older reported having used *S. divinorum* at least once in their lifetime. Young adults, ages 15-24 were much more likely to have used it than adults. The results from the *Canadian 2008-2009 Youth Smoking Survey* show that 5% of 15yr olds have used *S. divinorum* in the past year. For more information on these surveys, see the *Need More Info* section below.

#### **Health Canada's Role**

Health Canada continues to collect and consider safety information regarding *S. divinorum* and will continue to consult with key stakeholders including health officials in other countries and law enforcement officials here at home. This will assist in determining Health Canada's future approach to decision-making regarding the regulation of *S. divinorum* in Canada. Health Canada also continues to monitor the sale of unauthorized health products, including those that contain *S. divinorum* or its main active ingredient salvinorin A, and will take appropriate action when the department becomes aware of any unauthorized health products that may pose a risk to Canadians.

### Need More Info?

- Complaints about the illegal sale of drugs containing *S. divinorum* can be made to the **Health Products and Food Branch Inspectorate** at: [http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_44\\_consumer\\_consommateur\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_44_consumer_consommateur_cp-pc-eng.php)  
Tel: 1-800-267-9675.
- You can report any adverse reactions to the Canada Vigilance Program by one of the following three ways:  
Report online at the MedEffect™ Canada website at: <http://www.hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>  
Call toll-free at 1-866-234-2345  
Complete a Canada Vigilance Reporting Form and either:  
Fax toll-free to 1-866-678-6789  
Mail to: Canada Vigilance Program  
Health Canada  
AL 0701C  
Ottawa, ON K1A 0K9  
To have postage pre-paid, download the postage paid label from the MedEffect™ Canada website. The Canada Vigilance Reporting Form and the adverse reaction reporting guidelines may also be obtained via this website at : [http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei\\_form-eng.php](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei_form-eng.php)
- For information about the Government of Canada's **Anti-Drug Strategy**, go to: [www.nationalantidrugstrategy.gc.ca/](http://www.nationalantidrugstrategy.gc.ca/)  
The Prevention section on this site has a number of helpful resources for parents, including:
  - **Tips on Talking to Your Teenager**, at: [www.hc-sc.gc.ca/hc-ps/pubs/adp-apd/talk-aborder/index-eng.php](http://www.hc-sc.gc.ca/hc-ps/pubs/adp-apd/talk-aborder/index-eng.php)
  - **What to Do if Your Teen is Using Drugs**, at: [www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html](http://www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html)
  - Health Canada's **Not4Me** youth drug prevention section at: <http://www.hc-sc.gc.ca/hc-ps/drugs-drogues/youth-jeunes/facts-faits/index-eng.php>

- Information on natural health products and the **Natural Health Products Regulations** can be found at: [www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php)

For more on the surveys that have collected information about *Salvia divinorum* use in Canada, see:

- **The 2008-2009 Youth Smoking Survey**, at:  
<http://www.yss.uwaterloo.ca/index.cfm?section=5&page=288>
- **The 2009 Canadian Alcohol and Drug Use Monitoring Survey**, at:  
<http://www.hc-sc.gc.ca/hc-ps/drugs-drogues/stat/index-eng.php>
- **The 2009 Ontario Student Drug Use and Health Survey**, at:  
[http://www.camh.net/News\\_events/News\\_releases\\_and\\_media\\_advisories\\_and\\_b\\_ackgrounders/osduhs2009\\_advisory.html](http://www.camh.net/News_events/News_releases_and_media_advisories_and_b_ackgrounders/osduhs2009_advisory.html)

Additional Resources:

- U.S. Drug Enforcement Administration: **Drugs and Chemicals of Concern: Salvia divinorum and Salvinorin A** at:  
[www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)
- U.S. Department of Health & Human Services, **National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006** at:  
[www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf](http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf)
- For additional articles on health and safety issues go to the **It's Your Health** web section at: [www.healthcanada.gc.ca/iyh](http://www.healthcanada.gc.ca/iyh)

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

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DRAFT 13  
September 16, 2010

## Media Lines *Salvia divinorum*

### Issue

Since 2006, Health Canada has noted ongoing media interest regarding the availability of *Salvia divinorum* in Canada. Health Canada has also received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum*, particularly given reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties.

### Key Messages:

- Health Canada advises Canadians not to use products containing *S. divinorum* and/or salvinorin A because very little is known about the substance and its potential effects on the brain and/or body, and its impact on physical and mental functions.
- Because of its hallucinogenic properties, products containing *S. divinorum* and/or salvinorin A meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*.
- It is illegal to sell NHPs in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN). The illegal sale of products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*.
- Health Canada will continue to collect and study information about *S. divinorum* as it becomes available, and to consult with law enforcement and health officials domestically and internationally in order to determine the best way to manage the risks associated with its availability in Canada.

### Supplementary Messages:

#### *Salvia divinorum as a controlled substance:*

- In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA).
- Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and thus, do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

This is the only ~~the~~ past that I have concerns with.  
← reversed

Long Term?  
This applies to long term effects.  
only does it not.

Based on comments and info reviewed, we know the short term effects may  
be listed in the IYH. As the ESS-WG stated ~~it~~ s. divinorum acts in similar  
fashion as LSD, and it is mostly the long term effects that are unknown ~~and~~  
of flashbacks? ~~There~~



- Several countries (Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) have placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Although some individual U.S. states have implemented laws restricting its use, sale and/or distribution, *Salvia divinorum* and salvinorin A are not regulated under the federal *Controlled Substances Act* in the United States.

#### Questions and Answers:

##### **Q1 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why isn't it illegal?**

A1 – Because *S. divinorum* meets the definition of an NHP under the *Natural Health Product Regulations*, it is illegal to manufacture, sell or provide products containing *S. divinorum* and/or salvinorin A without their being authorized by Health Canada prior to sale. Health Canada is currently reviewing all the available information regarding *Salvia divinorum*, including the prevalence of its use in Canada, to determine whether it should be regulated under the *Controlled Drugs and Substances Act*.

##### **Q2 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?**

A2 – The *Natural Health Products Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *Salvia divinorum*.

##### **Q3 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A3 – *Salvia divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. Complaints about the illegal sale of drugs containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

##### **Q4 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum* as a controlled substance. What does that involve and what stage is it at?**

A4 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada is currently reviewing the available information to determine whether regulation of *Salvia divinorum* under the CDSA is warranted.

**Q5 – Didn't an internal report from Health Canada's Marketed Health Products Directorate recommend that *Salvia divinorum* be scheduled under the CDSA? Why has that recommendation not been acted upon?**

A5 – See A4

**Q6 – What is the significance of the adverse reaction reports that Health Canada has received with respect to the use of *Salvia divinorum*?**

A6 – Health Canada has received four domestic adverse reaction reports related to the use of *Salvia divinorum* as a hallucinogen through the Canada Vigilance database. The number of reports and the nature of reactions reported are, however, not adequate to fully characterize the risk of similar reactions among the general population

***If pressed on whether Health Canada has issued any kind of warning to Canadians about *Salvia divinorum****

A - Health Canada is developing an It's Your Health (IYH) article on *Salvia divinorum* to help inform the general public about the risks associated with the use of this substance.

### **Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

Data from the 2008-2009 Youth Smoking Survey indicates that:

- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;
- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year; and
- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using Salvia in their lifetime (0.2% in the past year); and

- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that:

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;
- 5.4% of students (grades 7-12) ever used *S. divinorum*; and
- the use of *S. divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

**Prepared by:** Cheryl Tremblay and Denis Arsenault, OCS, CSTD

**Input by:** Lisa Mackay IYH/PACCB, Suzanne Desjardins HECSB/ODARS, Hanan Abramovici HECSB/ODARS, Bruna Brands HECSB/ODARS, Jocelyn Kula, HECSB/OCS, Robin Marles HPFB/NHPD, Maggie Graham HPFB/NHPD, Stephanie Collins HPFB/NHPD, Mano Murty HPFB/MHPD, Robert Leitch HPFB/MHPD, Collin Pinto, HPFB/HPFBI

**Approved by:**

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MO (pending)  
PCO (pending)



Stephanie  
Chandler/HC-SC/GC/CA  
2010-09-17 10:06 AM

To Daniel Galarneau/HC-SC/GC/CA@HWC  
cc Denis Arsenault/HC-SC/GC/CA@HWC  
bcc  
Subject Fw: SALVIA - IYH & Media lines

Hi Daniel,

Here is the final drafts of the Salvia MLs and IYH before formal approvals. I have looked over both documents and do not have any additional comments.

Stephanie

----- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2010-09-17 10:03 AM -----

Lisa MacKay/HC-SC/GC/CA  
2010-09-16 02:19 PM

To Jocelyn Kula/HC-SC/GC/CA@HWC, Stephanie  
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Arsenault/HC-SC/GC/CA@HWC, Hanan  
Abramovici/HC-SC/GC/CA@HWC, Bruna  
Brands/HC-SC/GC/CA@HWC, Christine  
Roush/HC-SC/GC/CA@HWC, Bronwyn  
Cline/HC-SC/GC/CA@HWC, Valerie  
Hurry/HC-SC/GC/CA@HWC, Robin  
Marles/HC-SC/GC/CA@HWC, Maggie  
Graham/HC-SC/GC/CA@HWC, Stephanie  
Collins/HC-SC/GC/CA@HWC, Scott  
Jordan/HC-SC/GC/CA@HWC, Robert  
Leitch/HC-SC/GC/CA@HWC, Mano  
Murty/HC-SC/GC/CA@HWC, Shahid  
Perwaiz/HC-SC/GC/CA@HWC, Elizabeth  
Keeping/HC-SC/GC/CA@HWC, Blossom  
Leung/HC-SC/GC/CA@HWC, Collin  
Pinto/HC-SC/GC/CA@HWC  
cc Lisa MacKay/HC-SC/GC/CA@HWC  
Subject SALVIA - IYH & Media lines

Hello all,

I think I have managed to input all the suggested changes and comments into the documents. I wanted to give everyone one last look before sending it for formal approval. I will be away Friday - Tuesday, so if possible could you please send me any changes or comments by end of day Tuesday, September 21. I will input any additional changes and send the documents for formal approval on Wednesday.



IYH Salvia divinatorum\_v17 clean Sept2010.doc Salvia Media Lines\_v13 clean Sept2010.doc

Thank you for all your efforts on this!

Lisa Mackay

It's Your Health Project Manager/Gestionnaire du projet Votre santé et vous

Strategic Communications and Ministerial Services Division / Division des communications stratégiques  
et des services ministériels

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## **Salvia divinorum**

### **Issue**

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff, incense special, and salvia.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs. As of **MONTH** 2010 Health Canada has not authorized for sale any products containing *S. divinorum*.

Health Canada recommends that you avoid using this plant because very little is known about the effects it may have on your body and/or brain functions. There is also no way to predict how it will affect you with each use.

### **Risks Associated with the Use of *Salvia divinorum***

*S. divinorum* is known to have both physical and mental effects. The effects of *S. divinorum*, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product
- how much is used
- the purity of the product (products that contain *S. divinorum* may be mixed with other substances)
- how it is taken, for example, whether the product is chewed, swallowed or smoked
- the user's mood and expectations

While scientists know which brain receptors are targeted by the active ingredient, salvinorin A, very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or if it can cause permanent damage
- how it interacts with other substances, including other drugs, natural health products and alcohol
- the potential of *S. divinorum* to produce physical dependence and/or addiction

### **Minimizing Your Risk**

Hallucinogens like *S. divinorum* work by modifying functions in the brain. Health Canada recommends that you avoid using *S. divinorum* because very little is known about the effects it may have on your body and/or brain functions. There is also no way to predict how it will affect you with each use. Just because a drug is plant-based or “natural”, does not mean that it is safe.

Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs, such as marijuana, cocaine, ecstasy, LSD and other substances that distort reality. See the “*Need More Info?*” section below for links to resources that can help you with this.

### **Legal Status of *Salvia divinorum***

#### In Canada

Because of its hallucinogenic properties, products containing *S. divinorum* or salvinorin A meet the definition of a Natural Health Product (NHP) in accordance with the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*. It is illegal to sell drugs or NHPs in Canada, unless they have been reviewed and authorized for sale by Health Canada. In the case of NHPs, they need to be labelled with one of the following:

- a Natural Product Number (NPN); or
- an Exemption Number (EN); or
- a Drug Identification Number - Homeopathic Medicine Number (DIN-HM).

As of **DATE** 2010 no products containing *S. divinorum* or salvinorin A have been authorized by Health Canada for sale. The sale of unauthorized drugs and NHPs is illegal, and may be subject to compliance and enforcement actions by the Department.

Neither *S. divinorum* nor salvinorin A are currently regulated under the *Controlled Drugs and Substances Act* (CDSA). Health Canada is currently considering the available information to determine whether regulation as a controlled substance is warranted.

#### In Other Countries

Several countries including but not limited to Australia, Belgium, Germany, Italy, Japan, etc., have placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on their sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution, for example, it is illegal for *S. divinorum* to be sold to anyone under the age of 18.

#### **Background**

The leaves of this plant have been used traditionally by the Mazatec people for medicinal and mystical purposes.

Products that claim to contain *S. divinorum* or its main active ingredient, salvinorin A are widely available on the Internet and are sold in various "head shops" and natural food stores. The products are sold in a number of forms, including fresh or dried leaves, liquids or seeds and plant cuttings for growing purposes.

Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, less than 2% of Canadians age 15 and older reported having used *S. divinorum* at least once in their lifetime. Young adults, ages 15-24 were much more likely to have used it than adults. The results from the *Canadian 2008-2009 Youth Smoking Survey* show that 5% of 15yr olds have used *S. divinorum* in the past year. For more information on these surveys, see the *Need More Info* section below.

#### **Health Canada's Role**



Health Canada continues to collect and consider safety information regarding *S. divinorum* and will continue to consult with key stakeholders including health officials in other countries and law enforcement officials here at home. This will assist in determining Health Canada's future approach to decision-making regarding the regulation of *S. divinorum* in Canada. Health Canada also continues to monitor the sale of unauthorized health products, including those that contain *S. divinorum* or its main active ingredient salvinorin A, and will take appropriate action when the department becomes aware of any unauthorized health products that may pose a risk to Canadians.

### Need More Info?

- Complaints about the illegal sale of drugs containing *S. divinorum* can be made to the **Health Products and Food Branch Inspectorate** at: [http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_44\\_consumer\\_consommateur\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_44_consumer_consommateur_cp-pc-eng.php)  
Tel: 1-800-267-9675.
- You can report any adverse reactions to the Canada Vigilance Program by one of the following three ways:  
Report online at the MedEffect™ Canada website at: <http://www.hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>  
Call toll-free at 1-866-234-2345  
Complete a Canada Vigilance Reporting Form and either:  
Fax toll-free to 1-866-678-6789  
Mail to: Canada Vigilance Program  
Health Canada  
AL 0701C  
Ottawa, ON K1A 0K9  
To have postage pre-paid, download the postage paid label from the MedEffect™ Canada website. The Canada Vigilance Reporting Form and the adverse reaction reporting guidelines may also be obtained via this website at : [http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei\\_form-eng.php](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei_form-eng.php)
- For information about the Government of Canada's ***Anti-Drug Strategy***, go to: [www.nationalantidrugstrategy.gc.ca/](http://www.nationalantidrugstrategy.gc.ca/)  
The Prevention section on this site has a number of helpful resources for parents, including:
  - **Tips on Talking to Your Teenager**, at: [www.hc-sc.gc.ca/hc-ps/pubs/adp-adp/talk-aborder/index-eng.php](http://www.hc-sc.gc.ca/hc-ps/pubs/adp-adp/talk-aborder/index-eng.php)
  - **What to Do if Your Teen is Using Drugs**, at: [www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html](http://www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html)
  - Health Canada's **Not4Me** youth drug prevention section at: <http://www.hc-sc.gc.ca/hc-ps/drugs-drogues/youth-jeunes/facts-faits/index-eng.php>

- Information on natural health products and the **Natural Health Products Regulations** can be found at: [www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php)

For more on the surveys that have collected information about *Salvia divinorum* use in Canada, see:

- **The 2008-2009 Youth Smoking Survey**, at:  
<http://www.yss.uwaterloo.ca/index.cfm?section=5&page=288>
- **The 2009 Canadian Alcohol and Drug Use Monitoring Survey**, at:  
<http://www.hc-sc.gc.ca/hc-ps/drugs-drogues/stat/index-eng.php>
- **The 2009 Ontario Student Drug Use and Health Survey**, at:  
[http://www.camh.net/News\\_events/News\\_releases\\_and\\_media\\_advisories\\_and\\_b\\_ackgrounders/osduhs2009\\_advisory.html](http://www.camh.net/News_events/News_releases_and_media_advisories_and_b_ackgrounders/osduhs2009_advisory.html)

Additional Resources:

- U.S. Drug Enforcement Administration: **Drugs and Chemicals of Concern: Salvia divinorum and Salvinorin A** at:  
[www.dea diversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.dea diversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)
- U.S. Department of Health & Human Services, **National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006** at:  
[www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf](http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf)
- For additional articles on health and safety issues go to the **It's Your Health** web section at: [www.healthcanada.gc.ca/iyh](http://www.healthcanada.gc.ca/iyh)

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

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PACCB IYH - Lisa Mackay: 613-954-0105 – [Lisa.Mackay@hc-sc.gc.ca](mailto:Lisa.Mackay@hc-sc.gc.ca)

Comments from: HECSB - CSTD (OCS&ODARS) & HPFB – NHPD, MHPD & HPFBI

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HPFB-NHPD: Valerie Hurry, Robin Marles, Maggie Graham, Stephanie Collins  
HPFB-MHPD: Scott Jordan, Robert Leitch, Mano Murty, Shahid Perwaiz  
HPFBI : Collin Pinto  
HPFB comms: Elizabeth Keeping, Blossom Leung

DRAFT 13  
September 16, 2010

**Media Lines**  
***Salvia divinorum***

**Issue**

Since 2006, Health Canada has noted ongoing media interest regarding the availability of *Salvia divinorum* in Canada. Health Canada has also received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum*, particularly given reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties.

**Key Messages:**

- Health Canada advises Canadians not to use products containing *S. divinorum* and/or salvinorin A because very little is known about the substance and its potential effects on the brain and/or body, and its impact on physical and mental functions.
- Because of its hallucinogenic properties, products containing *S. divinorum* and/or salvinorin A meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*.
- It is illegal to sell NHPs in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN). The illegal sale of products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*.
- Health Canada will continue to collect and study information about *S. divinorum* as it becomes available, and to consult with law enforcement and health officials domestically and internationally in order to determine the best way to manage the risks associated with its availability in Canada.

**Supplementary Messages:**

***Salvia divinorum as a controlled substance:***

- In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA).
- Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and thus, do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

- Several countries (Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) have placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Although some individual U.S. states have implemented laws restricting its use, sale and/or distribution, *Salvia divinorum* and salvinorin A are not regulated under the federal *Controlled Substances Act* in the United States.

#### Questions and Answers:

##### **Q1 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why isn't it illegal?**

A1 – Because *S. divinorum* meets the definition of an NHP under the *Natural Health Product Regulations*, it is illegal to manufacture, sell or provide products containing *S. divinorum* and/or salvinorin A without their being authorized by Health Canada prior to sale. Health Canada is currently reviewing all the available information regarding *Salvia divinorum*, including the prevalence of its use in Canada, to determine whether it should be regulated under the *Controlled Drugs and Substances Act*.

##### **Q2 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?**

A2 – The *Natural Health Products Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *Salvia divinorum*.

##### **Q3 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A3 – *Salvia divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. Complaints about the illegal sale of drugs containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

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A4 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada is currently reviewing the available information to determine whether regulation of *Salvia divinorum* under the CDSA is warranted.

**Q5 – Didn't an internal report from Health Canada's Marketed Health Products Directorate recommend that *Salvia divinorum* be scheduled under the CDSA? Why has that recommendation not been acted upon?**

A5 – See A4

**Q6 – What is the significance of the adverse reaction reports that Health Canada has received with respect to the use of *Salvia divinorum*?**

A6 – Health Canada has received four domestic adverse reaction reports related to the use of *Salvia divinorum* as a hallucinogen through the Canada Vigilance database. The number of reports and the nature of reactions reported are, however, not adequate to fully characterize the risk of similar reactions among the general population

***If pressed on whether Health Canada has issued any kind of warning to Canadians about *Salvia divinorum****

A - Health Canada is developing an It's Your Health (IYH) article on *Salvia divinorum* to help inform the general public about the risks associated with the use of this substance.

### **Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

Data from the 2008-2009 Youth Smoking Survey indicates that:

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- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year; and
- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using Salvia in their lifetime (0.2% in the past year); and

- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that:

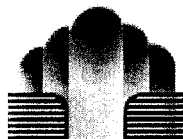
- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;
- 5.4% of students (grades 7-12) ever used *S. divinorum*; and
- the use of *S. divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

**Prepared by:** Cheryl Tremblay and Denis Arsenault, OCS, CSTD

**Input by:** Lisa Mackay IYH/PACCB, Suzanne Desjardins HECSB/ODARS, Hanan Abramovici HECSB/ODARS, Bruna Brands HECSB/ODARS, Jocelyn Kula, HECSB/OCS, Robin Marles HPFB/NHPD, Maggie Graham HPFB/NHPD, Stephanie Collins HPFB/NHPD, Mano Murty HPFB/MHPD, Robert Leitch HPFB/MHPD, Collin Pinto, HPFB/HPFBI

**Approved by:**

[Robin Marles] Director, Bureau of Clinical Trials, NHPD (pending)  
[NAME] Director, Policy and Regulatory Affairs, NHPD (pending)  
[NAME] Director, Marketed Biologics, Biotechnology and Natural Health Products  
Bureau,  
MHPD (pending)  
[NAME] Director, HPFBI (pending)  
Diane Allan, Director, OCS, CSTD, HECS (pending)  
Suzanne Desjardins, Director, ODARS, CSTD, HECS (pending)  
Cathy Sabiston, DG, CSTD, HECS (pending)  
[NAME], DG, MHPD (pending)  
[NAME], DG, NHPD (pending)  
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Meena Ballantyne, ADM, HPFB (pending)  
Anne Lamar, ADM, PACCB (pending)  
DMO (pending)  
MO (pending)  
PCO (pending)



Jocelyn Kula/HC-SC/GC/CA  
2010-09-19 09:38 PM

To Stephanie Chandler/HC-SC/GC/CA@HWC, Daniel  
Galarneau/HC-SC/GC/CA@HWC

cc

bcc

Subject Fw: SALVIA - IYH & Media lines

History: This message has been replied to.

I presume you have both reviewed. Pls let me know your findings and whether we are OK with this version. It will be good to have this doc finally out there.....that said, I would like to be sure there is consistency with the QP on salvia (I suggested changes to Diane btw as I just thought it was premature for us to be so definitive on our policy position in an anticipatory QP) and with the discussions of the CSS-WG.....

Pls let me know as we should try to observe Lisa's timelines.  
JK

---

Jocelyn Kula  
Manager/ Gestionnaire  
Regulatory Policy Division/ Division des politiques réglementaires  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0125 Fax: (613) 946-4224  
----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2010-09-19 09:36 PM -----

Lisa MacKay/HC-SC/GC/CA  
2010-09-16 02:19 PM

To Jocelyn Kula/HC-SC/GC/CA@HWC, Stephanie  
Chandler/HC-SC/GC/CA@HWC, Suzanne  
Desjardins/HC-SC/GC/CA@HWC, Denis  
Arsenault/HC-SC/GC/CA@HWC, Hanan  
Abramovici/HC-SC/GC/CA@HWC, Bruna  
Brands/HC-SC/GC/CA@HWC, Christine  
Roush/HC-SC/GC/CA@HWC, Bronwyn  
Cline/HC-SC/GC/CA@HWC, Valerie  
Hurry/HC-SC/GC/CA@HWC, Robin  
Marles/HC-SC/GC/CA@HWC, Maggie  
Graham/HC-SC/GC/CA@HWC, Stephanie  
Collins/HC-SC/GC/CA@HWC, Scott  
Jordan/HC-SC/GC/CA@HWC, Robert  
Leitch/HC-SC/GC/CA@HWC, Mano  
Murty/HC-SC/GC/CA@HWC, Shahid  
Perwaiz/HC-SC/GC/CA@HWC, Elizabeth  
Keeping/HC-SC/GC/CA@HWC, Blossom  
Leung/HC-SC/GC/CA@HWC, Collin  
Pinto/HC-SC/GC/CA@HWC

cc Lisa MacKay/HC-SC/GC/CA@HWC

Subject SALVIA - IYH & Media lines

Hello all,

I think I have managed to input all the suggested changes and comments into the documents. I wanted to

give everyone one last look before sending it for formal approval. I will be away Friday - Tuesday, so if possible could you please send me any changes or comments by end of day Tuesday, September 21. I will input any additional changes and send the documents for formal approval on Wednesday.



IYH Salvia divinorum\_v17 clean Sept2010.doc Salvia Media Lines\_v13 clean Sept2010.doc

Thank you for all your efforts on this!

Lisa Mackay

It's Your Health Project Manager/Gestionnaire du projet Votre santé et vous

Strategic Communications and Ministerial Services Division / Division des communications stratégiques  
et des services ministériels

Public Affairs, Consultation and Communications Branch/ Direction générale des affaires publiques, de la  
consultation et des communications

Health Canada | Santé Canada

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Fax 613.952.8644

Lisa\_Mackay@hc-sc.gc.ca





Stephanie  
Chandler/HC-SC/GC/CA  
2010-09-21 10:06 AM

To Lisa MacKay/HC-SC/GC/CA@HWC  
cc Blossom Leung/HC-SC/GC/CA@HWC, Bronwyn  
Cline/HC-SC/GC/CA@HWC, Bruna  
Brands/HC-SC/GC/CA@HWC, Christine  
bcc  
Subject Re: SALVIA - IYH & Media lines 

Hi Lisa,

OCS has no other comments with regard to the IYH, but has one minor change to the MLs (which probably won't require another round of consultations?).



Salvia Media Lines\_v13 clean Sept2010\_OCS.doc

Thanks,

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
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E-Mail: stephanie.chandler@hc-sc.gc.ca  
Lisa MacKay/HC-SC/GC/CA

Lisa MacKay/HC-SC/GC/CA  
2010-09-16 02:19 PM

To Jocelyn Kula/HC-SC/GC/CA@HWC, Stephanie  
Chandler/HC-SC/GC/CA@HWC, Suzanne  
Desjardins/HC-SC/GC/CA@HWC, Denis  
Arsenault/HC-SC/GC/CA@HWC, Hanan  
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Pinto/HC-SC/GC/CA@HWC  
cc Lisa MacKay/HC-SC/GC/CA@HWC  
Subject SALVIA - IYH & Media lines

DRAFT 13  
September 16, 2010



**Media Lines**  
***Salvia divinorum***

**Issue**

Since 2006, Health Canada has noted ongoing media interest regarding the availability of *Salvia divinorum* in Canada. Health Canada has also received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum*, particularly given reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties.

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**Prepared by:** Cheryl Tremblay and Denis Arsenault, OCS, CSTD

**Input by:** Lisa Mackay IYH/PACCB, Suzanne Desjardins HECSB/ODARS, Hanan Abramovici HECSB/ODARS, Bruna Brands HECSB/ODARS, Jocelyn Kula, HECSB/OCS, Robin Marles HPFB/NHPD, Maggie Graham HPFB/NHPD, Stephanie Collins HPFB/NHPD, Mano Murty HPFB/MHPD, Robert Leitch HPFB/MHPD, Collin Pinto, HPFB/HPFBI

**Approved by:**

[Robin Marles] Director, Bureau of Clinical Trials, NHPD (pending)  
[NAME] Director, Policy and Regulatory Affairs, NHPD (pending)  
[NAME] Director, Marketed Biologics, Biotechnology and Natural Health Products Bureau,  
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HPFB Legal (pending)  
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Meena Ballantyne, ADM, HPFB (pending)  
Anne Lamar, ADM, PACCB (pending)  
DMO (pending)  
MO (pending)  
PCO (pending)

DRAFT 13  
September 16, 2010

### Media Lines *Salvia divinorum*

#### Issue

Since 2006, Health Canada has noted ongoing media interest regarding the availability of *Salvia divinorum* in Canada. Health Canada has also received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum*, particularly given reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties.

#### Key Messages:

- Health Canada advises Canadians not to use products containing *S. divinorum* and/or salvinorin A because very little is known about the substance and its potential long-term effects on the brain and/or body, and its impact on physical and mental functions.
- Because of its hallucinogenic properties, products containing *S. divinorum* and/or salvinorin A meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*.
- It is illegal to sell NHPs in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN). The illegal sale of products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*.
- Health Canada will continue to collect and study information about *S. divinorum* as it becomes available, and to consult with law enforcement and health officials domestically and internationally in order to determine the best way to manage the risks associated with its availability in Canada.

**Comment [S1]:** Given that the IYH lists numerous effects of Salvia, the addition of the word 'long-term' seems more consistent

#### Supplementary Messages:

##### ***Salvia divinorum as a controlled substance:***

- In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA).
- Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and thus, do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

- Several countries (Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) have placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Although some individual U.S. states have implemented laws restricting its use, sale and/or distribution, *Salvia divinorum* and salvinorin A are not regulated under the federal *Controlled Substances Act* in the United States.

**Questions and Answers:**

**Q1 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why isn't it illegal?**

A1 – Because *S. divinorum* meets the definition of an NHP under the *Natural Health Product Regulations*, it is illegal to manufacture, sell or provide products containing *S. divinorum* and/or salvinorin A without their being authorized by Health Canada prior to sale. Health Canada is currently reviewing all the available information regarding *Salvia divinorum*, including the prevalence of its use in Canada, to determine whether it should be regulated under the *Controlled Drugs and Substances Act*.

**Q2 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?**

A2 – The *Natural Health Products Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *Salvia divinorum*.

**Q3 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A3 – *Salvia divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. Complaints about the illegal sale of drugs containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

**Q4 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum* as a controlled substance. What does that involve and what stage is it at?**

A4 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada is currently reviewing the available information to determine whether regulation of *Salvia divinorum* under the CDSA is warranted.

**Q5 – Didn't an internal report from Health Canada's Marketed Health Products Directorate recommend that *Salvia divinorum* be scheduled under the CDSA? Why has that recommendation not been acted upon?**

A5 – See A4

**Q6 – What is the significance of the adverse reaction reports that Health Canada has received with respect to the use of *Salvia divinorum*?**

A6 – Health Canada has received four domestic adverse reaction reports related to the use of *Salvia divinorum* as a hallucinogen through the Canada Vigilance database. The number of reports and the nature of reactions reported are, however, not adequate to fully characterize the risk of similar reactions among the general population

***If pressed on whether Health Canada has issued any kind of warning to Canadians about *Salvia divinorum****

A - Health Canada is developing an It's Your Health (IYH) article on *Salvia divinorum* to help inform the general public about the risks associated with the use of this substance.

### **Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

Data from the 2008-2009 Youth Smoking Survey indicates that:

- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;
- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year; and
- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using Salvia in their lifetime (0.2% in the past year); and



- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that:

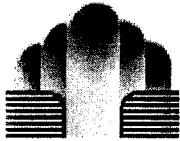
- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;
- 5.4% of students (grades 7-12) ever used *S. divinorum*; and
- the use of *S. divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

**Prepared by:** Cheryl Tremblay and Denis Arsenault, OCS, CSTD

**Input by:** Lisa Mackay IYH/PACCB, Suzanne Desjardins HECSB/ODARS, Hanan Abramovici HECSB/ODARS, Bruna Brands HECSB/ODARS, Jocelyn Kula, HECSB/OCS, Robin Marles HPFB/NHPD, Maggie Graham HPFB/NHPD, Stephanie Collins HPFB/NHPD, Mano Murty HPFB/MHPD, Robert Leitch HPFB/MHPD, Collin Pinto, HPFB/HPFBI

**Approved by:**

[Robin Marles] Director, Bureau of Clinical Trials, NHPD (pending)  
[NAME] Director, Policy and Regulatory Affairs, NHPD (pending)  
[NAME] Director, Marketed Biologics, Biotechnology and Natural Health Products  
Bureau,  
MHPD (pending)  
[NAME] Director, HPFBI (pending)  
Diane Allan, Director, OCS, CSTD, HECS (pending)  
Suzanne Desjardins, Director, ODARS, CSTD, HECS (pending)  
Cathy Sabiston, DG, CSTD, HECS (pending)  
[NAME], DG, MHPD (pending)  
[NAME], DG, NHPD (pending)  
[NAME] DG, HPFBI (pending)  
Ken Polk, Communications Executive, HPFB (pending)  
Kathleen Malone, Senior Media Relations, PACCB (pending)  
Warren Braun, Director, Strategic Communications, PACCB (pending)  
Peter Yendall, Director, Public Affairs, PACCB (pending)  
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HPFB Legal (pending)  
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Meena Ballantyne, ADM, HPFB (pending)  
Anne Lamar, ADM, PACCB (pending)  
DMO (pending)  
MO (pending)  
PCO (pending)



Jocelyn Kula/HC-SC/GC/CA  
2010-09-30 11:39 PM

To :Stephanie Chandler/HC-SC/GC/CA@HWC  
cc  
bcc  
Subject Fw: Approval - Salvia ML & IYH

fyi

---

Jocelyn Kula  
Manager/ Gestionnaire  
Regulatory Policy Division/ Division des politiques réglementaires  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
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----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2010-09-30 11:39 PM -----



Nicole  
Prentice/HC-SC/GC/CA  
2010-09-30 02:38 PM

To Suzanne Desjardins/HC-SC/GC/CA@HWC  
cc Diane Allan/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Valence Nebie/HC-SC/GC/CA@HWC  
Subject Fw: Approval - Salvia ML & IYH

Hi Suzanne,

Attached below is the IYH article and media lines on Salvia for your approval by Monday, October 4 COB. Jocelyn & Diane have reviewed and approved already.

Diane - Please note, we accepted all your changes, however, made an addition change to the first key message so it would read better.

Thanks in advance.



IYH Salvia divinatorum\_v18 clean Sept2010.doc Salvia Media Lines\_Sept30.doc

Nicole Prentice  
Junior Communications Officer | Agente junior des Communications  
Regulatory Communications and Media Relations Division | Division des communications réglementaires et des relations avec les médias  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la consultation et des communications  
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Fax: 613.948.8085

----- Forwarded by Nicole Prentice/HC-SC/GC/CA on 2010-09-30 02:34 PM -----

Christine  
Roush/HC-SC/GC/CA

To Nicole Prentice/HC-SC/GC/CA@HWC

2010-09-30 02:27 PM

cc

Subject Fw: Approval - Salvia ML & IYH

I made a change to the first key message. Was there anything else you were concerned about?

[attachment "MLs - S. divinatorum-revcr\_Sept30.doc" deleted by Nicole Prentice/HC-SC/GC/CA]

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
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E-mail / courriel : christine\_roush@hc-sc.gc.ca

----- Forwarded by Christine Roush/HC-SC/GC/CA on 2010-09-30 02:26 PM -----

Diane Allan/HC-SC/GC/CA

2010-09-29 09:39 AM

To Nicole Prentice/HC-SC/GC/CA@HWC

cc Christine Roush/HC-SC/GC/CA@HWC, CSTD-OCS-DO,  
Jocelyn Kula/HC-SC/GC/CA@HWC

Subject Re: Fw: Approval - Salvia ML & IYH

Approved with a few minor changes to media lines.

[attachment "Salvia Media Lines\_v14 clean Sept2010.doc" deleted by Nicole Prentice/HC-SC/GC/CA]

Diane Allan

Director / Directrice  
Office of Controlled Substances / Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch / Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
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Fax: 613-946-4224

Nicole Prentice/HC-SC/GC/CA



Nicole  
Prentice/HC-SC/GC/CA

2010-09-28 02:09 PM

To Diane Allan/HC-SC/GC/CA@HWC

cc Jocelyn Kula/HC-SC/GC/CA@HWC, Christine  
Roush/HC-SC/GC/CA@HWC, CSTD-OCS-DO

Subject Fw: Approval - Salvia ML & IYH

Hi Diane,

Attached below is the IYH article and media lines on Salvia for your approval by Wednesday, September 29 COB. Jocelyn has reviewed and approved already.

Thanks in advance.

[attachment "IYH Salvia divinatorum\_v18 clean Sept2010.doc" deleted by Nicole Prentice/HC-SC/GC/CA]  
[attachment "Salvia Media Lines\_v14 clean Sept2010.doc" deleted by Nicole Prentice/HC-SC/GC/CA]  
[attachment "Approval Slip - Salvia HECSB.doc" deleted by Nicole Prentice/HC-SC/GC/CA]

Nicole Prentice

Junior Communications Officer | Agente junior de Communications

Regulatory Communications and Media Relations Division | Division des communications réglementaires  
et des relations avec les médias

Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la  
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----- Forwarded by Nicole Prentice/HC-SC/GC/CA on 2010-09-28 02:04 PM -----

**Christine**

**Roush/HC-SC/GC/CA**

2010-09-28 01:55 PM

To Nicole Prentice/HC-SC/GC/CA@HWC

cc Bronwyn Cline/HC-SC/GC/CA@HWC

Subject Re: Approval - Salvia ML & IYH 

Nicole - could you please take care of approvals of this It's Your Health article. The article and approval slip are below. thx. Jocelyn Kula has already reviewed and approved.

Christine Roush

Senior Communications Advisor/

Conseillère principale en communications

Public Affairs, Consultation and Communications Branch/

Direction générale des affaires publiques,

de la consultation et des communications

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Fax/Facsimile : 948-8085

E-mail / courriel : christine\_roush@hc-sc.gc.ca

Lisa MacKay/HC-SC/GC/CA

**Lisa MacKay/HC-SC/GC/CA**

2010-09-28 01:40 PM

To Christine Roush/HC-SC/GC/CA@HWC, Bronwyn  
Cline/HC-SC/GC/CA@HWC

cc Lisa MacKay/HC-SC/GC/CA@HWC

Subject Approval - Salvia ML & IYH

Hello,

On to the next stage! Could you please send the documents around for approval and return them to me by  
cob Tuesday, Cotober 12.

Thank you

Lisa Mackay

It's Your Health Project Manager/Gestionnaire du projet Votre santé et vous

Strategic Communications and Ministerial Services Division / Division des communications stratégiques  
et des services ministériels

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Lisa\_Mackay@hc-sc.gc.ca

DRAFT 13  
September 16, 2010

**Media Lines**  
***Salvia divinorum***

**Issue**

Since 2006, Health Canada has noted ongoing media interest regarding the availability of *Salvia divinorum* in Canada. Health Canada has also received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum*, particularly given reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties.

**Key Messages:**

- Canadians should not use products containing *S. divinorum* and/or salvinorin A because very little is known about the substance and its potential effects on the brain and/or body, and its impact on physical and mental functions. Deleted: Health Canada advises  
Deleted: to
- Because of their hallucinogenic properties, products containing *S. divinorum* and/or salvinorin A meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*. Deleted: its
- It is illegal to sell NHPs in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN). The illegal sale of products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*.
- Health Canada will continue to collect and study information about *S. divinorum* as it becomes available, and to consult with law enforcement and health officials domestically and internationally in order to determine the best way to manage the risks associated with its availability in Canada.

**Supplementary Messages:**

***Salvia divinorum as a controlled substance:***

- In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA).
- Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and thus, do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

- Several countries (Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) have placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Although some individual U.S. states have implemented laws restricting its use, sale and/or distribution, *Salvia divinorum* and salvinorin A are not regulated under the federal *Controlled Substances Act* in the United States.

#### Questions and Answers:

##### **Q1 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why isn't it illegal?**

A1 – Because *S. divinorum* meets the definition of a Natural Health Product (NHP) under the *Natural Health Product Regulations*, it is illegal to manufacture, sell or provide products containing *S. divinorum* and/or salvinorin A without their being authorized by Health Canada prior to sale. Health Canada is currently reviewing all the available information regarding *Salvia divinorum*, including the prevalence of its use in Canada, to determine whether it should be regulated under the *Controlled Drugs and Substances Act*.

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##### **Q2 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?**

A2 – The *Natural Health Products Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *Salvia divinorum*.

##### **Q3 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A3 – *Salvia divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. Complaints about the illegal sale of drugs containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

##### **Q4 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum* as a controlled substance. What does that involve and what stage is it at?**

A4 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada is currently reviewing the available information to determine whether regulation of *Salvia divinorum* under the CDSA is warranted.

**Q5 – Didn't an internal report from Health Canada's Marketed Health Products Directorate recommend that *Salvia divinorum* be scheduled under the CDSA? Why has that recommendation not been acted upon?**

A5 – See A4

**Q6 – What is the significance of the adverse reaction reports that Health Canada has received with respect to the use of *Salvia divinorum*?**

A6 – Health Canada has received four domestic adverse reaction reports related to the use of *Salvia divinorum* as a hallucinogen through the Canada Vigilance database. The number of reports and the nature of reactions reported are, however, not adequate to fully characterize the risk of similar reactions among the general population

***If pressed on whether Health Canada has issued any kind of warning to Canadians about *Salvia divinorum****

A - Health Canada is developing an It's Your Health (IYH) article on *Salvia divinorum* to help inform the general public about the risks associated with the use of this substance.

### **Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

Data from the 2008-2009 Youth Smoking Survey indicates that:

- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;
- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year; and,
- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using Salvia in their lifetime (0.2% in the past year); and



- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

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- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;
- 5.4% of students (grades 7-12) ever used *S. divinorum*; and
- the use of *S. divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

**Prepared by:** Cheryl Tremblay and Denis Arsenault, OCS, CSTD

**Input by:** Lisa Mackay IYH/PACCB, Suzanne Desjardins HECSB/ODARS, Hanan Abramovici HECSB/ODARS, Bruna Brands HECSB/ODARS, Jocelyn Kula, HECSB/OCS, Robin Marles HPFB/NHPD, Maggie Graham HPFB/NHPD, Stephanie Collins HPFB/NHPD, Mano Murty HPFB/MHPD, Robert Leitch HPFB/MHPD, Shahid Perwaiz HPFB/MHPD, Collin Pinto, HPFB/HPFBI

**Approved by:**

Robin Marles, Director, Bureau of Clinical Trials, NHPD (pending)  
Lindsay Blaney, Director, Policy and Regulatory Affairs, NHPD (pending)  
Duc Vu, Director, Marketed Biologics, Biotechnology and Natural Health Products  
Bureau, MHPD (pending)  
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Diane Allan, Director, OCS, CSTD, HECS (pending)  
Suzanne Desjardins, Director, ODARS, CSTD, HECS (pending)  
Cathy Sabiston, DG, CSTD, HECS (pending)  
Chris Turner, DG, MHPD (pending)  
Nancy Richards, DG, NHPD (pending)  
Diana Dowthwaite, DG, HPFBI (pending)  
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Jean Tessier, Senior Media Relations, PACCB (pending)  
Warren Braun, Director, Strategic Communications, PACCB (pending)  
Peter Yendall, Director, Public Affairs, PACCB (pending)  
HECS Legal (pending)  
HPFB Legal (pending)  
Paul Glover, ADM, HECSB (pending)  
Meena Ballantyne, ADM, HPFB (pending)  
Anne Lamar, ADM, PACCB (pending)  
DMO (pending)  
MO (pending)  
PCO (pending)

## **Salvia divinorum**

### **Issue**

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff, incense special, and salvia.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs. As of [REDACTED] 2010 Health Canada has not authorized for sale any products containing *S. divinorum*.

Health Canada recommends that you avoid using this plant because very little is known about the effects it may have on your body and/or brain functions. There is also no way to predict how it will affect you with each use.

### **Risks Associated with the Use of *Salvia divinorum***

*S. divinorum* is known to have both physical and mental effects. The effects of *S. divinorum*, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product
- how much is used
- the purity of the product (products that contain *S. divinorum* may be mixed with other substances)
- how it is taken, for example, whether the product is chewed, swallowed or smoked
- the user's mood and expectations

While scientists know which brain receptors are targeted by the active ingredient, salvinorin A, very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or if it can cause permanent damage
- how it interacts with other substances, including other drugs, natural health products and alcohol
- the potential of *S. divinorum* to produce physical dependence and/or addiction

### **Minimizing Your Risk**

Hallucinogens like *S. divinorum* work by modifying functions in the brain. Health Canada recommends that you avoid using *S. divinorum* because very little is known about the effects it may have on your body and/or brain functions. There is also no way to predict how it will affect you with each use. Just because a drug is plant-based or “natural”, does not mean that it is safe.

Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs, such as marijuana, cocaine, ecstasy, LSD and other substances that distort reality. See the “*Need More Info?*” section below for links to resources that can help you with this.

### **Legal Status of *Salvia divinorum***

#### In Canada

Because of its hallucinogenic properties, products containing *S. divinorum* or salvinorin A meet the definition of a Natural Health Product (NHP) in accordance with the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*. It is illegal to sell drugs or NHPs in Canada, unless they have been reviewed and authorized for sale by Health Canada. In the case of NHPs, they need to be labelled with one of the following:

- a Natural Product Number (NPN); or
- an Exemption Number (EN); or
- a Drug Identification Number - Homeopathic Medicine Number (DIN-HM).

As of **December** 2010 no products containing *S. divinorum* or salvinorin A have been authorized by Health Canada for sale. The sale of unauthorized drugs and NHPs is illegal, and may be subject to compliance and enforcement actions by the Department.

Neither *S. divinorum* nor salvinorin A are currently regulated under the *Controlled Drugs and Substances Act* (CDSA). Health Canada is currently considering the available information to determine whether regulation as a controlled substance is warranted.

#### In Other Countries

Several countries including but not limited to Australia, Belgium, Germany, Italy, Japan, etc., have placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on their sale and/or import. For example, several states have made it illegal to manufacture, distribute,

import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution. For example, in some states it is illegal for *S. divinorum* to be sold to anyone under the age of 18.

## Background

The leaves of this plant have been used traditionally by the Mazatec people for medicinal and mystical purposes.

Products that claim to contain *S. divinorum* or its main active ingredient, salvinorin A are widely available on the Internet and are sold in various "head shops" and natural food stores. The products are sold in a number of forms, including fresh or dried leaves, liquids or seeds and plant cuttings for growing purposes.

Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, less than 2% of Canadians age 15 and older reported having used *S. divinorum* at least once in their lifetime. Youth, ages 15-24 were much more likely to have used it than adults. The results from the *Canadian 2008-2009 Youth Smoking Survey* show that 5% of 15yr olds have used *S. divinorum* in the past year. For more information on these surveys, see the *Need More Info* section below.

## Health Canada's Role

Health Canada continues to collect and consider safety information regarding *S. divinorum* and will continue to consult with key stakeholders including health officials in other countries and law enforcement officials here at home. This will assist in determining Health Canada's future approach to decision-making regarding the regulation of *S. divinorum* in Canada. Health Canada also continues to monitor the sale of unauthorized health products, including those that contain *S. divinorum* or its main active ingredient salvinorin A, and will take appropriate action when the department becomes aware of any unauthorized health products that may pose a risk to Canadians.

## Need More Info?

- Complaints about the illegal sale of drugs containing *S. divinorum* can be made to the **Health Products and Food Branch Inspectorate** at: [http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_44\\_consumer\\_consommateur\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_44_consumer_consommateur_cp-pc-eng.php)  
Tel: 1-800-267-9675.
- You can report any adverse reactions to the Canada Vigilance Program by one of the following three ways:  
Report online at the MedEffect™ Canada website at: <http://www.hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>  
Call toll-free at 1-866-234-2345  
Complete a Canada Vigilance Reporting Form and either:

Fax toll-free to 1-866-678-6789

Mail to: Canada Vigilance Program

Health Canada

AL 0701C

Ottawa, ON K1A 0K9

To have postage pre-paid, download the postage paid label from the MedEffect™ Canada website. The Canada Vigilance Reporting Form and the adverse reaction reporting guidelines may also be obtained via this website at : [http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei\\_form-eng.php](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei_form-eng.php)

- For information about the Government of Canada's Anti-Drug Strategy, go to: [www.nationalantidrugstrategy.gc.ca/](http://www.nationalantidrugstrategy.gc.ca/)  
The Prevention section on this site has a number of helpful resources for parents, including:
  - **Tips on Talking to Your Teenager**, at: [www.hc-sc.gc.ca/hc-ps/pubs/adp-apd/talk-aborder/index-eng.php](http://www.hc-sc.gc.ca/hc-ps/pubs/adp-apd/talk-aborder/index-eng.php)
  - **What to Do if Your Teen is Using Drugs**, at: [www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html](http://www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html)
  - Health Canada's **Not4Me** youth drug prevention section at: <http://www.hc-sc.gc.ca/hc-ps/drugs-drogues/youth-jeunes/facts-faits/index-eng.php>
- Information on natural health products and the Natural Health Products Regulations can be found at: [www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php)

For more on the surveys that have collected information about *Salvia divinorum* use in Canada, see:

- **The 2008-2009 Youth Smoking Survey**, at: <http://www.yss.uwaterloo.ca/index.cfm?section=5&page=288>
- **The 2009 Canadian Alcohol and Drug Use Monitoring Survey**, at: <http://www.hc-sc.gc.ca/hc-ps/drugs-drogues/stat/index-eng.php>
- **The 2009 Ontario Student Drug Use and Health Survey**, at: [http://www.camh.net/News\\_events/News\\_releases\\_and\\_media\\_advisories\\_and\\_ackgrounders/osduhs2009\\_advisory.html](http://www.camh.net/News_events/News_releases_and_media_advisories_and_ackgrounders/osduhs2009_advisory.html)

Additional Resources:

- U.S. Drug Enforcement Administration: **Drugs and Chemicals of Concern: *Salvia divinorum* and Salvinorin A** at: [www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)
- U.S. Department of Health & Human Services, **National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006** at: [www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf](http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf)

- For additional articles on health and safety issues go to the **It's Your Health** web section at: [www.healthcanada.gc.ca/iyh](http://www.healthcanada.gc.ca/iyh)

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

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PACCB IYH - Lisa Mackay: 613-954-0105 – [Lisa.Mackay@hc-sc.gc.ca](mailto:Lisa.Mackay@hc-sc.gc.ca)

Comments from: HECSB - CSTD (OCS&ODARS) & HPFB – NHPD, MHPD & HPFBI

Contacts: HECSB: Jocelyn Kula, Stephanie Chandler, Suzanne Desjardin, Denis  
Arsenault, Hanan Abramovici, Bruna Brands  
HECSB comms: Christine Roush, Bronwyn Cline  
HPFB-NHPD: Valerie Hurry, Robin Marles, Maggie Graham, Stephanie  
Collins  
HPFB-MHPD: Scott Jordan, Robert Leitch, Mano Murty, Shahid Perwaiz  
HPFBI : Collin Pinto  
HPFB comms: Elizabeth Keeping, Blossom Leung

## **Salvia divinorum**

### **Issue**

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff, incense special, and salvia.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs. As of [REDACTED] 2010 Health Canada has not authorized for sale any products containing *S. divinorum*.

Health Canada recommends that you avoid using this plant because very little is known about the effects it may have on your body and/or brain functions. There is also no way to predict how it will affect you with each use.

### **Risks Associated with the Use of *Salvia divinorum***

*S. divinorum* is known to have both physical and mental effects. The effects of *S. divinorum*, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product
- how much is used
- the purity of the product (products that contain *S. divinorum* may be mixed with other substances)
- how it is taken, for example, whether the product is chewed, swallowed or smoked
- the user's mood and expectations

While scientists know which brain receptors are targeted by the active ingredient, salvinorin A, very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or if it can cause permanent damage
- how it interacts with other substances, including other drugs, natural health products and alcohol
- the potential of *S. divinorum* to produce physical dependence and/or addiction

### **Minimizing Your Risk**

Hallucinogens like *S. divinorum* work by modifying functions in the brain. Health Canada recommends that you avoid using *S. divinorum* because very little is known about the effects it may have on your body and/or brain functions. There is also no way to predict how it will affect you with each use. Just because a drug is plant-based or “natural”, does not mean that it is safe.

Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs, such as marijuana, cocaine, ecstasy, LSD and other substances that distort reality. See the “*Need More Info?*” section below for links to resources that can help you with this.

### **Legal Status of *Salvia divinorum***

#### In Canada



Because of its hallucinogenic properties, products containing *S. divinorum* or salvinorin A meet the definition of a Natural Health Product (NHP) in accordance with the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*. It is illegal to sell drugs or NHPs in Canada, unless they have been reviewed and authorized for sale by Health Canada. In the case of NHPs, they need to be labelled with one of the following:

- a Natural Product Number (NPN); or
- an Exemption Number (EN); or
- a Drug Identification Number - Homeopathic Medicine Number (DIN-HM).

As of **DAI** 2010 no products containing *S. divinorum* or salvinorin A have been authorized by Health Canada for sale. The sale of unauthorized drugs and NHPs is illegal, and may be subject to compliance and enforcement actions by the Department.

Neither *S. divinorum* nor salvinorin A are currently regulated under the *Controlled Drugs and Substances Act* (CDSA). Health Canada is currently considering the available information to determine whether regulation as a controlled substance is warranted.

#### In Other Countries

Several countries including but not limited to Australia, Belgium, Germany, Italy, Japan, etc., have placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on their sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution, for example, it is illegal for *S. divinorum* to be sold to anyone under the age of 18.

#### **Background**

The leaves of this plant have been used traditionally by the Mazatec people for medicinal and mystical purposes.

Products that claim to contain *S. divinorum* or its main active ingredient, salvinorin A are widely available on the Internet and are sold in various “head shops” and natural food stores. The products are sold in a number of forms, including fresh or dried leaves, liquids or seeds and plant cuttings for growing purposes.

Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, less than 2% of Canadians age 15 and older reported having used *S. divinorum* at least once in their lifetime. Young adults, ages 15-24 were much more likely to have used it than adults. The results from the *Canadian 2008-2009 Youth Smoking Survey* show that 5% of 15yr olds have used *S. divinorum* in the past year. For more information on these surveys, see the *Need More Info* section below.

#### **Health Canada's Role**

Health Canada continues to collect and consider safety information regarding *S. divinorum* and will continue to consult with key stakeholders including health officials in other countries and law enforcement officials here at home. This will assist in determining Health Canada's future approach to decision-making regarding the regulation of *S. divinorum* in Canada. Health Canada also continues to monitor the sale of unauthorized health products, including those that contain *S. divinorum* or its main active ingredient salvinin A, and will take appropriate action when the department becomes aware of any unauthorized health products that may pose a risk to Canadians.

### Need More Info?

- Complaints about the illegal sale of drugs containing *S. divinorum* can be made to the **Health Products and Food Branch Inspectorate** at: [http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_44\\_consumer\\_consommateur\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_44_consumer_consommateur_cp-pc-eng.php)  
Tel: 1-800-267-9675.
- You can report any adverse reactions to the Canada Vigilance Program by one of the following three ways:  
Report online at the MedEffect™ Canada website at: <http://www.hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>  
Call toll-free at 1-866-234-2345  
Complete a Canada Vigilance Reporting Form and either:  
Fax toll-free to 1-866-678-6789  
Mail to: Canada Vigilance Program  
Health Canada  
AL 0701C  
Ottawa, ON K1A 0K9  
To have postage pre-paid, download the postage paid label from the MedEffect™ Canada website. The Canada Vigilance Reporting Form and the adverse reaction reporting guidelines may also be obtained via this website at : [http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei\\_form-eng.php](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei_form-eng.php)
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  - **What to Do if Your Teen is Using Drugs**, at: [www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html](http://www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html)
  - Health Canada's **Not4Me** youth drug prevention section at: <http://www.hc-sc.gc.ca/hc-ps/drugs-drogues/youth-jeunes/facts-faits/index-eng.php>

- Information on natural health products and the ***Natural Health Products Regulations*** can be found at: [www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php)

For more on the surveys that have collected information about *Salvia divinorum* use in Canada, see:

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<http://www.hc-sc.gc.ca/hc-ps/drugs-drogues/stat/index-eng.php>
- **The 2009 Ontario Student Drug Use and Health Survey**, at:  
[http://www.camh.net/News\\_events/News\\_releases\\_and\\_media\\_advisories\\_and\\_b\\_ackgrounders/osduhs2009\\_advisory.html](http://www.camh.net/News_events/News_releases_and_media_advisories_and_b_ackgrounders/osduhs2009_advisory.html)

Additional Resources:

- U.S. Drug Enforcement Administration: **Drugs and Chemicals of Concern: *Salvia divinorum* and Salvinorin A** at:  
[www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)
- U.S. Department of Health & Human Services, **National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006** at:  
[www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf](http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf)
- For additional articles on health and safety issues go to the ***It's Your Health*** web section at: [www.healthcanada.gc.ca/iyh](http://www.healthcanada.gc.ca/iyh)

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PACCB IYH - Lisa Mackay: 613-954-0105 – [Lisa.Mackay@hc-sc.gc.ca](mailto:Lisa.Mackay@hc-sc.gc.ca)

Comments from: HECSB - CSTD (OCS&ODARS) & HPFB – NHPD, MHPD & HPFBI

Contacts: HECSB: Jocelyn Kula, Stephanie Chandler, Suzanne Desjardin, Denis Arsenault, Hanan Abramovici, Bruna Brands  
HECSB comms: Christine Roush, Bronwyn Cline  
HPFB-NHPD: Valerie Hurry, Robin Marles, Maggie Graham, Stephanie Collins  
HPFB-MHPD: Scott Jordan, Robert Leitch, Mano Murty, Shahid Perwaiz  
HPFBI : Collin Pinto  
HPFB comms: Elizabeth Keeping, Blossom Leung

**Response to Docket # 10-122057-968**

**s.19(1)**

To: [REDACTED]

Dear [REDACTED]

I am writing in response to your email enquiry dated October 6, 2010, in which you have requested information concerning the legal status of Salvia.

In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA). However, when *S. divinorum* is sold or marketed to modify brain function (such as for use as a hallucinogen), it meets the definition of a natural health product under the *Natural Health Products Regulations* (NHPR). It is illegal to manufacture, sell or provide natural health products without their being authorized by Health Canada prior to sale. As of October 2010 no such products containing *S. divinorum* or salvinorin A have been authorized by Health Canada for sale.

*Salvia divinorum* products that are not in compliance with the NHPR may be subject to compliance and enforcement action by Health Canada. Complaints about the illegal sale of drugs containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

Health Canada recommends that you avoid using this plant because very little is known about the effects it may have on your body and/or brain functions. There is also no way to predict how it will affect you with each use. Health Canada is currently reviewing all the available information regarding *Salvia divinorum* to determine whether it should be regulated under the CDSA.

Please do not hesitate to contact me should you have any further questions.

Sincerely,

Jocelyn Kula  
A/Director  
Office of Controlled Substances  
Controlled Substances and Tobacco Directorate  
Healthy Environments and Consumer Safety Directorate  
(613) 952-2177



**Fw: URGENT Follow-up - Salvia (Canadian Press)**  
Denis Arsenault to: Stephanie Chandler  
Cc: Daniel Galarneau

2010-10-15 09:35 AM

Hi Stephanie,

For action.

Denis

---

Denis Arsenault, A/Manager / Gestionnaire p.i.  
Regulatory Policy Division /  
Division des politiques réglementaires,  
Office of Controlled Substances /  
Bureau des substances contrôlées,  
Health Canada / Santé Canada  
Tel/Tél: (613) 957-6828  
Fax / Télécopieur : (613) 946-4224  
E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca

----- Forwarded by Denis Arsenault/HC-SC/GC/CA on 2010-10-15 09:34 AM -----

From: Christine Roush/HC-SC/GC/CA  
To: "Jocelyn Kula" <jocelyn.kula@hc-sc.gc.ca>  
Cc: "Denis Arsenault" <denis.arsenault@hc-sc.gc.ca>, "Nicole Prentice"  
<nicole.prentice@hc-sc.gc.ca>  
Date: 2010-10-15 08:35 AM  
Subject: Fw: URGENT Follow-up - Salvia (Canadian Press)

---

A follow up request on Salvia - with a short turnaround time of noon - we will see if we can buy more time.  
Nicole Prentice

----- Original Message -----

**From:** Nicole Prentice  
**Sent:** 2010-10-14 10:36 PM EDT  
**To:** Christine Roush  
**Subject:** URGENT Follow-up - Salvia (Canadian Press)

For your review,

I have pulled what I can for these. I have French from 8-10 so can you pass this to OCS and HPFB in the morning when you get in. I am not sure we will be able to make this deadline, especially if we have to draft new responses.

Context: Every story I've read about this has said that salvia divinorum is perfectly legal and has gone on to quote a Health Canada official saying something to the effect that there's nothing the government can do to regulate salvia until there's more research or evidence of abuse. Many stories quote the police saying there's nothing they can do because it's legal. I've seen it openly for sale in head shops a stone's throw from Parliament Hill as recently as yesterday. As recently as today, I've seen websites, some based in Canada, offering this stuff for sale online. Yet your Q1 answer says it's illegal to sell it. So . . .

**Q1) Is this a recent change? Something to do with changes to the natural health products legislation?**

A1) For OCS/HPFB input? [Suggest: There have been no recent changes to the natural health products legislation.]

**Q2) Why isn't the law being enforced?**

A2) The *Natural Health Products Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *Salvia divinorum*.

*Salvia divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. Complaints about the illegal sale of drugs containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

**Q3) Why do police seem unaware that they can, in fact, do something about the sale of salvia?**

A3) For OCS input?

**Q4) I assume from A1 that while it's illegal to sell products containing salvia divinorum or salvinorin A, it's not illegal to possess it or use it? That any regulation of use and possession would need to be done under the Controlled Substances Act?**

A4) See A2.

In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA). Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and thus, do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

Several countries (Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) have placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Although some individual U.S. states have implemented laws restricting its use, sale and/or distribution, *Salvia divinorum* and salvinorin A are not regulated under the federal *Controlled Substances Act* in the United States.

Health Canada is currently reviewing the available information to determine whether regulation of *Salvia divinorum* under the CDSA is warranted.

**Nicole Prentice**

Junior Communications Officer | Agente junior des Communications  
Regulatory Communications and Media Relations Division | Division des communications  
réglementaires et des relations avec les médias  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires  
publiques, de la consultation et des communications  
Health Canada | Santé Canada  
Tel: 613.941.3107

s.19(1)

Fax: 613.948.8085

----- Forwarded by Nicole Prentice/HC-SC/GC/CA on 2010-10-14 10:09 PM -----

From: Christelle Legault/HC-SC/GC/CA  
To: "Senior Communications Advisor Christine Roush" <christine.roush@hc-sc.gc.ca>, "Nicole Prentice" <nicole.prentice@hc-sc.gc.ca>, Dave Stephens/HC-SC/GC/CA  
Cc: Jean Tessier/HC-SC/GC/CA  
Date: 2010-10-14 06:10 PM  
Subject: Urgent Follow-up - Salvia (Canadian Press)

---

Hi Christine,

Please see follow-up question below on Salvia. Reporter will need something by noon tomorrow.

Thanks,

C.

Christelle Legault  
Media Relations Officer | Agente des relations avec les médias  
Health Canada | Santé Canada  
Tel. | Tél.: 613.957.2988

---

**From:** [REDACTED]  
**Sent:** 2010-10-14 05:58 PM AST  
**To:** Christelle Legault  
**Subject:** RE: Health Canada - Salvia

Thanks for all that information. Your answer to Q1 raises a couple more questions though, which I hope you can answer by noon tomorrow, since I have to write this tomorrow (sorry!).

Every story I've read about this has said that salvia divinorum is perfectly legal and has gone on to quote a Health Canada official saying something to the effect that there's nothing the government can do to regulate salvia until there's more research or evidence of abuse. Many stories quote the police saying there's nothing they can do because it's legal. I've seen it openly for sale in head shops a stone's throw from Parliament Hill as recently as yesterday. As recently as today, I've seen websites, some based in Canada, offering this stuff for sale online. Yet your Q1 answer says it's illegal to sell it. So. . .

- 1) Is this a recent change? Something to do with changes to the natural health products legislation?
- 2) Why isn't the law being enforced?
- 3) Why do police seem unaware that they can, in fact, do something about the sale of salvia?
- 4) I assume from A1 that while it's illegal to sell products containing salvia divinorum or salvinorin A, it's not illegal to possess it or use it? That any regulation of use and possession would need to be done under the Controlled Substances Act?

Sorry for the new questions but I confess the A1 answer kinda threw me for a loop. Not at all what I was expecting, given everything I'd read about the legality of salvia in Canada up to now.

Thanks again for your help.

Joan

s.19(1)

**From:** Christelle Legault [mailto:christelle.legault@hc-sc.gc.ca]  
**Sent:** October 14, 2010 5:32 PM  
**To:** [REDACTED]  
**Subject:** Health Canada - Salvia

Hi [REDACTED]

As requested, please find below information in response to your questions regarding Salvia.

\*\*\*\*\*

**Q1 - What is the latest update on Salvia?**

A1 - Canadians should not use products containing *S. divinorum* and/or salvinorin A because very little is known about the substance and its potential effects on the brain and/or body, and its impact on physical and mental functions. Because of their hallucinogenic properties, products containing *S. divinorum* and/or salvinorin A meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*.

It is illegal to sell NHPs in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN). The illegal sale of products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*.

To date, Health Canada has not licensed for sale any drug or NHP which contains salvia as an ingredient.

**Q2 - What does Health Canada need (in terms of evidence) to make a decision on whether it should be listed as a controlled substance?**

A2 - A controlled substance is any type of drug that the federal government has categorized as having a higher-than-average potential for abuse or addiction. Such drugs are divided into categories based on their potential for abuse or addiction. Controlled substances range from illegal street drugs to prescription medications.

Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted.

These include:

- Overall risk to public health and safety posed by the substance.
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);



- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- International requirements and trends in international control;

**Q3 - Is Health Canada waiting for people to write in and complain? Are there any studies on this currently under way? Are there any pro-active steps being taken to come to a conclusion? Is Health Canada conducting research or aware of any research taking place?**

A3 - Health Canada is currently reviewing the available information to determine whether regulation of *Salvia divinorum* under the CDSA is warranted.

Health Canada is not aware of any groups specifically carrying out research on *S. divinorum*. It is however, continuing to collect and study information about the plant as it becomes available, and will consider this information as it moves forward with its scheduling assessment.

***With respect to Salvia being examined by the Canadian Alcohol and Drug Use Monitoring Survey 2009:***

Health Canada is monitoring the use of this substance, and in fact the release of Canadian Alcohol and Drug Use Monitoring Survey 2009 marks the first reporting of the prevalence of use of *Salvia* among the Canadian population. Among Canadians aged 15 years and older, the prevalence of lifetime use of *Salvia* was 1.6% and past year use was 0.2%. When examined by age group only lifetime use can be released due to the small numbers of Canadians reporting the use of this substance. Among youth (15 to 24 years) 7.3% reported lifetime use and only 0.5% of adults (25 years and older) reported having ever used this substance. Because this is a relatively new substance, Health Canada will be closely monitoring its use over the next years.

\*\*\*\*\*

Regards,

Christelle Legault  
Media Relations Officer | Agente des relations avec les médias  
Regulatory Communications and Media Relations Division |  
Division des communications réglementaires et des relations avec les médias  
Public Affairs, Consultation and Communications Branch |  
Direction générale des affaires publiques, de la consultation et des communications  
Health Canada | Santé Canada  
Tel. | Tél.: 613.957.2988 Fax | Téléc.: 613.952.7747



**Fw: URGENT Follow-up - Salvia (Canadian Press)**

Denis Arsenault to: Jocelyn Kula

Cc: CSTD-OCS-DO, Stephanie Chandler, Daniel Galarneau

2010-10-15 10:24 AM

For approval.

Denis

Denis Arsenault, A/Manager / Gestionnaire p.i.

Regulatory Policy Division /

Division des politiques réglementaires,

Office of Controlled Substances /

Bureau des substances contrôlées,

Health Canada / Santé Canada

Tel/Tél: (613) 957-6828

Fax / Télécopieur : (613) 946-4224

E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca

----- Forwarded by Denis Arsenault/HC-SC/GC/CA on 2010-10-15 10:23 AM -----

From: Stephanie Chandler/HC-SC/GC/CA  
To: Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2010-10-15 10:20 AM  
Subject: Fw: URGENT Follow-up - Salvia (Canadian Press)

Hi Denis,

Please note A1 requires input from HPFB.

Regards,

Stephanie

Stephanie Chandler

Junior Regulatory Project Officer

Regulatory Policy Division/ Division de la politique réglementaire

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs

Health Canada/ Santé Canada

Tel: (613) 946-0124, Fax: (613) 946-4224

E-Mail: stephanie.chandler@hc-sc.gc.ca

----- Forwarded by Denis Arsenault/HC-SC/GC/CA on 2010-10-15 09:34 AM -----

From: Christine Roush/HC-SC/GC/CA  
To: "Jocelyn Kula" <jocelyn.kula@hc-sc.gc.ca>  
Cc: "Denis Arsenault" <denis.arsenault@hc-sc.gc.ca>, "Nicole Prentice" <nicole.prentice@hc-sc.gc.ca>  
Date: 2010-10-15 08:35 AM  
Subject: Fw: URGENT Follow-up - Salvia (Canadian Press)

A follow up request on Salvia - with a short turnaround time of noon - we will see if we can buy more time.  
Nicole Prentice



**Re: Fw: Urgent: Sales of hallucinogenic salvia no longer legal in Canada**   
Stephanie Chandler to: Denis Arsenault

2010-10-19 09:35 AM

As requested,

Yes, this is not a recent change. When *S. divinorum* is marketed with a claim to modify brain function (such as for use as a hallucinogen), it meets the definition of a natural health product under the *Natural Health Products Regulations* (NHPR). It is illegal to manufacture, sell or provide natural health products without their being authorized by Health Canada prior to sale.

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

---

Denis Arsenault      Could you prepare a blurb in response. Denis      2010-10-19 09:27:26 AM

From: Denis Arsenault/HC-SC/GC/CA  
To: Stephanie Chandler/HC-SC/GC/CA@HWC  
Cc: Daniel Galarneau/HC-SC/GC/CA@HWC  
Date: 2010-10-19 09:27 AM  
Subject: Fw: Urgent: Sales of hallucinogenic salvia no longer legal in Canada

Could you prepare a blurb in response.

Denis

---

Denis Arsenault, A/Manager / Gestionnaire p.i.  
Regulatory Policy Division /  
Division des politiques réglementaires,  
Office of Controlled Substances /  
Bureau des substances contrôlées,  
Health Canada / Santé Canada  
Tel/Tél: (613) 957-6828  
Fax / Télécopieur : (613) 946-4224  
E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca

---- Forwarded by Denis Arsenault/HC-SC/GC/CA on 2010-10-19 09:26 AM ----

From: Stephanie Szick/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC  
Cc: CSTD-OCS-DO, Isabel Shanahan/HC-SC/GC/CA@HWC  
Date: 2010-10-19 09:20 AM  
Subject: Urgent: Sales of hallucinogenic salvia no longer legal in Canada

hi both

need quick reply before 9:30 today for MO daily call -- per trail below and Q from Jesse ---

Can we confirm -- if the products containing these substances (*S.divinorum* and/or *salvinorin*) have

**always been illegal (at least in the recent past). This isn't a change, right?**

I am quite certain the reply is yes, but ask for confirmation.

Thank you,  
Stephanie

----- Forwarded by Stephanie Szick/HC-SC/GC/CA on 2010-10-19 09:15 AM -----

From: Jesse Arnup-Blondin/HC-SC/GC/CA  
To: "Stephanie Szick" <stephanie.szick@hc-sc.gc.ca>  
Date: 2010-10-19 08:40 AM  
Subject: Urgent: Sales of hallucinogenic salvia no longer legal in Canada

---

Can you pls get confirmation of answer to my question below before 9:30 MO call in case there are questions abt clippings?

Thanks,

Jesse  
Jesse Arnup-Blondin

----- Original Message -----

**From:** Jesse Arnup-Blondin  
**Sent:** 2010-10-18 03:38 PM EDT  
**To:** Christine Roush  
**Cc:** Dave Stephens; Heather Leclerc; Jocelyn Kula; Stephanie Szick  
**Subject:** Re: Fw: Fw: CP: Sales of hallucinogenic salvia no longer legal in  
Canada

Thanks, Christine - I was just looking at these.

While the articles make it sound like this is a new prohibition, my understanding is that products containing these substances have always been illegal (at least in the recent past). This isn't a change, right?

Jesse

Christine Roush      Fyi - not sure if you received this CP story on sa...      2010-10-18 03:36:30 PM



**Fw: Urgent: Sales of hallucinogenic salvia no longer legal in Canada**

Denis Arsenault to: Jocelyn Kula

2010-10-19 09:47 AM

Cc: Stephanie Chandler

FYI

Denis

Denis Arsenault, A/Manager / Gestionnaire p.i.

Regulatory Policy Division /

Division des politiques réglementaires,

Office of Controlled Substances /

Bureau des substances contrôlées,

Health Canada / Santé Canada

Tel/Tél: (613) 957-6828

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E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca

----- Forwarded by Denis Arsenault/HC-SC/GC/CA on 2010-10-19 09:46 AM -----

From: Denis Arsenault/HC-SC/GC/CA

To: Stephanie Szick/HC-SC/GC/CA@HWC

Date: 2010-10-19 09:44 AM

Subject: Re: Urgent: Sales of hallucinogenic salvia no longer legal in Canada

This is not a recent change. When *S. divinorum* is marketed with a claim to modify brain function (such as for use as a hallucinogen), it meets the definition of a natural health product under the *Natural Health Products Regulations* (NHPR). It is illegal to sell NHPs in Canada unless they have been reviewed and approved by Health Canada and labelled with a Natural Product Number (NPN) or Exemption Number or Drug Identification Number - Homeopathic Medicine (DIN-HM).

Denis

Denis Arsenault, A/Manager / Gestionnaire p.i.

Regulatory Policy Division /

Division des politiques réglementaires,

Office of Controlled Substances /

Bureau des substances contrôlées,

Health Canada / Santé Canada

Tel/Tél: (613) 957-6828

Fax / Télécopieur : (613) 946-4224

E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca

Stephanie Szick hi both need quick reply before 9:30 today for M...

2010-10-19 09:20:55 AM

From: Stephanie Szick/HC-SC/GC/CA

To: Jocelyn Kula/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC

Cc: CSTD-OCS-DO, Isabel Shanahan/HC-SC/GC/CA@HWC

Date: 2010-10-19 09:20 AM

Subject: Urgent: Sales of hallucinogenic salvia no longer legal in Canada

hi both

need quick reply before 9:30 today for MO daily call -- per trail below and Q from Jesse ---

Can we confirm -- if the products containing these substances (S.divinorum and/or salvinorin) have always been illegal (at least in the recent past). This isn't a change, right?

I am quite certain the reply is yes, but ask for confirmation.

Thank you,  
Stephanie

----- Forwarded by Stephanie Szick/HC-SC/GC/CA on 2010-10-19 09:15 AM -----

From: Jesse Arnup-Blondin/HC-SC/GC/CA  
To: "Stephanie Szick" <stephanie.szick@hc-sc.gc.ca>  
Date: 2010-10-19 08:40 AM  
Subject: Urgent: Sales of hallucinogenic salvia no longer legal in Canada

---

Can you pls get confirmation of answer to my question below before 9:30 MO call in case there are questions abt clippings?

Thanks,

Jesse  
Jesse Arnup-Blondin

----- Original Message -----

**From:** Jesse Arnup-Blondin  
**Sent:** 2010-10-18 03:38 PM EDT  
**To:** Christine Roush  
**Cc:** Dave Stephens; Heather Leclerc; Jocelyn Kula; Stephanie Szick  
**Subject:** Re: Fw: Fw: CP: Sales of hallucinogenic salvia no longer legal in Canada

Thanks, Christine - I was just looking at these.

While the articles make it sound like this is a new prohibition, my understanding is that products containing these substances have always been illegal (at least in the recent past). This isn't a change, right?

Jesse

Christine Roush      Fyi - not sure if you received this CP story on sa...      2010-10-18 03:36:30 PM

**Re: Salvia Pictures** 

Collin Pinto to: Suzanne Desjardins

2010-10-19 10:36 AM

Cc: Blossom Leung, Bronwyn Cline, Bruna Brands, Christine Roush, Denis Arsenault, Elizabeth Keeping, Hanan Abramovici, Jocelyn Kula, Lisa MacKay, Maggie Graham, Mano Murty, Robert Leitch, Robin Marles, Scott Jordan, Shahid Perwaiz, Stephanie Chandler, Stephanie Collins, Valerie Hurry, Irshad Mulla

---


Will have a look.

Collin

Suzanne Desjardins/HC-SC/GC/CA



**Suzanne  
Desjardins/HC-SC/GC/CA**  
2010-10-19 10:30 AM

To Lisa MacKay/HC-SC/GC/CA@HWC  
cc Blossom Leung/HC-SC/GC/CA@HWC, Bronwyn Cline/HC-SC/GC/CA@HWC, Bruna Brands/HC-SC/GC/CA@HWC, Christine Roush/HC-SC/GC/CA@HWC, Collin Pinto/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, Elizabeth Keeping/HC-SC/GC/CA@HWC, Hanan Abramovici/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Lisa MacKay/HC-SC/GC/CA@HWC, Maggie Graham/HC-SC/GC/CA@HWC, Mano Murty/HC-SC/GC/CA@HWC, Robert Leitch/HC-SC/GC/CA@HWC, Robin Marles/HC-SC/GC/CA@HWC, Scott Jordan/HC-SC/GC/CA@HWC, Shahid Perwaiz/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC, Stephanie Collins/HC-SC/GC/CA@HWC, Valerie Hurry/HC-SC/GC/CA@HWC  
Subject Re: Salvia Pictures 

Hi Lisa,

While we could find some on the internet, there is copyright issues. Perhaps the Inspectorate would have some?

Suzanne

---

Lisa MacKay

Hello all, We have changed the format of IYH so...

2010-10-19 10:23:57 AM

From: Lisa MacKay/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, Hanan Abramovici/HC-SC/GC/CA@HWC, Bruna Brands/HC-SC/GC/CA@HWC, Christine Roush/HC-SC/GC/CA@HWC, Bronwyn Cline/HC-SC/GC/CA@HWC, Valerie Hurry/HC-SC/GC/CA@HWC, Robin Marles/HC-SC/GC/CA@HWC, Maggie Graham/HC-SC/GC/CA@HWC, Stephanie Collins/HC-SC/GC/CA@HWC, Scott Jordan/HC-SC/GC/CA@HWC, Robert Leitch/HC-SC/GC/CA@HWC, Mano Murty/HC-SC/GC/CA@HWC, Shahid Perwaiz/HC-SC/GC/CA@HWC, Elizabeth

Keeping/HC-SC/GC/CA@HWC, Blossom Leung/HC-SC/GC/CA@HWC, Collin  
Pinto/HC-SC/GC/CA@HWC  
Cc: Lisa MacKay/HC-SC/GC/CA@HWC  
Date: 2010-10-19 10:23 AM  
Subject: Salvia Pictures

---

Hello all,

We have changed the format of IYH somewhat and we now try to include pictures when posting all new and updated articles. I was wondering if any of you had access to any Salvia pictures that I can use in the article? I think it would also be very helpful to parents to know what to watch for.

Thank you!

Lisa Mackay

It's Your Health Project Manager/Gestionnaire du projet Votre santé et vous

Consumer Information Bureau / Bureau d'information aux consommateurs

Marketing and Communications Services Directorate/Direction des services de marketing et de communications

Public Affairs, Consultation and Communications Branch/ Direction générale des affaires publiques, de la consultation et des communications

Health Canada | Santé Canada

Tel 613.954.0105

Lisa\_Mackay@hc-sc.gc.ca





Re: Fw: Urgent: Sales of hallucinogenic salvia no longer legal in Canada   
Stephanie Chandler to: Denis Arsenault

2010-10-19 09:35 AM

As requested,

Yes, this is not a recent change. When *S. divinorum* is marketed with a claim to modify brain function (such as for use as a hallucinogen), it meets the definition of a natural health product under the *Natural Health Products Regulations* (NHPR). It is illegal to manufacture, sell or provide natural health products without their being authorized by Health Canada prior to sale.

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

---

Denis Arsenault      Could you prepare a blurb in response. Denis      2010-10-19 09:27:26 AM

From: Denis Arsenault/HC-SC/GC/CA  
To: Stephanie Chandler/HC-SC/GC/CA@HWC  
Cc: Daniel Galarneau/HC-SC/GC/CA@HWC  
Date: 2010-10-19 09:27 AM  
Subject: Fw: Urgent: Sales of hallucinogenic salvia no longer legal in Canada

Could you prepare a blurb in response.

Denis

---

Denis Arsenault, A/Manager / Gestionnaire p.i.  
Regulatory Policy Division /  
Division des politiques réglementaires,  
Office of Controlled Substances /  
Bureau des substances contrôlées,  
Health Canada / Santé Canada  
Tel/Tél: (613) 957-6828  
Fax / Télécopieur : (613) 946-4224  
E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca  
---- Forwarded by Denis Arsenault/HC-SC/GC/CA on 2010-10-19 09:26 AM ----

From: Stephanie Szick/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC  
Cc: CSTD-OCS-DO, Isabel Shanahan/HC-SC/GC/CA@HWC  
Date: 2010-10-19 09:20 AM  
Subject: Urgent: Sales of hallucinogenic salvia no longer legal in Canada

hi both

need quick reply before 9:30 today for MO daily call -- per trail below and Q from Jesse ---

Can we confirm -- if the products containing these substances (*S.divinorum* and/or *salvinorin*) have

always been illegal (at least in the recent past). This isn't a change, right?

I am quite certain the reply is yes, but ask for confirmation.

Thank you,  
Stephanie

----- Forwarded by Stephanie Szick/HC-SC/GC/CA on 2010-10-19 09:15 AM -----

From: Jesse Arnup-Blondin/HC-SC/GC/CA  
To: "Stephanie Szick" <stephanie.szick@hc-sc.gc.ca>  
Date: 2010-10-19 08:40 AM  
Subject: Urgent: Sales of hallucinogenic salvia no longer legal in Canada

---

Can you pls get confirmation of answer to my question below before 9:30 MO call in case there are questions abt clippings?

Thanks,

Jesse

Jesse Arnup-Blondin

----- Original Message -----

**From:** Jesse Arnup-Blondin  
**Sent:** 2010-10-18 03:38 PM EDT  
**To:** Christine Roush  
**Cc:** Dave Stephens; Heather Leclerc; Jocelyn Kula; Stephanie Szick  
**Subject:** Re: Fw: Fw: CP: Sales of hallucinogenic salvia no longer legal in

Canada

Thanks, Christine - I was just looking at these.

While the articles make it sound like this is a new prohibition, my understanding is that products containing these substances have always been illegal (at least in the recent past). This isn't a change, right?

Jesse

---

Christine Roush      Fyi - not sure if you received this CP story on sa...      2010-10-18 03:36:30 PM

From: Christine Roush/HC-SC/GC/CA  
To: stephanie.szick@hc-sc.gc.ca  
Cc: "Jesse Arnup-Blondin" <jesse.arnup-blondin@hc-sc.gc.ca>, "Dave Stephens" <dave.stephens@hc-sc.gc.ca>, "Jocelyn Kula" <jocelyn.kula@hc-sc.gc.ca>, "Heather Leclerc" <heather.leclerc@hc-sc.gc.ca>  
Date: 2010-10-18 03:36 PM  
Subject: Fw: Fw: CP: Sales of hallucinogenic salvia no longer legal in Canada

---

Fyi - not sure if you received this CP story on salvia. Jocelyn and I will be discussing the issue with HPFB Comms and Inspectorate to see if a HC response or statement is warranted.

Ken Polk

----- Original Message -----

**From:** Ken Polk  
**Sent:** 2010-10-18 02:20 PM EDT  
**To:** Jean Tessier

**Cc:** Elizabeth Keeping; Christine Roush  
**Subject:** Re: Fw: CP: Sales of hallucinogenic salvia no longer legal in  
Canada  
I checked with Beth. There doesn't seem to be anything more we can say on this one. I am looping in  
Christine for the HECS view.

Ken Polk  
Senior Communications Executive/ Gestionnaire principal des communications  
Strategic Communications Directorate / Direction générale des communications stratégiques  
Public Affairs, Consultation and Communications Branch / Direction générale des affaires publiques, de  
la consultation et des communications  
Health Canada / Santé Canada

Tel: (613) 941-0698 Cell: (613)219-0903 Fax: (613) 957-8805

Jean Tessier      Hey.... Any reaction to this...if there are correctio...      2010-10-18 01:20:42 PM

From:            Jean Tessier/HC-SC/GC/CA  
To:              Ken Polk/HC-SC/GC/CA@HWC  
Date:            2010-10-18 01:20 PM  
Subject:         Fw: CP: Sales of hallucinogenic salvia no longer legal in Canada

Hey....

Any reaction to this...if there are corrections to make to this...or a statement that might improve our  
position, we still may have a window to get it in.

HC\_Media\_SC

----- Original Message -----

**From:** HC\_Media\_SC  
**Sent:** 2010-10-18 12:24 PM EDT  
**Subject:** CP: Sales of hallucinogenic salvia no longer legal in Canada  
Distribution group/Groupe de distribution: Pharmaceuticals Biologics and Genetic Therapies - Produits  
pharmaceutiques biologiques et thérapies génétiques - HPFB/DGPSA,

Oct 18 2010 12:03:00

The Canadian Press

**Sales of hallucinogenic salvia no longer legal in Canada**

OTTAWA \_ Canada is no longer a safe legal haven for salvia  
divinorum, the potent hallucinogenic plant that is sold openly  
online and in head shops across the country.

Yet no one seems aware of the law and \*\*>Health Canada<\*\* is not  
enforcing it.

Websites and shopkeepers are still advertising the plant as a  
perfectly legal head trip for Canadians eager to join the thousands  
of ``pschonauts" who've posted videos of their psychedelic salvia  
voyages on YouTube.

An estimated 1.6 per cent of Canadians aged 15 or older have  
already taken at least one ride on salvia, according to the 2009  
Canadian Alcohol and Drug Use Monitoring Survey, the first to

measure use of the plant.

For those aged 15-24, the number rises to 7.3 per cent.

Yet the federal government says products containing salvia divinorum and its active ingredient, salvinorin A, are considered natural health products and, as such, must be authorized by \*\*>Health Canada<\*\* before they can be sold.

"It is illegal to sell NHPs (natural health products) in Canada unless they have been reviewed by \*\*>Health Canada<\*\* and authorized for sale," Christelle Legault, a spokesperson for \*\*>Health Canada<\*\*, told The Canadian Press in an email.

"To date, \*\*>Health Canada<\*\* has not licensed for sale any drug or NHP which contains salvia as an ingredient."

Legault added: "The illegal sale of products containing S. divinorum and/or salvinorin A may be subject to compliance and enforcement action under the Food and Drugs Act."

This comes as news to head shops that are openly selling vials of salvia extract \_ for \$20 to \$80 per gram, depending on the potency \_ within spitting distance of Parliament Hill.

One shopkeeper, who asked not to be identified, said he's had no notification that the plant, also known as diviner's sage and magic mint, can no longer be legally sold in Canada. He said he purchases the extract from a Canadian supplier.

It's news to the police as well, who've complained in the past that their hands are tied when it comes to salvia, which has been known to produce some adverse reactions, including one case reported by \*\*>Health Canada<\*\* in 2006 in which a teenage boy became incoherent and suicidal and threatened to kill police officers.

"Until the government makes it illegal, there's nothing we can do about it," said Robin Percival, communications strategist for drugs and organized crime at RCMP national headquarters.

Informed that \*\*>Health Canada<\*\* says it is, in fact, illegal to sell salvia without authorization under the Natural Health Products Regulations, Percival said: "I don't think we have any jurisdiction there."

Indeed, it would appear that enforcement of the regulations is entirely up to \*\*>Health Canada<\*'s Health Products and Food Branch Inspectorate.

Asked why \*\*>Health Canada<\*\* has not stopped the illegal sale of salvia, department spokesman Gary Holub said complaints can be referred to the inspectorate by calling 1-800-267-9675.

However, an open letter from the inspectorate to "all interested parties" on Aug. 27 suggests the inspectorate has not yet really begun in earnest to enforce the Natural Health Products Regulations.

The letter recounts that the regulations came into force in 2004. Due to the large backlog of products that needed to be assessed for safety and quality before they could be licensed by \*\*>Health Canada<\*\*, suppliers were given until June 2008 to submit applications for licensing.

It appears the process took longer than expected and only now is the inspectorate preparing to actually enforce the regulations.

The letter advises that a new compliance and enforcement policy has now been adopted, which is to be fully implemented in February. In the meantime, suppliers are being given a six-month transition period during which those who've taken steps to become compliant and have made a submission for licensing will be "considered a lower priority for enforcement, unless a risk to health or additional non-compliances are identified."

The chances of salvia ever receiving \*\*>Health Canada<\*\*\*'s seal of approval seem slim, given the department's dim view of the product.

"Canadians should not use products containing *S. divinorum* and/or salvinorin A because very little is known about the substance and its potential effects on the brain and/or body and its impact on physical and mental functions," said department spokesperson Legault.

Indeed, she said \*\*>Health Canada<\*\*\* is currently reviewing available information about the plant to determine whether it should be included in the Controlled Drugs and Substances Act, which regulates or bans drugs deemed to have a higher-than-average risk of abuse or addiction.

Salvia is already banned or regulated in about a dozen countries including Australia, Japan, Germany and Belgium, and some dozen states in the U.S.

---

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Thank you.  
Media Monitoring Team  
Health Canada

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Merci.  
L'Équipe de surveillance des médias  
Santé Canada



**Fw: Urgent: Sales of hallucinogenic salvia no longer legal in Canada**  
Denis Arsenault to: Jocelyn Kula  
Cc: Stephanie Chandler

2010-10-19 10:43 AM

Just saw this.

Denis

Denis Arsenault, A/Manager / Gestionnaire p.i.  
Regulatory Policy Division /  
Division des politiques réglementaires,  
Office of Controlled Substances /  
Bureau des substances contrôlées,  
Health Canada / Santé Canada  
Tel/Tél: (613) 957-6828  
Fax / Télécopieur : (613) 946-4224  
E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca

----- Forwarded by Denis Arsenault/HC-SC/GC/CA on 2010-10-19 10:33 AM -----

From: Stephanie Szick/HC-SC/GC/CA  
To: Denis Arsenault/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC  
Date: 2010-10-19 10:06 AM  
Subject: Fw: Urgent: Sales of hallucinogenic salvia no longer legal in Canada

spoke too soon...please see follow up Q below....

Let me know thanks!

----- Forwarded by Stephanie Szick/HC-SC/GC/CA on 2010-10-19 10:05 AM -----

From: Jesse Arnup-Blondin/HC-SC/GC/CA  
To: Stephanie Szick/HC-SC/GC/CA@HWC  
Date: 2010-10-19 10:00 AM  
Subject: Re: Fw: Urgent: Sales of hallucinogenic salvia no longer legal in Canada

Thanks, Stephanie. One more follow-up question.

So, if a product doesn't claim to modify brain function (i.e. doesn't make a health claim), they could sell it even without an NPN or DIN-HM?

Stephanie Szick and a little more bumfl ----- Forwarded by Steph... 2010-10-19 09:55:47 AM

From: Stephanie Szick/HC-SC/GC/CA  
To: Jesse Arnup-Blondin/HC-SC/GC/CA@HWC  
Date: 2010-10-19 09:55 AM  
Subject: Fw: Urgent: Sales of hallucinogenic salvia no longer legal in Canada

and a little more bumfl

----- Forwarded by Stephanie Szick/HC-SC/GC/CA on 2010-10-19 09:55 AM -----

From: Jocelyn Kula/HC-SC/GC/CA  
To: stephanie.szick@hc-sc.gc.ca  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2010-10-19 09:51 AM  
Subject: Fw: Urgent: Sales of hallucinogenic salvia no longer legal in Canada

---

I think the real issue here is a distinction in what the two legislative frameworks govern.....at the end of the day, the FDR don't make anything or drug or product illegal, they make the sale of something illegal if you don't meet the requirements. By contrast, the CDSA prohibits all activities with substances listed in Schedules (which salvia is not), ie. makes a substance virtually "illegal" (although we don't use that terminology) unless they are authorized by regulation.....

JK

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2010-10-19 09:47 AM -----

From: Denis Arsenault/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2010-10-19 09:47 AM  
Subject: Fw: Urgent: Sales of hallucinogenic salvia no longer legal in Canada

---

FYI

Denis

---

Denis Arsenault, A/Manager / Gestionnaire p.i.  
Regulatory Policy Division /  
Division des politiques réglementaires,  
Office of Controlled Substances /  
Bureau des substances contrôlées,  
Health Canada / Santé Canada  
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Fax / Télécopieur : (613) 946-4224  
E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca

----- Forwarded by Denis Arsenault/HC-SC/GC/CA on 2010-10-19 09:46 AM -----

From: Denis Arsenault/HC-SC/GC/CA  
To: Stephanie Szick/HC-SC/GC/CA@HWC  
Date: 2010-10-19 09:44 AM  
Subject: Re: Urgent: Sales of hallucinogenic salvia no longer legal in Canada

---

**Page(s) 001341 to\à 001341**

**Is(Are) exempted pursuant to section(s)  
est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**23**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**





**Fw: Urgent - Salvia**  
Stephanie Chandler to: Denis Arsenault  
Cc: Daniel Galarnau

2010-10-20 01:43 PM

As requested.

Would you be able to provide me with a little bit more detail that we can share with MO?

-what are we doing to assess

OCS is currently finalizing an Issue Analysis Summary which analyzes the potential benefits and risks of scheduling Salvia under the CDSA, as well as other mechanisms for the control of this substance. The final Summary will be used to determine what action to control Salvia is most appropriate.

-what factors do we consider

Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in the control and/or scheduling;
- Chemical and/or pharmacological similarity to substances listed in the Schedules to the CDSA;
- Legitimate use of the substance, including therapeutic, scientific, industrial or commercial uses;
- Potential for abuse and/or addiction liability;
- Evidence of extent of actual abuse of the substance in Canada and internationally; and
- Risk to personal and public health and safety.

**s.21(1)(a)**

-do we have a sense of what decision will be

OCS brought a draft Issue Analysis Summary regarding the potential scheduling of Salvia to the Controlled Substances Scheduling Working Group (CSS-WG) for their recommendation. This group includes HECSB, HPFB and HPFBI members and is responsible for assessing substances to determine whether they should be placed in a Schedule to the CDSA and its Regulations. [REDACTED]

**s.21(1)(b)**

[REDACTED] OCS is currently working to finalize the Issue Analysis Summary in light of this recommendation. This recommendation will be approved by the Director of OCS and then sent to the Director General of CSTD for concurrence.

-timing for decision:

At this time, OCS is unable to provide a timeline as to when the above described approval process will be completed.

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
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E-Mail: stephanie.chandler@hc-sc.gc.ca

----- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2010-10-20 01:02 PM -----

From: Denis Arsenault/HC-SC/GC/CA  
To: Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2010-10-20 12:58 PM  
Subject: Fw: Urgent - Salvia

Denis

Denis Arsenault, A/Manager / Gestionnaire p.i.  
Regulatory Policy Division /  
Division des politiques réglementaires,  
Office of Controlled Substances /  
Bureau des substances contrôlées,  
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E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca

----- Forwarded by Denis Arsenault/HC-SC/GC/CA on 2010-10-20 12:58 PM -----

From: Jocelyn Kula/HC-SC/GC/CA  
To: Jesse Arnup-Blondin/HC-SC/GC/CA@HWC  
Cc: stephanie.szick@hc-sc.gc.ca, Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2010-10-20 12:55 PM  
Subject: Re: Urgent - Salvia

Hi Jesse

We are on it.

Denis- for action pls. Need something by 2:30 so we have time to get through DGO.....

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

Jesse Arnup-Blondin Hello - I understand someone from HPFB wa... 2010-10-20 12:38:50 PM

From: Jesse Arnup-Blondin/HC-SC/GC/CA  
To: stephanie.szick@hc-sc.gc.ca, Jocelyn Kula/HC-SC/GC/CA@HWC  
Date: 2010-10-20 12:38 PM  
Subject: Urgent - Salvia

s.21(1)(a)

s.21(1)(b)

Hello -

I understand someone from HPFB was trying to reach someone from OCS but was unable this morning.

I understand from media inquiries earlier this week that we are currently assessing whether its regulation under the CDSA is warranted.

Would you be able to provide me with a little bit more detail that we can share with MO?

- what are we doing to assess
- what factors do we consider
- do we have a sense of what decision will be
- timing for decision.

A phone conversation or a few lines in an email would be perfect - nothing too detailed needed.

Thank you!

Jesse  
952 5457

s.21(1)(a)  
s.21(1)(b)



To:  
Cc:  
Bcc:  
Subject: **Fw: Urgent - Salvia**

Would you be able to provide me with a little bit more detail that we can share with MO?

-what are we doing to assess

OCS is currently finalizing an Issue Analysis Summary which analyzes the potential benefits and risks of scheduling Salvia under the CDSA, as well as other mechanisms for the control of this substance. The final Summary will be used to determine what action to control Salvia is most appropriate ~~at this time~~.

-what factors do we consider

Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

} check with Triana

-do we have a sense of what decision will be

OCS brought a draft Issue Analysis Summary regarding the potential scheduling of Salvia to the Controlled Substances Scheduling Working Group (CSS-WG) for their recommendation. This group includes HECSB, HPFB and HPFBI members and is responsible for assessing substances to determine whether they should be placed in a Schedule to the CDSA and its Regulations. [redacted]

[redacted] OCS is currently working to finalize the Issue Analysis Summary in light of this recommendation.

-timing for decision. → *concerned by DCS*

At this time, OCS is unable to provide a timeline as to when this decision will be finalized.

- to be approved by director OCS

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
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E-Mail: stephanie.chandler@hc-sc.gc.ca  
----- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2010-10-20 01:02 PM -----

From: Denis Arsenault/HC-SC/GC/CA  
To: Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2010-10-20 12:58 PM  
Subject: Fw: Urgent - Salvia

Denis

Denis Arsenault, A/Manager / Gestionnaire p.i.  
Regulatory Policy Division /

Division des politiques réglementaires,  
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Cc: stephanie.szick@hc-sc.gc.ca, Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2010-10-20 12:55 PM  
Subject: Re: Urgent - Salvia

---

Hi Jesse

We are on it.

Denis- for action pls. Need something by 2:30 so we have time to get through DGO.....

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

Jesse Arnup-Blondin Hello - I understand someone from HPFB wa...

2010-10-20 12:38:50 PM



Re: Urgent - Salvia  
Denis Arsenault to: Jocelyn Kula  
Cc: Stephanie Chandler, Daniel Galarneau

2010-10-20 02:09 PM

Hi Jocelyn,

Below are our proposed responses.

*All scheduling assessments involve the development of a that summarizes info available regarding the scheduling factors*

**What are we doing to assess?**

OCS is currently finalizing an Issue Analysis Summary which analyzes the potential benefits and risks of scheduling Salvia under the CDSA, as well as other mechanisms for the control of this substance. The final Summary will be used to determine what action to control Salvia is most appropriate.

**What factors do we consider?**

Health Canada considers several factors in determining whether regulation of a substance under the Controlled Drugs and Substances Act (CDSA) is warranted. These include:

- International requirements and trends in the control and/or scheduling;
- Chemical and/or pharmacological similarity to substances listed in the Schedules to the CDSA;
- Legitimate use of the substance, including therapeutic, scientific, industrial or commercial uses;
- Potential for abuse and/or addiction liability;
- Evidence of extent of actual abuse of the substance in Canada and internationally; and
- Risk to personal and public health and safety.

*of an and identifies possible options for regulatory and non-rg. action.*

**Do we have a sense of what decision will be?**

OCS brought a draft Issue Analysis Summary regarding the potential scheduling of Salvia to the Controlled Substances Scheduling Working Group (CSS-WG) for their recommendation. This group includes HECSB, HPFB and HPFBI members and is responsible for assessing substances to determine whether they should be placed in a Schedule to the CDSA and its Regulations.

*A recent*

s.21(1)(a)  
s.21(1)(b)

**What is the timing for the decision?**

OCS is currently working to finalize the Issue Analysis Summary in light of the above noted CSS-WG recommendation. The IAS and the recommendation contained therein will be forwarded to the Director of OCS for review and approval by the end of October. Once approved, the recommended course of action will be presented to the Director General of CSTD for concurrence.

*A draft*

*used the*

*It has not yet been decided what schedule the substance will be added to.*

Denis

Denis Arsenault, A/Manager / Gestionnaire p.i.  
Regulatory Policy Division /  
Division des politiques réglementaires,  
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Bureau des substances contrôlées,  
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E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca

*intra departmental group consisting of reps from HECSB + HPFB*

*likely the proceed with a intent notice of intent in Canada*

*signed at informing stakeholder - all*

Jocelyn Kula

Hi Jesse We are on it.

2010-10-20 12:55:46 PM

From: Jocelyn Kula/HC-SC/GC/CA  
To: Jesse Arnup-Blondin/HC-SC/GC/CA@HWC  
Cc: stephanie.szick@hc-sc.gc.ca, Denis Arsenault/HC-SC/GC/CA@HWC



## Hallucinogenic salvia illegal in Canada, but still sold

*The Canadian Press*

Updated: Tue. Oct. 19 2010 9:04 AM ET

OTTAWA — Canada is no longer a safe legal haven for salvia divinorum, the potent hallucinogenic plant that is sold openly online and in head shops across the country.

Yet no one seems aware of the law and Health Canada is not enforcing it.

Websites and shopkeepers are still advertising the plant as a perfectly legal head trip for Canadians eager to join the thousands of "pschonauts" who've posted videos of their psychedelic salvia voyages on YouTube.

An estimated 1.6 per cent of Canadians aged 15 or older have already taken at least one ride on salvia, according to the 2009 Canadian Alcohol and Drug Use Monitoring Survey, the first to measure use of the plant.

For those aged 15-24, the number rises to 7.3 per cent.

Yet the federal government says products containing salvia divinorum and its active ingredient, salvinorin A, are considered natural health products and, as such, must be authorized by Health Canada before they can be sold.

"It is illegal to sell NHPs (natural health products) in Canada unless they have been reviewed by Health Canada and authorized for sale," Christelle Legault, a spokesperson for Health Canada, told The Canadian Press in an email.

"To date, Health Canada has not licensed for sale any drug or NHP which contains salvia as an ingredient."

Legault added: "The illegal sale of products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the Food and Drugs Act."

This comes as news to head shops that are openly selling vials of salvia extract -- for \$20 to \$80 per gram, depending on the potency -- within spitting distance of Parliament Hill.

One shopkeeper, who asked not to be identified, said he's had no notification that the plant, also known as diviner's sage and magic mint, can no longer be legally sold in Canada. He said he purchases the extract from a Canadian supplier.

It's news to the police as well, who've complained in the past that their hands are tied when it comes to salvia, which has been known to produce some adverse reactions, including one case reported by Health Canada in 2006 in which a teenage boy became incoherent and suicidal and threatened to kill police officers.

"Until the government makes it illegal, there's nothing we can do about it," said Robin Percival, communications strategist for drugs and organized crime at RCMP national headquarters.

Informed that Health Canada says it is, in fact, illegal to sell salvia without authorization under the Natural Health Products Regulations, Percival said: "I don't think we have any jurisdiction there."

Indeed, it would appear that enforcement of the regulations is entirely up to Health Canada's Health Products and Food Branch Inspectorate.

Asked why Health Canada has not stopped the illegal sale of salvia, department spokesman Gary Holub said complaints can be referred to the inspectorate by calling 1-800-267-9675.

However, an open letter from the inspectorate to "all interested parties" on Aug. 27 suggests the inspectorate has not yet really begun in earnest to enforce the Natural Health Products Regulations.

The letter recounts that the regulations came into force in 2004. Due to the large backlog of

products that needed to be assessed for safety and quality before they could be licensed by Health Canada, suppliers were given until June 2008 to submit applications for licensing.

It appears the process took longer than expected and only now is the inspectorate preparing to actually enforce the regulations.

The letter advises that a new compliance and enforcement policy has now been adopted, which is to be fully implemented in February. In the meantime, suppliers are being given a six-month transition period during which those who've taken steps to become compliant and have made a submission for licensing will be "considered a lower priority for enforcement, unless a risk to health or additional non-compliances are identified."

The chances of salvia ever receiving Health Canada's seal of approval seem slim, given the department's dim view of the product.

"Canadians should not use products containing *S. divinorum* and/or salvinorin A because very little is known about the substance and its potential effects on the brain and/or body and its impact on physical and mental functions," said department spokesperson Legault.

Indeed, she said Health Canada is currently reviewing available information about the plant to determine whether it should be included in the Controlled Drugs and Substances Act, which regulates or bans drugs deemed to have a higher-than-average risk of abuse or addiction.

Salvia is already banned or regulated in about a dozen countries including Australia, Japan, Germany and Belgium, and some dozen states in the U.S.





Home > Drugs & Health Products > Compliance & Enforcement > Information by Health Product > Natural Health Products

## Cover Letter - The Inspectorate's Natural Health Products Compliance and Enforcement Policy (POL-0044)

Health Products and Food Branch Inspectorate  
Graham Spry Building, 3rd Floor  
250 Lanark Avenue  
Address Locator 2003B  
OTTAWA, Ontario  
K1A 0K9

Date August 27, 2010

To: All Interested Parties

I am pleased to inform you that the document entitled "Natural Health Products Compliance and Enforcement Policy" (POL-0044) (NHP C&E Policy) is now available on the Compliance and Enforcement section of Health Canada's website.

This policy describes the compliance and enforcement approach respecting natural health products (NHPs) under the *Food and Drugs Act (FDA)* and the *Natural Health Products Regulations (NHPR)* and is to be used in conjunction with the Compliance and Enforcement Policy (POL-0001). This policy replaces the previous policy "Compliance Policy for Natural Health Products" last revised in 2008 as well as the "Compliance Guide for NHPs" (Version 2.1, 2007).

The implementation of this new NHP C&E Policy is being followed by a six month compliance promotion transition period described in this cover letter. This period of compliance promotion will allow for the transition from the old policy to the new policy regarding the product licensing requirements for NHPs.

This policy is also being implemented with the "Annex to the NHP Compliance and Enforcement Policy for exempt NHPs under the Natural Health Products (Unprocessed Product Licence Applications) Regulations (NHP-UPLAR)". The annex has been developed in order to provide clarification on the compliance and enforcement approach for products that are exempt under the NHP-UPLAR. This Annex is meant to be used in conjunction with the new NHP C&E Policy, and will remain in effect for 30 months until the NHP-UPLAR are repealed.

### Background

On January 1<sup>st</sup>, 2004 the NHPR came into force. At that time, it was acknowledged that there would be a large number of NHPs already available on the market that may not be in full compliance with the NHPR. In particular, products already on the market would not have product licences as required by the NHPR as they would first need to be assessed for safety and quality by the Natural Health Products Directorate (NHPD).

To aid in this "transitional period" during the existence of the product licensing backlog, the Compliance Policy for NHPs was developed. This policy provided guidance for the prioritization of compliance and enforcement actions. It outlined a risk based approach, f001350

category approach which outlined that: if an active submission number was granted by the NHPD for a product by a specific deadline, the product would be considered a lower priority for compliance and enforcement activities, unless a risk to health was identified.

June 1<sup>st</sup> 2008 was the last deadline for submissions outlined in the previous Compliance Policy for NHPs. As such, all regulated parties associated with products currently available on the market should have already taken steps to come into compliance with the product licensing requirements, in obtaining a submission number from the NHPD in order to be considered a lower priority for enforcement under the previous Compliance Policy for NHPs.

### **Public Consultation**

In November of 2009, Health Canada's NHP Program (the NHPD, the Marketed Health Products Directorate and the Inspectorate) conducted workshop sessions across Canada and received stakeholder feedback that was taken into consideration in the development of the new NHP C&E Policy. Feedback from these sessions suggested that the implementation of a new compliance and enforcement approach for unlicensed NHPs should be dependant on the pending resolution of the product licensing backlog and the establishment of performance targets for product licence application review. In addition, a period of compliance education and awareness to transition into a new policy was desired as well as enhanced outreach to consumer, retailer and practitioner groups.

As such, Health Canada is implementing the new C&E Policy along with the coming into force of the new NHP-UPLAR, as well as the implementation of the new NHPD Application Management Policy (August 2010), which will both provide predictability in the product licensing process as well as allowing for the legal sale of certain NHPs. As well, the compliance promotion transition period described below will allow for the transition from the previous Compliance Policy for NHPs to this new policy. In May and June of 2010, Health Canada held information sessions across Canada informing stakeholders of the new NHP Approach including the NHP-UPLAR, the new NHP C&E Policy and the NHPD Application Management Policy.

### **Compliance Promotion Transition Period**

The posting of this new NHP C&E Policy is being followed by a six month compliance promotion transition period respecting the product licensing requirements which will precede the full implementation of the policy.

During the compliance promotion transition period, regulated parties that have already taken steps to come into compliance with the product licensing requirements and have an active submission number with the NHPD will be considered a lower priority for enforcement, unless a risk to health or additional non-compliances are identified. This position is consistent with the position which was outlined in the previous Compliance Policy for NHPs (2008). During this period, compliance and enforcement efforts will focus on regulated parties that have not taken steps to come into compliance and/or products that pose a risk to health.

### **Full Implementation of the new NHP C&E Policy**

Full implementation of the new policy is anticipated to begin in February of 2011 at which time NHPs without a product licence or exemption number may be subject to compliance and enforcement activities and should not be available for sale or imported for sale into Canada.

Inquiries about this document can be addressed to the Drug Compliance Verification and Investigation Unit, Fax: (613) 946-5636 or by E-Mail: [DCVIU\\_UVCEM@hc-sc.gc.ca](mailto:DCVIU_UVCEM@hc-sc.gc.ca).

**Original signed by**

**Cover Letter - The Inspectorate's Natural Health Products Compliance and Enforcement P... Page 3 of 3**

**Diana Dowthwaite  
Director General**

**Date Modified: 2004-01-01**



Health  
Canada

Santé  
Canada

**Our Mandate:**

To promote good nutrition and informed use of drugs, food, medical devices and natural health products, and to maximize the safety and efficacy of drugs, food, natural health products, medical devices, biologics and related biotechnology products in the Canadian marketplace and health system.

# **Health Products and Food Branch Inspectorate**

## **Natural Health Products Compliance and Enforcement Policy**

**(POL-0044)**

**Supersedes:**

**Compliance Policy for Natural Health Products (September 2008)  
and Natural Health Products Compliance Guide (January 2007)**

**Date issued:**

**August 27, 2010**

**Date of implementation:**

**August 27, 2010**

**Disclaimer:**

*This document does not constitute part of the Food and Drugs Act (Act) or its associated Regulations and in the event of any inconsistency or conflict between that Act or Regulations and this document, the Act or the Regulations take precedence. This document is an administrative document that is intended to facilitate compliance by the regulated party with the Act, the Regulations and the applicable administrative policies. This document is not intended to provide legal advice regarding the interpretation of the Act or Regulations. If a regulated party has questions about their legal obligations or responsibilities under the Act or Regulations, they should seek the advice of legal counsel.*

**Canada**

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## **1.0 Purpose**

The purpose of this policy is to describe Health Canada's approach to compliance and enforcement of Natural Health Products (NHPs) under the *Natural Health Products Regulations* (NHPR) and the *Food and Drugs Act* (FDA).

The main objective of this policy is to foster fairness, transparency and uniformity in the compliance and enforcement approach taken by Health Canada in instances of non-compliance.

This policy replaces and supersedes the Compliance Policy for Natural Health Products (implemented in 2004, and revised in September 2008). It also replaces the Natural Health Products Compliance Guide (Version 2.1 Jan. 2008). This policy is to be used in conjunction with Health Canada's Compliance and Enforcement Policy (POL-0001) ([http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/pol/pol\\_1\\_tc-tm-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/pol/pol_1_tc-tm-eng.php)).

## **2.0 Background**

The NHPR came into force on January 1, 2004. These regulations fall under the FDA, and as such, NHPs are legally considered to be drugs in regards to the FDA. The FDA and the NHPR apply to all NHPs as defined in the NHPR and they set out requirements for the manufacturing, packaging, labelling, importing, storing, distributing, selling and advertising of NHPs.

The NHPR are intended to ensure that all Canadians have ready access to NHPs that are safe, effective and of high quality, while respecting freedom of choice and philosophical and cultural diversity. Compliance with the FDA and NHPR helps ensure this mandate is being met and allows consumers to have greater confidence in the products they choose. It is essential that the NHP industry, Health Canada, health care practitioners and the public all work together to help maintain confidence that NHPs being made available for sale in Canada are safe, effective and of high quality.

Within Health Canada, the NHPR are administered by the Natural Health Products Program which is comprised of the Natural Health Products Directorate (NHPD), the Marketed Health Products Directorate (MHPD) and the Inspectorate (which has staff within the Health Products and Food Branch (HPFB) as well as the Regions and Programs Branch (RAPB)). Compliance and enforcement activities are primarily led by Health Canada inspectors situated within the Inspectorate.

## **3.0 Scope**

This policy applies to instances of non-compliance with the FDA and/or the NHPR as they relate to NHPs, with the exception of NHPs used in clinical trials involving human subjects (Part 4 of the NHPR).

This policy describes Health Canada's compliance and enforcement approach when instances of non-compliance with the FDA and/or NHPR are identified.

## **4.0 Definitions**

The source of the definitions has been indicated in parenthesis as follows:

- *Food and Drugs Act* (FDA)
- *Natural Health Products Regulations* (NHPR)
- Compliance and Enforcement Policy (POL-0001)

*Definitions may have been adjusted from their original source to fit the context of this policy.*

**Adverse Reaction:** (NHPR) means a noxious and unintended response to an NHP that occurs at any dose used or tested for the diagnosis, treatment or prevention of a disease or for modifying an organic function.

**Advertisement:** (FDA) includes any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of a drug (including an NHP) under the FDA or the NHPR.

**Compliance:** (POL-0001) the state of conformity of a regulated party (including a corporation, institution, individual or other legal entity) or an NHP with the FDA or the NHPR.

**Compliance Verification:** (POL-0001) actions taken by the Inspectorate to verify compliance in response to information regarding a known or suspected non-compliance with the FDA and/or NHPR.

**Distributor:** (NHPR) a person who sells an NHP to another person for the purpose of further sale by that other person.

**Enforcement:** (POL-0001) actions that may be taken to induce, encourage or compel compliance with the FDA and the NHPR.

**Importer:** (NHPR) a person who imports an NHP into Canada for the purpose of sale.

**Inspector:** (FDA) any person designated as an inspector for the purpose of the enforcement of the FDA and the NHPR under subsection 22(1) of the FDA.

**Label:** (FDA) includes any legend, word or mark attached to, included in, belonging to or accompanying any drug (including an NHP) or package.

**Manufacturer:** (NHPR) means a person who fabricates or processes an NHP for the purpose of sale, but does not include a pharmacist or other health care practitioner who, at the request of a patient, compounds an NHP for the purpose of sale to that patient.

**Market Authorization:** a product licence issued by Health Canada, authorizing the sale of an NHP, issued pursuant to section 7 of the NHPR on the basis of information submitted in a licence application to the NHPD. The market authorization is in the form of an eight (8) digit numerical code following the acronym NPN (Natural Product Number) or DIN-HM (Homeopathic Medicine Number).

**Natural Health Product:** (NHPR) a substance set out in Schedule 1 to the NHPR or a combination of substances in which all the medicinal ingredients are substances set out in Schedule 1, a homeopathic medicine or a traditional medicine that is manufactured, sold or represented for use in:

- a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
- b) restoring or correcting organic functions in humans; or
- c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

However, a natural health product does not include a substance set out in Schedule 2 to the NHPR, any combination of substances that includes a substance set out in Schedule 2 or a homeopathic medicine or a traditional medicine that is or includes a substance set out in Schedule 2. Also, in accordance with subsection 2(2) of the NHPR, a substance or combination of substances or a traditional medicine is not considered to be a natural health product if its sale, under the *Food and Drug Regulations (FDR)*, is required to be pursuant to a prescription when it is sold other than in accordance with section C.01.043 of the FDR.

**Non-Compliance:** a state of nonconformity with a specific regulatory requirement of the FDA and/or the NHPR.

**Package:** (FDA) includes any thing in which any drug (including an NHP) is wholly or partly contained, placed or packed.

**Recommended conditions of use:** (NHPR) the recommended use or purpose; dosage form; recommended route of administration; recommended dose; recommended duration of use, if any; and its risk information, including any cautions, warnings, contra-indications or known adverse reactions of an NHP.

**Sell:** (FDA) offer for sale, expose for sale, have in possession for sale and distribute, whether or not the distribution is made for consideration.

**Specifications:** (NHPR) means a description of an NHP that contains the information described in subsection 44(2) of the NHPR.

## 5.0 Policy

### 5.1 Policy Statement

It is the responsibility of the regulated party to ensure that NHPs being sold, advertised, manufactured, packaged, labelled, imported, distributed or stored comply with the FDA and the NHPR. In accordance with Compliance and Enforcement Policy (POL-0001) ([http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/pol/pol\\_1\\_tc-tm-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/pol/pol_1_tc-tm-eng.php)), where non-compliance with the FDA and/or the NHPR is identified by the Inspectorate, it is brought to the attention of the regulated party (ie. the company or individual involved). It is then the regulated party's responsibility to take timely and appropriate action to comply with legislative and regulatory requirements. Compliance is normally achieved through a cooperative approach among the regulated party, the Inspectorate and other relevant organizations within Health Canada. However, a number of enforcement options are available if necessary, particularly when the regulated party is unable or unwilling to correct non-compliance. The Inspectorate's role is to ensure that the regulated party complies with the regulatory decisions. The primary objective of the response strategy is to manage the risk to Canadians and use the most appropriate level of intervention to ensure that the responsible regulated party brings the product or activity into compliance. In identifying the appropriate enforcement action, many factors are considered including the risk to health, the likelihood of compliance by the regulated party (considering their history of compliance, intent and degree of cooperation being offered) and available resources.



## **5.2 Guiding Principles**

This policy is founded on the principles contained in the Inspectorate's Compliance and Enforcement Policy POL-0001. Risk management principles are guided by Health Canada's Decision Making Framework (<http://www.hc-sc.gc.ca/sr-sr/advice-avis/decision/index-eng.php>).

## **5.3 Responsibilities**

As indicated in POL-0001, where non-compliance is brought to the attention of a regulated party it is the regulated party's responsibility to take timely and appropriate action to comply with regulatory requirements and to ensure that appropriate risk management actions are taken.

It is the responsibility of the Inspectorate to conduct compliance and enforcement activities related to NHPs. Where the Inspectorate identifies or is notified of a potential non-compliance, the primary objective of the response strategy is to manage the risk to Canadians and use the most appropriate level of intervention to help ensure that the regulated party brings the product or activity into compliance.

## **6.0 Identified Non-Compliance**

The safety of Canadians is the highest priority for Health Canada. Generally, Health Canada becomes aware of instances of non-compliance of NHPs primarily through consumer or trade complaints, and/or referrals from internal and external partners. When a complaint is received, the Inspectorate aims to prioritize the potential non-compliance according to the possible level of risk it may pose in order to most effectively apply departmental resources on a risk based approach. Generally, non-compliances that Health Canada considers to be a higher risk are assigned the highest priority for Inspectorate compliance verification, and are expected to result in immediate risk management actions by the regulated party as needed.

This section is intended to provide guidance regarding the initial risk classification of various non-compliances with the NHPR or FDA. Several non-compliances with the FDA or NHPR have been classified according to their initial level of risk classification. For the purpose of this policy, these have been defined as:

- Higher risk non-compliances
- Non-compliances that may pose a risk to health and;
- Lower risk non-compliances

These initial classifications are intended to provide guidance only. The circumstances surrounding a situation could modify the risk and/or resulting compliance and enforcement actions from that outlined below. In some instances, the Inspectorate may request that a formal risk assessment be conducted by the NHPD or other partners, in order to make a determination on the risk to health of a particular non-compliance. The level of risk could increase or decrease at any time if new information emerges.

## **6.1 Higher Risk Non-Compliances**

There are a number of instances of non-compliance which are initially considered by Health Canada to pose a higher risk to health. Immediate risk management actions are expected in these circumstances. This section outlines some of the situations in which Health Canada may consider as instance(s) of non compliance posing a higher risk to health. This list is not exhaustive and is in no particular order. Details regarding the enforcement approach for instances of higher risk non-compliances can be found in section 7 of this policy.

### ***Non-Compliance with Licensing Requirements***

#### ***6.1.1 Unlicensed products sold and/or imported for sale***

As per section 4 of the NHPR, all NHPs require a product licence to be sold. A product licence demonstrates that a product has been assessed by Health Canada for its safety, efficacy and quality. NHPs that have not undergone this assessment are considered to pose a risk to health. For example, the product may not be labelled with adequate risk information, it may contain an ingredient unsuitable for vulnerable sub-populations such as children or pregnant women, it may contain levels of bacterial or chemical contaminants that do not conform to NHPD requirements and therefore the specifications for product testing may not be appropriate. The safety, efficacy and quality of an NHP are assessed through the product licensing process. Counterfeit products are considered to be unlicensed products and do not adhere to numerous requirements in the FDA and the NHPR. For more information refer to the Policy on Counterfeit Health Products (POL-0048) ([http://www.hc-sc.gc.ca/dhp-mps/compli-conform/activit/pol\\_0048\\_counterfeit-contrefacon-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/activit/pol_0048_counterfeit-contrefacon-eng.php)). For more information regarding product licensing, refer to the Product Licensing Guidance Document ([http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/license-licence\\_guide\\_tc-tm-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/license-licence_guide_tc-tm-eng.php)).

#### ***6.1.2 Unlicensed sites conducting licensable activities***

As per section 27 of the NHPR, manufacturers, packagers, labellers and importers are required to hold a valid site licence. A site licence demonstrates that Health Canada has assessed the application and determined that the applicant has provided the required documentation to be issued a site licence. Applicants must demonstrate that the activities being conducted at the site are being conducted in accordance with Good Manufacturing Practices (GMPs), as outlined in Part 3 of the NHPR. GMPs help ensure the consistent quality of an NHP. All NHPs must be manufactured, packaged, labelled, imported, distributed and stored in accordance with these GMPs as per section 43 of the NHPR. Products from unlicensed sites have not provided the evidence required through the site licensing process to demonstrate that they have been manufactured, packaged, labelled, or imported in accordance with GMPs and may thus pose a higher risk to health. GMP non-compliances for licensed sites are further outlined in section 6.2.3 of this policy. For more information on site licensing, refer to the Site Licensing Guidance Document (<http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/slgsd-drle-eng.php>).

#### ***Importation of NHPs from Foreign Sites***

Canadian importers of NHPs must be licensed and the onus is on them to provide evidence that imported products come from sites that meet Canadian GMPs under Part 3 of the NHPR

or equivalent standards. All foreign sites are listed on an importer's site licence to demonstrate they are in compliance with the GMP requirements.

***Non-Compliances that may be identified with licensed products:***

***6.1.3 Licensed products subsequently labelled and/or advertised with an unauthorized Schedule A claim***

As per section 3 of the FDA, an NHP cannot be labelled or advertised to the general public for the prevention, treatment or cure of diseases listed in Schedule A of the FDA. On June 1, 2008 regulatory amendments were made to the *Food and Drug Regulations (FDR)* and the NHPR to allow the sale and advertising of NHPs that only make preventative claims for diseases listed in Schedule A, provided that the product has been reviewed and authorized by Health Canada. Claims of treatment or cure of a disease listed in Schedule A are still prohibited. For further information refer to the Canada Gazette (<http://gazette.gc.ca/archives/p2/2007/2007-12-26/html/sor-dors288-eng.html>). Diseases listed in Schedule A of the FDA, such as cancer and diabetes, all require medical intervention. The use of products through self-medication for serious diseases may result in harm to the consumer. The complete list of schedule A diseases can be found in the FDA (<http://laws.justice.gc.ca/eng/F-27/page-3.html#anchors:1>). A product labelled and/or advertised with an unauthorized Schedule A claim is also considered to be non-compliant with additional parts of the FDA or NHPR as referenced in sections 6.2.1 and 6.2.2 of this policy.

***6.1.4 Licensed product does not meet its specifications or is adulterated***

Under section 44 of the NHPR, every NHP available for sale must comply with the specifications approved by the NHPD for the licensed product. Specification requirements include: product purity, quantity and identity of the medicinal ingredients, potency if applicable, and testing methods. Non-compliance with this section of the NHPR may result in a product posing a higher risk to health. For example, an NHP may be contaminated with bacteria and mold, toxic metals such as mercury, lead, cadmium and arsenic, and residues of pesticides, PCBs, dioxins, or solvents; it may be super-potent or sub-potent or contain misidentified ingredients.

While product specifications cannot speak to every possible substance that could be present in an NHP, paragraph 8(b) of the FDA generally prohibits the sale of an NHP that is adulterated. An NHP may be considered adulterated if it contains an extraneous, improper or inferior (sub-standard to the product specifications) ingredient or a substance not reasonably expected to be found in the NHP. An NHP may also be considered adulterated when its specifications speak to a substance being present up to a certain level and the substance is present at a level above that limit. Adulterated NHPs may pose a higher risk to health, depending on the nature of the adulterant

The sale of an NHP which contains an undeclared prescription drug will be considered an enforcement priority due to the nature of the risks involved with drugs containing Schedule F ingredients. Health Canada will consider the sale of these products to be in violation of section 8(b) of the FDA. It is the responsibility of the regulated party to ensure that every

NHP meets its specifications and is not adulterated. Tolerance limits for some microbial and chemical contaminants are set out in the NHPD guidance document, Evidence for the Quality of Finished Natural Health Products (<http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/eq-paq-eng.php>).

## **6.2. Non-Compliances that may pose a risk to health**

There may be other instances of non-compliance that could pose a risk to health. Upon assessment of the specific circumstances surrounding a non-compliance, the risk could increase or decrease at any time. This section outlines some of these instances of non-compliance, in no particular order.

### ***6.2.1 Product is not labelled or packaged in accordance with Part 5 of the NHPR***

Part 5 of the NHPR sets out the labelling and packaging requirements for NHPs available for sale to the public. This part does not apply to sale that is restricted to a manufacturer or distributor (Section 86 of the NHPR). Part 5 outlines requirements for information to be in accordance with the terms of the product licence (e.g., the recommended use, dose, risk information etc.), additional labelling requirements (e.g., expiry date, importer information etc.) as well as presentation of labelling information on NHPs (e.g., NPN on the principle display panel, bilingual labelling, security packaging etc.). A product that is not labelled in accordance with its product licence and Part 5 of the NHPR may not contain enough information to be used safely. For example, a product may contain incorrect or incomplete risk information. In accordance with section 9(2) of the FDA, an NHP that is not labelled or packaged in accordance with the NHPR is considered to be labelled or packaged contrary to subsection 9(1). Thus its sale may contravene s. 9(1) as being sold in a false, misleading or deceptive manner. See section 6.2.2 of this policy. Non-compliance with Part 5 of the NHPR may result in a product that is determined to pose a higher risk to health once assessed. For more information, refer to the Labelling Guidance Document (<http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/labelling-etiquetage-eng.php>).

### ***6.2.2 Product is sold and/or advertised in a false, misleading or deceptive manner***

Section 9(1) of the FDA sets out that no person shall label, package, treat, process, sell or advertise any health product in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety. In order to allow consumers to make an appropriate and informed choice, advertising of NHPs should clearly communicate the intended use of the product in a manner that is consistent with the product licence. A product that is being labelled, sold or advertised in a manner consistent with that product's terms of market authorization, absent other factors, would not generally be false or misleading, or likely to create an erroneous impression with respect to its character, value, quantity, composition, merit or safety. Unauthorized claims made in conjunction with authorized products may be misinterpreted by the consumer as being authorized claims, as such these claims may contravene section 9(1) of the FDA by misleading consumers to believe the products are authorized to be sold with those claims. Any products or advertising materials brought to the attention of Health Canada will be evaluated and may be subject to compliance and enforcement actions on the basis of section 9 of the FDA. The Inspectorate and the MHPD work closely on advertising complaints with the Advertising Preclearance Agencies. Further information can be found in the document

Regulatory Requirements for Advertising (<http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/index-eng.php>). Of particular interest is the Consumer Advertising Guidelines for Marketed Health Products (for Nonprescription Drugs including Natural Health Products) ([http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/pol/guide-ldir\\_consom\\_consum-eng.php](http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/pol/guide-ldir_consom_consum-eng.php)).

### **6.2.3 Good Manufacturing Practices (GMP) non-compliances**

Part 3 of the NHPR sets out the requirements for GMPs. Compliance with this part is required for all those who manufacture, package, label, import, distribute or store NHPs. GMPs are ongoing practices designed to ensure an effective overall approach to product quality control and risk management. They do so by setting appropriate standards and practices for places, people, processes and products. For example, setting out that premises and equipment must be clean to prevent contamination; that quality assurance people are present and have appropriate expertise to control the activities and approve release of products; that processes are in place for proper sanitation and operations such as the ability to conduct a product recall; and that products meet their specifications and appropriate records are maintained. GMP violations may adversely affect the quality of the products and may result in different levels of risk based on the specific violation. Violations of GMP provisions are to be assessed by the regulated party to determine if risk management actions are required with respect to the products or any processes related to the activities. Further information can be found in the Good Manufacturing Practices Guidance Document (<http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/gmp-bpf-eng.php>).

### **6.3 Lower Risk Non-Compliances**

Instances of non-compliance that do not result in a product or activity posing a risk to health and in which corrective actions can be taken in a timely manner by the regulated party may be considered a lower priority for Health Canada enforcement measures.

## **7.0 Compliance and Enforcement Approach**

POL-0001 and the policy position stated in section 5.1 of this policy summarize the overall compliance and enforcement approach in relation to NHPs. As indicated, the risk to health, as well as a number of additional factors, such as the likelihood of compliance by the regulated party, are taken into consideration in determining the compliance and enforcement approach and risk management tools employed. Generally, as the risk to health increases, coupled with additional factors, such as a low likelihood of compliance by the regulated party, the likelihood that risk management tools will be used also increases.

In response to instances of non compliance, the Inspectorate has a number of compliance measures available to address the situation. The Inspectorate may request that the regulated party take certain voluntary measures in response to an identified non-compliance. There are also a number of powers that can be used by the Inspectorate, where intervention is warranted, which are further detailed in POL-0001. Voluntary measures by the regulated party may include but are not limited to: corrective actions to prevent recurrence, a product stop sale, recall or public communications pieces. Measures available to the Inspectorate may include but are not limited to: warning letters, public communications pieces, product seizures, and importation refusals or the issuance of import alerts. The NHPR contain additional post-licensing tools that may be used to address non-compliance. These tools include:

- a request for additional safety information under section 16 or 24 of the NHPR,
- a direction to stop sale under section 17 of the NHPR, and;
- a suspension or cancellation of a product or site licence under sections 18 or 19 and sections 39 or 40 respectively.

Further information can be found in the NHP Post Licensing Guidance Document ([http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/plgd\\_psdldr-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/plgd_psdldr-eng.php)).

The Inspectorate and regulated parties have a shared responsibility for monitoring compliance with the FDA and its Regulations. Where the non-compliance identified might impact the safety, efficacy or quality of the NHP, the Inspectorate expects that the regulated party will immediately stop the sale and/or importation of the product or the activity being conducted. The Inspectorate expects that the regulated party will take immediate action to assess the risk associated with the non-compliance to determine the risk management actions required as well as take preventative action to achieve and maintain compliance. The stop sale should not be lifted until such a time that compliance is achieved and appropriate risk management actions have been taken. The Inspectorate expects that the regulated party will take full responsibility for product recalls. Further compliance and enforcement actions in accordance with POL-0001 may be taken if a regulated party fails to voluntarily recall a product. Any recall initiated must be reported to the Inspectorate within 3 days after the day on which the recall is commenced along with the necessary recall information as per section 62 of the NHPR in accordance with the Inspectorate's Recall Policy (POL-0016) ([http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/drugs-drogués/pol\\_0016\\_recall\\_policy-politique\\_retrait\\_ltr-doc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/drugs-drogués/pol_0016_recall_policy-politique_retrait_ltr-doc-eng.php)).

In general, the Inspectorate will work with the regulated party using the appropriate level of oversight based on the level of risk in accordance with POL-0001. Enforcement actions may be taken at any time where warranted by circumstances such as lack of cooperation or an inability to address the noncompliance. Failure of companies to respond to written notices or letters advising of recommended compliance actions are interpreted as an indication that the company does not intend to voluntarily comply and that enforcement action is required. Companies with a history of failure to provide adequate response to noncompliance(s) may be subject to immediate enforcement action.

When an issue of non-compliance is identified that does not impact the safety, efficacy or quality of an NHP, the company should ensure that appropriate corrective actions have been taken to resolve the non-compliance in a timely and effective manner and to prevent future recurrence. When identified to the Inspectorate, the Inspectorate may work with the regulated party using a lower level of enforcement oversight. If it is determined at any time that the non-compliance may pose a higher risk to health, further risk management actions may be required.

Continued non-compliance may result in the recommendation by the Inspectorate to the NHPD for actions such as requests for safety information under section 16 of the NHPR related to the product and/or the recommendation to issue an intent to suspend for a product or site licence under sections 18 or 39 of the NHPR respectively, or in cases where there is a risk to health, an immediate suspension of a product or site licence under section 19 or 40 of the NHPR.

Outlined below are some examples of how the compliance and enforcement approach may be applied in some instances of non-compliance, in accordance with POL-0001. The examples provided are intended to

serve as a general guide and do not include all instances of non-compliance. Circumstances surrounding the non-compliance may result in variance from the examples provided.

### **7.1 Unlicensed products being sold**

When the Inspectorate has reasonable grounds to believe that an NHP is being sold without a product licence in contravention of section 4 of the NHPR, the Inspectorate may issue a direction to stop sale to the manufacturer, distributor or importer of the unlicensed product. In addition, the Inspectorate may request that the manufacturer, distributor or importer initiate a product recall to the retail level in accordance with the Inspectorate Recall Policy. Recall information as required by section 62 of the NHPR must be provided to the Inspectorate within 3 calendar days of recall initiation. For licenses which have been suspended or cancelled under the NHPR, the stop sale and recall of any products available for sale should be initiated immediately upon the cancellation or suspension date. For more information refer to the Inspectorate's Recall Policy (POL-0016) ([http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/drugs-drogues/pol\\_0016\\_recall\\_policy-politique\\_retrait\\_ltr-doc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/drugs-drogues/pol_0016_recall_policy-politique_retrait_ltr-doc-eng.php)).

If it comes to Health Canada's attention that an unlicensed NHP is being sold at retail, the retailer may be asked to remove the unlicensed product from sale. In addition, the retailer may be requested to provide the name and address of the supplier of the product. If successful in obtaining the information, the inspector may follow up with the manufacturer, distributor or importer of the product and proceed as indicated above. If the retailer directly imports the product for sale, or in the case where the retailer does not offer the necessary cooperation to remove the product or provide information on the supplier, the retailer may be treated as the distributor or importer of the unlicensed product.

#### ***Follow Up Expectations***

The manufacturer, importer or distributor should respond to the Inspectorate in writing within the requested timeframe indicating that they have complied. If a satisfactory response is not received within the requested timeframe, the Inspectorate may take further enforcement actions in accordance with POL-0001. These activities may include product seizures under the authority of section 23 of the FDA. Further risk management actions may be required, including public a communications piece initiated by the company or Health Canada.

### **7.2 Unlicensed products being imported**

Unlicensed NHPs being imported into Canada and brought to the attention of the Inspectorate may be recommended for refusal of entry into Canada. Health Canada may also issue an import alert for an identified importer, or a lookout for the product, in order to monitor future importations. Further information can be found in the Import and Export Policy for Health Products under the Food and Drugs Act and its Regulations (POL-0060) ([http://www.hc-sc.gc.ca/dhp-mps/compli-conform/import-export/pol-0060\\_biu-uif-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/import-export/pol-0060_biu-uif-eng.php)) and the Guidance Document on the Import Requirements for Health Products under the Food and Drugs Act and its Regulations (GUI-0084) ([http://www.hc-sc.gc.ca/dhp-mps/compli-conform/import-export/gui-0084\\_biu-uif-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/import-export/gui-0084_biu-uif-eng.php)).

### **7.3 Unlicensed Sites Conducting Licensable Activities**

When the Inspectorate has reasonable grounds to believe that a site is conducting licensable activities without a site licence in contravention of section 27 of the NHPR, the Inspectorate may issue a notice to the site to cease the licensable activity until such a time that a site licence is obtained. The site may be requested to stop the sale of all products associated with the unlicensed activity under section 17 of the NHPR, as they may not be in compliance with Part 3 of the NHPR. In addition, the site should conduct a thorough assessment of each product to determine if further risk management actions are required, such as product recalls. In the case of an importer, products being imported into Canada and brought to the attention of the Inspectorate may be recommended for refusal of entry into Canada. For more information, refer to the Import and Export Policy for Health Products under the Food and Drugs Act and its Regulations (POL-0060) ([http://www.hc-sc.gc.ca/dhp-mps/compli-conform/import-export/pol-0060\\_biu-uif-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/import-export/pol-0060_biu-uif-eng.php)) and the Guidance Document on the Import Requirements for Health Products under the Food and Drugs Act and its Regulations (GUI-0084) ([http://www.hc-sc.gc.ca/dhp-mps/compli-conform/import-export/gui-0084\\_biu-uif-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/import-export/gui-0084_biu-uif-eng.php)).

#### ***Follow Up Expectations***

The site should respond to the Inspectorate within the requested timeframe indicating they have complied with the request to cease activities and stop sale of all products associated with the unlicensed activity. In addition, the site should provide an assessment of all products associated with the activity and any further risk management actions to be taken, such as product recalls. If a satisfactory response is not received within the timeframes, the Inspectorate may take further enforcement actions in accordance with POL-0001. These activities may include product and/or equipment seizures under the authority of section 23 of the FDA. Health Canada may also directly contact the product licence holders or distributors of the products associated with the unlicensed activity and take further compliance and enforcement actions. In the case of an importer, Health Canada may issue an import target to review future importations. If additional non-compliances with the FDA and NHPR are identified through the product assessment that could indicate a potential further risk to health, further risk management actions may be required including product recalls and a public communications piece initiated by the company or Health Canada.

### **7.4 Product labelling for the treatment or cure of any of the diseases, disorders or abnormal physical states referred to in Schedule A or in a manner that may pose a risk to health**

When the Inspectorate identifies an NHP that may be labelled for the treatment or cure of a Schedule A disease in contravention of section 3 of the FDA, the Inspectorate may issue a notice to the manufacturer, distributor or importer of the product to stop sale of the non-compliant NHP. In addition, the Inspectorate may request that the manufacturer, distributor or importer initiate a product recall to the retail level in accordance with the Inspectorate Recall Policy. Recall information as required by section 62 of the NHPR must be provided to the Inspectorate within 3 calendar days of recall initiation. The stop sale should not be lifted until such a time that compliance is achieved and appropriate risk management actions have been taken.

#### ***Follow Up Expectations***

The manufacturer, importer or distributor should respond to the Inspectorate in writing within the requested timeframe indicating they have complied. If a satisfactory response is not received within the requested timeframe, the Inspectorate may take further enforcement actions in accordance with POL-0001. These activities may include product seizures under the authority of section 23 of the



FDA or public communications pieces.

### **7.5 Product advertising for the treatment or cure of any of the diseases, disorders or abnormal physical states referred to in Schedule A**

When the Inspectorate identifies advertising materials for the treatment or cure of a Schedule A disease in contravention of section 3 of the FDA, the Inspectorate may issue a notice to the person responsible for the advertising to immediately cease the advertising activities. If the person responsible for the advertising is not the product licence holder, the Inspectorate may request that the person provide written notification to the product license holder of the advertising non-compliance.

#### ***Follow Up Expectations***

The person responsible for the advertising activities should respond to the Inspectorate in writing within the requested timeframe indicating that they have complied with the request. If a satisfactory response is not received within the requested timeframe, the Inspectorate may take further enforcement actions in accordance with POL-0001. These activities may include seizure of advertising materials, further contacting the product licence holder to inform them of the non-compliance and/or the issuance of a public communications piece.

## **8.0 Additional Considerations**

Additional compliance and enforcement considerations for regulated parties are outlined below:

### **8.1 Site information related to a product**

As per section 22 of the NHPR, every product licensee is required to provide the NHPD with all site information prior to commencing the sale of the NHP. This information is to be submitted to the NHPD through the notification process outlined in the Post Licensing Guidance Document ([http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/plgd\\_psdldr-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/plgd_psdldr-eng.php)). This information may be verified at any time by the Inspectorate or NHPD. The regulated party should keep this information readily available to provide to Health Canada upon request.

### **8.2 Post market surveillance, mandatory adverse reaction (AR) reporting and new scientific information**

Scientific information is continuously evolving. As such, there may be new scientific information that modifies the safety, efficacy or quality profile of a marketed NHP. It is the responsibility of the product licence holder to ensure the continued safety, efficacy and quality of the licensed NHP. Adverse Reaction (AR) reporting is an integral part of the post-market surveillance of NHPs and is a regulatory requirement for all product license holders, as set out in Section 24 of the NHPR. This includes the expedited reporting of all serious adverse reactions occurring within Canada and all serious unexpected adverse reactions occurring outside of Canada, and the preparation of a summary report of all adverse reactions to a licensed NHP on an annual basis. Regulated parties should have systems in place to monitor and assess adverse reactions received and take appropriate risk management actions. Failure to comply with post market requirements may present a potential risk to health and as such, may be subject to compliance and enforcement activities. It is important to

highlight that adverse reactions may also signify other non-compliances, including possible counterfeit products, labelling non-compliances, as well as GMP or product specification non-compliances (e.g. adulteration, contamination). Further information on mandatory expedited reporting of serious adverse reaction(s) and preparation of annual summary reports can be found in Health Canada's Guidance Document for Industry – Reporting Adverse Reactions to Marketed Health Products ([http://www.hc-sc.gc.ca/dhp-mps/pubs/medeff/\\_guide/2009-guidance-directrice\\_reporting-notification/index-eng.php/2009-guidance-directrice\\_reporting-notification/index-eng.php](http://www.hc-sc.gc.ca/dhp-mps/pubs/medeff/_guide/2009-guidance-directrice_reporting-notification/index-eng.php/2009-guidance-directrice_reporting-notification/index-eng.php)).

Should Health Canada become aware of new scientific evidence that could modify the safety, efficacy or quality profile of the product, Health Canada may contact the affected licensee(s) and request additional safety information under section 16 of the NHPR or section 24 of the NHPR (annual summary report and/or interim summary report). If there are reasonable grounds to believe that there may be an immediate risk to health, the product licence may be suspended under section 19 of the NHPR and compliance and enforcement actions may be taken.

### **8.3 Post market changes to licensed products**

NHPD must be informed of all post market changes made to licensed products. Under the NHPR, these are considered to be either amendments or notifications. Notifications are defined under section 12 of the NHPR and are considered to include changes which do not have a significant impact the safety, efficacy and/or quality of the product such as a change to the company information, site information, the addition or substitution of a non-medicinal ingredient that does not affect the safety or efficacy of the product, the brand name of the product, the common or proper name of any of the medicinal ingredients or the addition of risk information. Notifications should be submitted to the NHPD as soon as possible, but are required within 60 days of making the change to a marketed NHP.

Changes considered to be amendments as per section 11 of the NHPR require approval by the NHPD prior to making the change to the marketed product. These include but are not limited to: changes to the recommended dose, duration or recommended use or purpose, deletion or modification of risk information, a change to the source material or potency of any medicinal ingredient, certain changes to product specifications, among others. These changes may have an impact on the safety, efficacy or quality profile of the NHP and may significantly impact the assessment of information for which the product licence has been granted. Further information can be found in the Post Licensing Guidance Document ([http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/plgd\\_psdldr-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/plgd_psdldr-eng.php)).

## **9.0 Complaint Reporting**

The Inspectorate is committed to verifying complaints regarding the quality or safety of health products.

Complaints regarding potential non-compliance with the FDA and/or NHPR can be reported to the nearest regional Operational Center using the following guidelines:

- How to submit a consumer complaint (GUI-044) ([http://www.hc-sc.gc.ca/dhp-mps/compl-conform/prob-report-rapport/gui\\_44\\_consumer\\_consommateur\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compl-conform/prob-report-rapport/gui_44_consumer_consommateur_cp-pc-eng.php)) or
- How to submit a trade complaint (GUI-038) ([http://www.hc-sc.gc.ca/dhp-mps/compl-conform/prob-report-rapport/gui\\_38\\_trade-industrie\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compl-conform/prob-report-rapport/gui_38_trade-industrie_cp-pc-eng.php))

**Advertising:** If a complaint is regarding the advertising of an authorized NHP, the first route of adjudication of complaints should be through the advertising preclearance agencies. For further information, refer to the List of Canadian Advertising Preclearance Agencies ([http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/preclear-preapprob/pca-apa\\_list-eng.php](http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/preclear-preapprob/pca-apa_list-eng.php))

**Adverse Reactions:** In certain instances, a complaint may be related to an adverse reaction associated with the use of a particular NHP. Any suspected adverse reactions should be submitted to Canada Vigilance, and may be reported by phone to the Canada Vigilance regional offices at 1-866-678-6789, online, or by fax/mail. Electronic and hard copy forms are available through the MedEffect website (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php#a1>).

## 10.0 Reference Material

Below is a list of weblinks to related materials referenced in this policy. The list is not exhaustive. Most reference materials can be found from the NHPD website (<http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/index-eng.php>).

### **Policies:**

- **Compliance and Enforcement (POL-0001)**  
[http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/pol/pol\\_1\\_tc-tm-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/pol/pol_1_tc-tm-eng.php)
- **The Inspectorate Recall Policy (POL-0016)**  
[http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/drugs-drogues/pol\\_0016\\_tc-tm-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/drugs-drogues/pol_0016_tc-tm-eng.php)
- **Import and Export Policy for Health Products Under the Food and Drugs Act and its Regulations (POL-0060)**  
[http://www.hc-sc.gc.ca/dhp-mps/compli-conform/import-export/pol-0060\\_biu-uif-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/import-export/pol-0060_biu-uif-eng.php)
- **Policy on Counterfeit Health Products (POL-0048)**  
[http://www.hc-sc.gc.ca/dhp-mps/compli-conform/activit/pol\\_0048\\_counterfeit-contrefacon-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/activit/pol_0048_counterfeit-contrefacon-eng.php)

### **Guidance Documents:**

- **Post Licensing Guidance Document**  
[http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/plgd\\_psdldr-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/plgd_psdldr-eng.php)
- **Issuance of the final Consumer Advertising Guidelines for Marketed Health Products (for Non Prescription Drugs including Natural Health Products)**  
[http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/pol/guide-ldir\\_consom\\_consum-eng.php](http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/pol/guide-ldir_consom_consum-eng.php)

- **Health Canada's Guidance Document for Industry – Reporting Adverse Reactions to Marketed Health Products**

[http://www.hc-sc.gc.ca/dhp-mps/pubs/medeff/\\_guide/2009-guidance-directrice\\_reporting-notification/index-eng.php/2009-guidance-directrice\\_reporting-notification/index-eng.php](http://www.hc-sc.gc.ca/dhp-mps/pubs/medeff/_guide/2009-guidance-directrice_reporting-notification/index-eng.php/2009-guidance-directrice_reporting-notification/index-eng.php)

- **Guidance Document on the Import Requirements for Health Products under the Food and Drugs Act and its Regulations (GUI-0084)**

[http://www.hc-sc.gc.ca/dhp-mps/compli-conform/import-export/gui-0084\\_biu-uif-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/import-export/gui-0084_biu-uif-eng.php)

***Misc:***

- **Drug and Medical Device Recall Listings**

[http://www.hc-sc.gc.ca/dhp-mps/compli-conform/recall-retrait/\\_list/index-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/recall-retrait/_list/index-eng.php)

- **Licensed Natural Health Products Database**

<http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/lnhpd-bdpsnh-eng.php>



**Fw: DEMANDE MÉDIA - Salvia (RNC Media - Abitibi-Témiscamingue)**

Denis Arsenault to: Stephanie Chandler

2010-10-20 03:13 PM

Updated version.

Denis

Denis Arsenault, A/Manager / Gestionnaire p.i.  
Regulatory Policy Division /  
Division des politiques réglementaires,  
Office of Controlled Substances /  
Bureau des substances contrôlées,  
Health Canada / Santé Canada  
Tel/Tél: (613) 957-6828  
Fax / Télécopieur : (613) 946-4224  
E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca

----- Forwarded by Denis Arsenault/HC-SC/GC/CA on 2010-10-20 03:13 PM -----

From: Christine Roush/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC, Nicole Prentice/HC-SC/GC/CA@HWC  
Date: 2010-10-20 03:09 PM  
Subject: Fw: DEMANDE MÉDIA - Salvia (RNC Media - Abitibi-Témiscamingue)

Jocelyn/Denis - see this version below. HPFB just deleted (from Friday's text) the term illegal - since it implies criminal conviction and can lead to confusion about jurisdiction - ie HC vs RCMP. The rest of the text is the same as what we used for the CP story.

Christine Roush  
Senior Communications Advisor/

----- Forwarded by Christine Roush/HC-SC/GC/CA on 2010-10-20 03:07 PM -----

From: Elizabeth Keeping/HC-SC/GC/CA  
To: Nicole Prentice/HC-SC/GC/CA@HWC  
Cc: Christine Roush/HC-SC/GC/CA@HWC, Ken Polk/HC-SC/GC/CA@HWC  
Date: 2010-10-20 02:29 PM  
Subject: Re: Fw: DEMANDE MÉDIA - Salvia (RNC Media - Abitibi-Témiscamingue)

Hi Nicole -

Please note edits in the text below. We would prefer not to use the term illegal - since it implies criminal conviction and can lead to confusion about jurisdiction - ie HC vs RCMP.

Otherwise - looks fine.

Thanks,  
B

Nicole Prentice

Hello, I have pulled these responses from last...

2010-10-20 02:22:18 PM

From: Nicole Prentice/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC, Elizabeth Keeping/HC-SC/GC/CA@HWC  
Date: 2010-10-20 02:22 PM

001370

Subject: Fw: DEMANDE MÉDIA - Salvia (RNC Media - Abitibi-Témiscamingue)

Hello,

I have pulled these responses from last weeks approved response to the Canadian Press. As I am not fully bilingual, I am not sure if these responses completely answer the questions so your suggestions are very welcome.

If you are both OK with using these responses, I don't think any approvals will be necessary and we can just send to Christelle for translation. Let me know.

Thanks.

Q1 - Est-ce illégal ou simplement pas encore autorisé au Canada? (L'article cite la GRC qui dit qu'il ne peut rien faire auprès des acheteurs de salvia aussi longtemps que le gouvernement n'a pas légiféré pour rendre le produit illégal.)

A1) Canadians should not use products containing *S. divinorum* and/or salvinorin A because very little is known about the substance and its potential effects on the brain and/or body, and its impact on physical and mental functions. Because of their hallucinogenic properties, products containing *S. divinorum* and/or salvinorin A meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*.

← suggested by legal.

It is illegal a contravention of the Food and Drugs Act to sell NHPs in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN). The illegal sale of unapproved products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*.

To date, Health Canada has not licensed for sale any drug or NHP which contains salvia as an ingredient.

Q2 - Est-ce que la vente du salvia est toujours autorisé ou non au Canada?

A2) Currently, there is no product containing *Salvia divinorum* authorized for sale in Canada. Unauthorized products may be subject to compliance and enforcement action by Health Canada. Complaints about the illegal sale of unapproved products containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate by calling 1-800-267-9675.

Health Canada is currently assessing whether the regulation of *Salvia divinorum* and/or Salvinorin A under the CDSA is warranted.

### Nicole Prentice

Junior Communications Officer | Agente junior des Communications  
Regulatory Communications and Media Relations Division | Division des communications réglementaires et des relations avec les médias  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la consultation et des communications  
Health Canada | Santé Canada  
Tel: 613.941.3107  
Fax: 613.948.8085

is a health claim required?!

Administration of FDA by HP/FBI possession not illegal

If sold for the purpose of modifying or organizing function.

----- Forwarded by Nicole Prentice/HC-SC/GC/CA on 2010-10-20 02:09 PM -----

From: Christelle Legault/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC, Nicole Prentice/HC-SC/GC/CA@HWC, Dave Stephens/HC-SC/GC/CA, Paul Spendlove/HC-SC/GC/CA@HWC  
Date: 2010-10-20 01:57 PM  
Subject: DEMANDE MÉDIA - Salvia (RNC Media - Abitibi-Témiscamingue)

Please see French request below. We could use the response that was provided to Joan Bryden of the Canadian Press.

Deadline: 4:00pm today (no later than 5pm to reporter)

Thank you,

Christelle Legault  
Media Relations Officer | Agente des relations avec les médias  
Regulatory Communications and Media Relations Division |  
Division des communications réglementaires et des relations avec les médias  
Public Affairs, Consultation and Communications Branch |  
Direction générale des affaires publiques, de la consultation et des communications  
Health Canada | Santé Canada  
Tel. | Tél.: 613.957.2988 Fax | Téléc.: 613.952.7747

s.19(1)

----- Forwarded by Christelle Legault/HC-SC/GC/CA on 2010-10-20 01:55 PM -----



### Media Enquiry - Demande médiatique

Name/Nom :	Media/Média : RNC Media
Telephone/Téléphone :	Language/Langue : French-français
Cell Telephone/Téléphone cellulaire :	Fax/Télécopieur :
Email/Courriel :	
Date and Time Received Date et Heure de réception : 2010-10-20 01:39:36 PM	Date Completed Date d'achèvement :

Subject/Objet : Controlled Substances/Substances contrôlées, Natural Health Products/Produits de santé naturels

Question:

Add to the Question/ajouter a la question  
2010-10-20 1:39:37 PM (Christelle Legault)

RNC Média - Journaliste d'Abitibi-Témiscamingue

Objet: Salvia

Journaliste fait référence à l'article qui est paru dans la Press Canadienne sur le Salvia. Est un peu mélangé concernant le statut légal du salvia.

#### Questions

1 - Est-ce illégal ou simplement pas encore autorisé au Canada?

L'article cite la GRC qui dit qu'il ne peut rien faire auprès des acheteurs de salvia aussi longtemps que le gouvernement n'a pas légiféré pour rendre le produit illégal.

2 - Est-ce que la vente du salvia est toujours autorisé ou non au Canada?

Échéance: 17h Aujourd'hui

NOTE : Refer to media call from Joan Bryden - The Canadian Press.

**Response/Réponse :**

Add to the Response/ajouter a la réponse

**Action Taken/Mesures prises :**

Add to the Action Taken/ajouter au mesures prises

2010-10-20 1:54:30 PM (Christelle Legault)

Request sent to Christine Roush, Nicole Prentice, Dave Stephens,

Interview with spokesperson granted/Entrevue avec porte-parole accordé:  Yes-Oui  No-Non

Branch/Direction générale :

Spokesperson/Porte-parole :

Reporter's Deadline

Heure de tombée du journaliste :

Priority/Priorité : Regular

Telephone/Téléphone :

Story Run Date

Date de parution de l'article :

Status/Rapport de situation : Follow-up

**Comment/Commentaire :**

**Attachments/Pièces jointes :**

**Related Clippings/Coupures connexes :**

Media Relations Officer/Agente de relations avec les médias : Christelle Legault

**Edit History / Historique des révisions**

Send To / Transmettre à :

Branch Recipient:

Mail Recipients:

CN=Charles Mojsej/OU=HC-SC/O=GC/C=CA, CN=Peter Yendall/OU=HC-SC/O=GC/C=CA, CN=Jean

Tessier/OU=HC-SC/O=GC/C=CA, CN=Tim Vail/OU=HC-SC/O=GC/C=CA, CN=Jenny

VanAlstyne/OU=HC-SC/O=GC/C=CA



**Re: Fw: DEMANDE MÉDIA - Salvia (RNC Media - Abitibi-Témiscamingue)** 

**Ken Polk** to: Brook Bertrand, Denis Arsenault

2010-10-20 05:05 PM

Cc: Christine Roush, Daniel Galarneau, Jean Saint Pierre, Jocelyn Kula, Nicole Prentice, Stephanie Chandler, "Beth Keeping"

---

We are happy to join as well.

Cheers.

Brook Bertrand

----- Original Message -----

**From:** Brook Bertrand

**Sent:** 2010-10-20 04:58 PM EDT

**To:** Denis Arsenault

**Cc:** Christine Roush; Daniel Galarneau; Jean Saint Pierre; Jocelyn Kula; Ken Polk; Nicole Prentice; Stephanie Chandler

**Subject:** Re: Fw: DEMANDE MÉDIA - Salvia (RNC Media - Abitibi-Témiscamingue)

I am free all morning (until 11:45) and in the afternoon after 3

Please send an invitation with a call-in number

Regards,

**Brook Bertrand**

Natural Health Products Directorate /  
Direction des produits de santé naturels  
Health Canada /  
Santé Canada  
613-948-3537

---

Denis Arsenault

Hello Mr. Bertrand and Mr. Saint-Pierre, Would i...

2010-10-20 04:53:28 PM

**From:** Denis Arsenault/HC-SC/GC/CA

**To:** Brook Bertrand/HC-SC/GC/CA@HWC, Jean Saint Pierre/HC-SC/GC/CA@HWC

**Cc:** Jocelyn Kula/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC, Daniel Galarneau/HC-SC/GC/CA@HWC, Christine Roush/HC-SC/GC/CA@HWC, Nicole Prentice/HC-SC/GC/CA@HWC, Ken Polk/HC-SC/GC/CA@HWC

**Date:** 2010-10-20 04:53 PM

**Subject:** Fw: DEMANDE MÉDIA - Salvia (RNC Media - Abitibi-Témiscamingue)

---

Hello Mr. Bertrand and Mr. Saint-Pierre,

Would it be possible to convene a quick teleconference tomorrow morning to discuss the proposed responses to these questions? It is our view that the proposed responses may not fully answer the questions posed and may lead cause some confusion. As a result, there is a need to review the responses beyond the clarification of the legal/illegal distinction.

For example, it is our understanding that products containing salvia are would only be considered a NHP (and subject to the NHP regulations) *if they make a health claim*. This caveat is not specified in the response to Q1. While the response to Q2 may be technically correct, it does not address the status of

the salvia products actually sold (whether or not they make a health claim and can thus be considered a NHP).

Could you let us know your availability for a quick teleconference?

Thank You.

Denis

---

Denis Arsenault, A/Manager / Gestionnaire p.i.  
Regulatory Policy Division /  
Division des politiques réglementaires,  
Office of Controlled Substances /  
Bureau des substances contrôlées,  
Health Canada / Santé Canada  
Tel/Tél: (613) 957-6828  
Fax / Télécopieur : (613) 946-4224  
E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca  
—— Forwarded by Denis Arsenault/HC-SC/GC/CA on 2010-10-20 04:37 PM ——

---

From: Christine Roush/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC, Nicole Prentice/HC-SC/GC/CA@HWC  
Date: 2010-10-20 03:09 PM  
Subject: Fw: DEMANDE MÉDIA - Salvia (RNC Media - Abitibi-Témiscamingue)

---

Jocelyn/Denis - see this version below. HPFB just deleted (from Friday's text) the term illegal - since it implies criminal conviction and can lead to confusion about jurisdiction - ie HC vs RCMP. The rest of the text is the same as what we used for the CP story.

Christine Roush  
Senior Communications Advisor/

—— Forwarded by Christine Roush/HC-SC/GC/CA on 2010-10-20 03:07 PM ——

---

From: Elizabeth Keeping/HC-SC/GC/CA  
To: Nicole Prentice/HC-SC/GC/CA@HWC  
Cc: Christine Roush/HC-SC/GC/CA@HWC, Ken Polk/HC-SC/GC/CA@HWC  
Date: 2010-10-20 02:29 PM  
Subject: Re: Fw: DEMANDE MÉDIA - Salvia (RNC Media - Abitibi-Témiscamingue)

---

Hi Nicole -

Please note edits in the text below. We would prefer not to use the term illegal - since it implies criminal conviction and can lead to confusion about jurisdiction - ie HC vs RCMP.

Otherwise - looks fine.

Thanks,  
B

Nicole Prentice

Hello, I have pulled these responses from last...

2010-10-20 02:22:18 PM



**Re: Urgent - Salvia**  
**Jocelyn Kula** to: stephanie.szick, CSTD-DGO  
Cc: Denis Arsenault, Stephanie Chandler

2010-10-20 04:06 PM

Hi Stephanie

Pls see proposed response to Jesse's questions. Pls also note that we assume of course that the info is for internal use only.

**What are we doing to assess?**

All scheduling assessments involve the development of an Issue Analysis Summary that summarizes information about the substance being assessed in the context of each scheduling factor listed below, and identifies possible options for regulatory and non-regulatory action.

**What factors do we consider?**

Health Canada considers the following factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted:

- International requirements and trends in the control and/or scheduling;
- Chemical and/or pharmacological similarity to substances listed in the Schedules to the CDSA;
- Legitimate use of the substance, including therapeutic, scientific, industrial or commercial uses;
- Potential for abuse and/or addiction liability;
- Evidence of extent of actual abuse of the substance in Canada and internationally; and
- Risk to personal and public health and safety.

**Do we have a sense of what decision will be?**

At a recent Controlled Substances Scheduling Working Group (intradepartmental group consisting of representatives from HECSB and HPFB),

**What is the timing for the decision?**

A final draft of the Issue Analysis Summary will be forwarded to the Director of OCS for review and approval by the end of October. Once approved, the recommended course of action will be presented to the Director General of CSTD for concurrence.

Let me know if you have questions.

Jocelyn

s.21(1)(a)

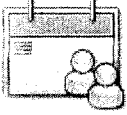
s.21(1)(b)

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

Jesse Arnup-Blondin Hello - I understand someone from HPFB wa... 2010-10-20 12:38:50 PM

From: Jesse Arnup-Blondin/HC-SC/GC/CA



**Salvia Media Response  
Calendar Entry**

2010-10-21 Thu 10:00 AM - 11:00 AM

No Location Information

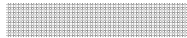
Required:	Brook Bertrand/HC-SC/GC/CA@HWC, Collin Pinto/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC
Optional:	Daniel Galarneau/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Ken Polk/HC-SC/GC/CA@HWC

**Description**

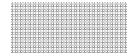
Hello,

Further to my e-mail yesterday, below is the contact information for this morning's teleconference.

Local Dial-in Number



Conference ID



**s.16(2)(c)**

Denis

---

Hello Mr. Bertrand and Mr. Saint-Pierre,

Would it be possible to convene a quick teleconference tomorrow morning to discuss the proposed responses to these questions? It is our view that the proposed responses may not fully answer the questions posed and may lead cause some confusion. As a result, there is a need to review the responses beyond the clarification of the legal/illegal distinction.

For example, it is our understanding that products containing salvia are would only be considered a NHP (and subject to the NHP regulations) *if they make a health claim*. This caveat is not specified in the response to Q1. While the response to Q2 may be technically correct, it does not address the status of the salvia products actually sold (whether or not they make a health claim and can thus be considered a NHP).

Could you let us know your availability for a quick teleconference?

Thank You.

Denis

---

Denis Arsenault, A/Manager / Gestionnaire p.i.  
Regulatory Policy Division /  
Division des politiques réglementaires,  
Office of Controlled Substances /  
Bureau des substances contrôlées,  
Health Canada / Santé Canada  
Tel/Tél: (613) 957-6828  
Fax / Télécopieur : (613) 946-4224  
E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca



**Fw: DEMANDE MÉDIA - Salvia (RNC Media - Abitibi-Témiscamingue)**

Denis Arsenault to: Stephanie Chandler, Daniel Galarneau

2010-10-21 11:47 AM

From: Denis Arsenault/HC-SC/GC/CA

To: Stephanie Chandler/HC-SC/GC/CA@HWC, Daniel Galarneau/HC-SC/GC/CA@HWC

---

Thoughts?

Denis

---

Denis Arsenault, A/Manager / Gestionnaire p.i.

Regulatory Policy Division /

Division des politiques réglementaires,

Office of Controlled Substances /

Bureau des substances contrôlées,

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Fax / Télécopieur : (613) 946-4224

E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca

— Forwarded by Denis Arsenault/HC-SC/GC/CA on 2010-10-21 11:47 AM —

From: Christine Roush/HC-SC/GC/CA

To: "Denis Arsenault" <denis.arsenault@hc-sc.gc.ca>

Cc: "Stephanie Chandler" <stephanie.chandler@hc-sc.gc.ca>, "Mr. Daniel Galarneau" <Daniel.Galarneau@hc-sc.gc.ca>, "Nicole Prentice" <nicole.prentice@hc-sc.gc.ca>

Date: 2010-10-21 11:44 AM

Subject: Fw: Fw: DEMANDE MÉDIA - Salvia (RNC Media - Abitibi-Témiscamingue)

---

Denis - pls let me know asap if you are ok with the rewrite of these answers below. Thx

Elizabeth Keeping

----- Original Message -----

From: Elizabeth Keeping

Sent: 2010-10-21 11:23 AM EDT

To: Nicole Prentice

Cc: Christine Roush; Ken Polk; Brook Bertrand

Subject: Re: Fw: DEMANDE MÉDIA - Salvia (RNC Media -  
Abitibi-Témiscamingue)

Hi,

Here's what we are proposing as the revised response. Please confirm with your program folks that they are comfortable with this before sending along to MR.

As mentioned, we can also use parts of this to respond to the Cambrian College student's question that just came in.

Cheers,  
Beth

Q1 - Est-ce illégal ou simplement pas encore autorisé au Canada? (L'article cite la GRC qui dit qu'il ne peut rien faire auprès des acheteurs de salvia aussi longtemps que le gouvernement n'a pas légiféré pour rendre le produit illégal.)

- Canadians should not use products containing *S. divinorum* and/or salvinorin A because very little is known about the substance and its potential effects on the brain and/or body, and its impact on physical and mental functions.

- When salvia products are sold for the purposes of modifying organic function (such as, for their hallucinogenic effect), they meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*.

It is a contravention of the *Food and Drugs Act* and the *Natural Health Products Regulations* to sell NHPs in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN) on the label. The sale of unauthorized natural health products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

To date, Health Canada has not licensed for sale any drug or NHP which contains salvia as an ingredient.

**Q2 - Est-ce que la vente du salvia est toujours autorisé ou non au Canada?**

- As previously indicated, salvia products sold for the purposes of modifying organic function (such as, for their hallucinogenic effect) are regulated as NHPs in Canada. To date, Health Canada has not licensed for sale any drug or NHP which contains salvia as an ingredient.
- Unauthorized drugs and NHPs may be subject to compliance and enforcement action by Health Canada. Complaints about the sale of unauthorized products containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate by calling 1-800-267-9675.
- Health Canada is currently assessing whether the regulation of *Salvia divinorum* and/or Salvinorin A under the *Controlled Drugs and Substances Act* is warranted.

Nicole Prentice

Hello, I have pulled these responses from last..

2010-10-20 02:22:18 PM

From: Nicole Prentice/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC, Elizabeth Keeping/HC-SC/GC/CA@HWC  
Date: 2010-10-20 02:22 PM  
Subject: Fw: DEMANDE MÉDIA - Salvia (RNC Media - Abitibi-Témiscamingue)

Hello,

I have pulled these responses from last weeks approved response to the Canadian Press. As I am not fully bilingual, I am not sure if these responses completely answer the questions so your suggestions are very welcome.

If you are both OK with using these responses, I don't think any approvals will be necessary and we can just send to Christelle for translation. Let me know.

001379



**Fw: DEMANDE MÉDIA - Salvia (RNC Media - Abitibi-Témiscamingue)**

Denis Arsenault to: Jocelyn Kula

2010-10-21 12:48 PM

Cc: Stephanie Chandler, Daniel Galarneau

Hi Jocelyn,

Further to our teleconference this morning with HPFB, below for your review and approval are the revised responses. The text in red represents HPFB's proposed changes, while the text in blue is ours (Daniel suggested this bullet be kept, but put at the end of the response).

On a side note, the last bullet in the response to Q1 is taken directly from the draft IYH. That being said, would it not be more accurate to say "Canadians should not *consume*..." rather than "Canadians should not use.."?

Denis

Denis Arsenault, A/Manager / Gestionnaire p.i.

Regulatory Policy Division /

Division des politiques réglementaires,

Office of Controlled Substances /

Bureau des substances contrôlées,

Health Canada / Santé Canada

Tel/Tél: (613) 957-6828

Fax / Télécopieur : (613) 946-4224

E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca

----- Forwarded by Denis Arsenault/HC-SC/GC/CA on 2010-10-21 12:39 PM -----

From: Stephanie Chandler/HC-SC/GC/CA  
To: Denis Arsenault/HC-SC/GC/CA@HWC  
Cc: Daniel Galarneau/HC-SC/GC/CA@HWC  
Date: 2010-10-21 12:31 PM  
Subject: Re: Fw: DEMANDE MÉDIA - Salvia (RNC Media - Abitibi-Témiscamingue)

As discussed.

**Q1 - Est-ce illégal ou simplement pas encore autorisé au Canada? (L'article cite la GRC qui dit qu'il ne peut rien faire auprès des acheteurs de salvia aussi longtemps que le gouvernement n'a pas légiféré pour rendre le produit illégal.)**

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To date, Health Canada has not licensed for sale any drug or NHP which contains salvia as an ingredient.

*Health Canada does not recommend the use of*

- ~~Canadians should not use~~ products containing *S. divinorum* and/or salvinorin A because very little is known about the substance and ~~its~~ <sup>their</sup> potential effects on the brain and/or body, and ~~its~~ <sup>their</sup> impact on physical and mental functions.

Q2 - Est-ce que la vente du salvia est toujours autorisé ou non au Canada?

- As previously indicated, salvia products sold for the purposes of modifying organic function (such as, for their hallucinogenic effect) are regulated as NHPs in Canada. To date, Health Canada has not ~~licensed for sale~~ any drug or NHP <sup>for sale</sup> which contains salvia as an ingredient. <sup>approved</sup>
- ~~Unauthorized drugs and NHPs may be subject to compliance and enforcement action by Health Canada.~~ Complaints about the sale of unauthorized products containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate by calling 1-800-267-9675.
- Health Canada is currently assessing whether the regulation of *Salvia divinorum* and/or Salvinorin A under the *Controlled Drugs and Substances Act* is warranted

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

Denis Arsenault

Thoughts? Denis

2010-10-21 11:47:45 AM

From: Denis Arsenault/HC-SC/GC/CA  
To: Stephanie Chandler/HC-SC/GC/CA@HWC, Daniel Galarneau/HC-SC/GC/CA@HWC  
Date: 2010-10-21 11:47 AM  
Subject: Fw: DEMANDE MÉDIA - Salvia (RNC Media - Abitibi-Témiscamingue)

Thoughts?

Denis

Denis Arsenault, A/Manager / Gestionnaire p.i.  
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**Fw: DEMANDE MÉDIA - Salvia (RNC Media - Abitibi-Témiscamingue)**

**Denis Arsenault** to: Jocelyn Kula

2010-10-21 01:15 PM

Cc: Stephanie Chandler, Daniel Galarneau

Hi Jocelyn,

As discussed, below for your approval are the revised responses. The text in red represents HPFB's proposed changes, while the text in blue and strikethrough represents our changes.

Denis

Denis Arsenault, A/Manager / Gestionnaire p.i.

Regulatory Policy Division /

Division des politiques réglementaires,

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E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca

— Forwarded by Denis Arsenault/HC-SC/GC/CA on 2010-10-21 01:07 PM —

From: Christine Roush/HC-SC/GC/CA

To: "Denis Arsenault" <denis.arsenault@hc-sc.gc.ca>

Cc: "Stephanie Chandler" <stephanie.chandler@hc-sc.gc.ca>, "Mr. Daniel Galarneau" <Daniel.Galarneau@hc-sc.gc.ca>, "Nicole Prentice" <nicole.prentice@hc-sc.gc.ca>

Date: 2010-10-21 11:44 AM

Subject: Fw: Fw: DEMANDE MÉDIA - Salvia (RNC Media - Abitibi-Témiscamingue)

Denis - pls let me know asap if you are ok with the rewrite of these answers below. Thx

Elizabeth Keeping

----- Original Message -----

**From:** Elizabeth Keeping

**Sent:** 2010-10-21 11:23 AM EDT

**To:** Nicole Prentice

**Cc:** Christine Roush; Ken Polk; Brook Bertrand

**Subject:** Re: Fw: DEMANDE MÉDIA - Salvia (RNC Media - Abitibi-Témiscamingue)

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Cheers,

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Q1 - Est-ce illégal ou simplement pas encore autorisé au Canada? (L'article cite la GRC qui dit qu'il ne peut rien faire auprès des acheteurs de salvia aussi longtemps que le gouvernement n'a pas légiféré pour rendre le produit illégal.)

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To date, Health Canada has not licensed for sale any drug or NHP which contains salvia as an ingredient.

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Nicole Prentice

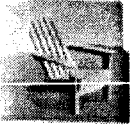
Hello, I have pulled these responses from last...

2010-10-20 02:22:18 PM

From: Nicole Prentice/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC, Elizabeth Keeping/HC-SC/GC/CA@HWC  
Date: 2010-10-20 02:22 PM  
Subject: Fw: DEMANDE MÉDIA - Salvia (RNC Media - Abitibi-Témiscamingue)

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**Fw: DEMANDE MÉDIA - Salvia (RNC Media - Abitibi-Témiscamingue)**

**Nicole Prentice** to: Denis Arsenault

2010-10-21 02:08 PM

Cc: Christine Roush, Jocelyn Kula, Stephanie Chandler, Daniel  
Galarneau, CSTD-OCS-DO

Hi again,

Will it be possible for us to get a response from you by 2:30 today? We won't be able to get another extension on this call so we will have to close it shortly.

Thanks in advance.

**Nicole Prentice**

Junior Communications Officer | Agente junior des Communications  
Regulatory Communications and Media Relations Division | Division des communications  
réglementaires et des relations avec les médias  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires  
publiques, de la consultation et des communications  
Health Canada | Santé Canada  
Tel: 613.941.3107  
Fax: 613.948.8085

— Forwarded by Nicole Prentice/HC-SC/GC/CA on 2010-10-21 02:05 PM —

From: Christine Roush/HC-SC/GC/CA  
To: "Denis Arsenault" <denis.arsenault@hc-sc.gc.ca>  
Cc: "Stephanie Chandler" <stephanie.chandler@hc-sc.gc.ca>, "Mr. Daniel Galarneau"  
<Daniel.Galarneau@hc-sc.gc.ca>, "Nicole Prentice" <nicole.prentice@hc-sc.gc.ca>  
Date: 2010-10-21 11:44 AM  
Subject: Fw: Fw: DEMANDE MÉDIA - Salvia (RNC Media - Abitibi-Témiscamingue)

Denis - pls let me know asap if you are ok with the rewrite of these answers below. Thx  
Elizabeth Keeping

----- Original Message -----

**From:** Elizabeth Keeping  
**Sent:** 2010-10-21 11:23 AM EDT  
**To:** Nicole Prentice  
**Cc:** Christine Roush; Ken Polk; Brook Bertrand  
**Subject:** Re: Fw: DEMANDE MÉDIA - Salvia (RNC Media -  
Abitibi-Témiscamingue)

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Here's what we are proposing as the revised response. Please confirm with your program folks that they are comfortable with this before sending along to MR.

As mentioned, we can also use parts of this to respond to the Cambrian College student's question that just came in.

Cheers,  
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Q1 - Est-ce illégal ou simplement pas encore autorisé au Canada? (L'article cite la GRC qui dit qu'il ne peut rien faire auprès des acheteurs de salvia aussi longtemps que le gouvernement n'a pas légiféré pour rendre le produit

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Nicole Prentice

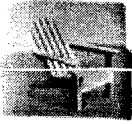
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**Re: Fw: DEMANDE MÉDIA - Salvia (RNC Media - Abitibi-Témiscamingue)** 

Nicole Prentice to: Jocelyn Kula

2010-10-21 03:14 PM

Cc: Daniel Galarneau, Denis Arseneault, Stephanie Chandler

Thanks everyone for this response. I know it was a bit more time consuming than others.

Nicole

Jocelyn Kula

Hi Nicole Denis et al in OCS had a teleconf with...

2010-10-21 02:32:32 PM

From: Jocelyn Kula/HC-SC/GC/CA  
To: Nicole Prentice/HC-SC/GC/CA@HWC  
Cc: Christine Roush/HC-SC/GC/CA@HWC, CSTD-OCS-DO, Daniel Galarneau/HC-SC/GC/CA@HWC,  
Denis Arseneault/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2010-10-21 02:32 PM  
Subject: Re: Fw: DEMANDE MÉDIA - Salvia (RNC Media - Abitibi-Témiscamingue)

Hi Nicole

Denis et al in OCS had a teleconf with HPFB this morning (Christine was on the call) and both sides have agreed to the following, with a few last revisions from me. Don't believe they warrant approval by HPFB again but that is up to you! Red text from HPFB, blue and strikeouts from OCS.

Approved for OCS

Jocelyn

**Q1 - Est-ce illégal ou simplement pas encore autorisé au Canada? (L'article cite la GRC qui dit qu'il ne peut rien faire auprès des acheteurs de salvia aussi longtemps que le gouvernement n'a pas légiféré pour rendre le produit illégal.)**

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---

Jocelyn Kula

Acting Director/ Directrice par intérim

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs

Health Canada/ Santé Canada

Tel: (613) 952-2177 Fax: (613) 946-4224

Nicole Prentice

Hi again, Will it be possible for us to get a respo...

2010-10-21 02:08:07 PM

# Issue Analysis Summary

DRAFT

## Scheduling *Salvia Divinorum* and/or Salvinorin A under the CDSA

Regulatory Policy Division  
Office of Controlled Substances  
Controlled Substances and Tobacco and Directorate

October 21, 2010

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1. APPROVALS
2. ISSUE
3. PURPOSE
4. CONTEXT
5. ASSESSMENT OF RISKS AND BENEFITS
6. IDENTIFICATION AND ANALYSIS OF OPTIONS
7. CONSIDERATIONS
8. RECOMMENDATION(S)
9. CONSULTATIONS
10. IMPLEMENTATION AND EVALUATION

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#### 1. APPROVALS

This Issue Analysis Summary is approved.

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Jocelyn Kula, A/Director  
Office of Controlled Substances  
Controlled Substances and Tobacco Directorate

---

[DD/MM/2010]

#### 2. ISSUE

Health Canada has received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *S. divinorum* and/or its main active ingredient salvinorin A, neither of which are currently regulated under the *Controlled Drugs and Substances Act* (CDSA). These requests are further to reports from scientific and media sources suggesting that *S. divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has also noted an

ongoing media interest regarding the availability of *S. divinorum* in Canada.

### 3. PURPOSE

To assess *Salvia divinorum* and/or salvinorin A against the criteria for the addition of a substance to one of the Schedules to the CDSA, and determine whether one or both substances should be regulated as controlled substances in Canada.

### 4. CONTEXT

*Salvia divinorum* is a species of sage which belongs to the mint family, and which is found in the form of dried leaves, extract and plant cuttings. Also known as "diviner's sage", the plant is known to induce illusions and hallucinations when chewed or smoked. Salvinorin A, the psychoactive ingredient in *S. divinorum* (also referred to chemically as a neoclerodane diterpene) is found primarily in the leaves, and to a lesser extent in the stem.<sup>1</sup>

*S. divinorum* is widely touted as a "legal" hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs among adolescents and young adults.<sup>2</sup> While very little is known about how and where *S. divinorum* is sold in Canada, it is suspected that it is mainly purchased over the Internet and/or bought at head shops or alternative life style stores, etc. *S. divinorum* cuttings are also available from a number of garden supply companies.

The use of *S. divinorum* as a psychotropic agent first came to Health Canada's attention in 2002. In 2004, Health Canada received four adverse drug reaction (ADR) reports associated with the use of *S. divinorum* as a hallucinogen, with three being considered non-serious (requiring no medical attention) and the fourth being considered serious (medical intervention was required). The serious ADR report involved the concomitant use of alcohol in a person diagnosed with Attention Deficit Disorder.

Further to the receipt of the aforementioned ADRs, the Marketed Health Products Directorate (MHPD) and the Natural Health Products Directorate (NHPD) of the Health Products and Food Branch (HPFB) prepared an issue analysis summary (IAS), which recommended that *S. divinorum* and its active ingredient salvinorin A be regulated as controlled substances. This recommendation was maintained when the IAS was updated in November 2006.

Later, in December 2005, MHPD and NHPD prepared a Signal Assessment (SA) (updated in June 2007) that eventually led to the preparation of a Health Risk Assessment (HRA), which concluded that *S. divinorum* or salvinorin A-containing health products would constitute a Type

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<sup>1</sup> U.S. Department of Justice Drug Enforcement Administration. 2002. Drugs and Chemicals of Concern: Salvia Divinorum (salvinorin A, divinorin A) URL:

[http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm) Nov 2008

<sup>2</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.



II Health Risk according to the Health Hazard Classification of the Recall Policy of the Health Products and Food Branch Inspectorate (HBFBI). Such a risk is defined as “a situation in which the use of, or exposure to, a product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote”.

Further to an Assistant Deputy Minister (ADM) discussion in April 2007, the Drug Strategy and Controlled Substances Directorate (DSCSD) organized a meeting with MHPD, NHPD and HPFBI to discuss *S. divinorum*. HPFBI was to determine appropriate compliance activities regarding *S. divinorum* and consult with the Canada Border Services Agency (CBSA) regarding the movement of products containing *S. divinorum* into and out of Canada.

On September 13, 2007, a further meeting between DSCSD, MHPD, NHPD and HPFBI led to the conclusion that DSCSD would conduct a scheduling assessment of *S. divinorum* in order to explore the possibility of scheduling this substance under the CDSA.

In September 2008, the Director Generals of DSCSD, MHPD, TPD and the HPFBI agreed that media lines and an “It’s Your Health” article on *S. divinorum* would be prepared.

#### **4.1 Relevant Legislative Frameworks in Canada**

##### **4.1.1 Food and Drug Regulations (under the Food and Drugs Act)**

The *Food and Drug Regulations* (F&DR) serve to ensure the safety, efficacy, and quality of health products offered for sale in Canada, including drugs and medical devices. Prior to being given market authorization, a manufacturer must present substantive scientific evidence that their product is safe, efficacious and of high quality. For drugs, Health Canada reviews this information carefully and, if the review is satisfactory, a Notice of Compliance (NOC) is issued and appropriate Drug Identification Numbers (DINs) are assigned.

A “drug” is defined under the F&DR as any substance or mixture of substances manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
- (b) restoration, correction or modification of organic functions in human beings or animals, or
- (c) disinfection in premises in which food is manufactured, prepared or kept;

As no products containing *S. divinorum* or its extracts have been reviewed and approved by Health Canada as of July 2010, it is illegal to market *S. divinorum* when it is represented as a drug.

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#### 4.1.2 Natural Health Products Regulations (under the Food and Drugs Act)

The *Natural Health Products Regulations* (NHPR) aim to provide Canadians with ready access to natural health products (NHPs) that are safe, effective, and of high quality, while respecting freedom of choice and philosophical and cultural diversity. The NHPR require that all licensed products display a Natural Product Number (NPN), or, in the case of a homeopathic medicine, a Drug Identification Number - Homeopathic Medicine (DIN-HM), on their labels. These numbers are issued once a product is authorized for sale in Canada further to the submission of a product license application in which the applicant attests to all of the conditions set out in a *natural health product monograph* prepared and published by the Natural Health Products Directorate or submission of a product license application that provides sufficient evidence of quality, safety and efficacy that is assessed and approved by NHPD by the non-compendial route. The NHPR also require that all manufacturers, packagers, labelers, and importers be licensed which in turn requires the presence of procedures respecting distribution records, product recalls, product handling, storage and delivery, and all other aspects of Good Manufacturing Practices as set out in the NHPR.

The definition of an NHP under the NHPR has both a function and substance component. The function component refers to those substances that are manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
- (b) restoring or correcting organic functions in humans; or
- (c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

The substance component refers to the requirement that all of the medicinal ingredients of an NHP must be substances set out in Schedule 1 to the NHPR, which is a list of included substances, <sup>included those substances that are</sup> substances that are traditional medicines or that are homeopathic medicines, and <sup>that of which</sup> none of the ingredients are substances set out on Schedule 2 which is a list of excluded substances, <sup>Excluded substances include</sup> e.g. any substance listed on Schedules I to V of the ~~Controlled Drugs and Substances Act~~ <sup>CDSA</sup>. Section 2(2) of the NHPR excludes those substances (except homeopathic medicines) whose sale is required to be pursuant to a prescription as per Section C.01.043 and thus Schedule F to the F&DR. As per section 93(1)(b)(vi) of the NHPR, every natural health product must be labeled with its authorized recommended use or purpose. In the case of *S. divinorum*, it is generally marketed for its hallucinogenic properties which are considered a modification of an organic function. Therefore products containing it and manufactured, sold or represented for that purpose, meet the definition of an NHP.

As of July 2010, no products containing *S. divinorum* have been reviewed and approved by

Health Canada and no NPNs or DIN-HMs have been issued. Therefore sales of *S. divinorum* are illegal under the NHPR if it is represented for use as a hallucinogen or if other health claims such as with regard to modifying organic functions are made.

#### **4.1.3 Controlled Drugs and Substances Act and its Regulations**

The CDSA provides a legislative framework for the control of substances that can alter mental processes and that may produce harm to the health of an individual or to society when diverted or misused. Except as authorized under its regulations, activities such as possession, possession for the purposes of trafficking, trafficking, importation, exportation, possession for the purposes of exportation and production of controlled substances are prohibited under the CDSA.

The substances regulated under the CDSA are grouped into eight Schedules, and each Schedule is associated with particular offences and penalties as described in Part I of the CDSA.

In determining whether a substance should be regulated as a controlled substance, and into which Schedule of the CDSA it should be placed, Health Canada considers the following factors:

- International requirements and trends in the control and/or scheduling ~~of the substance~~;
- Chemical and/or pharmacological similarity to substances listed in the Schedules to the CDSA;
- Legitimate use of the substance, including therapeutic, scientific, industrial or commercial uses;
- Potential for abuse and/or addiction liability ~~of the substance~~;
- Evidence of extent of actual abuse of the substance in Canada and internationally; and
- Risk to personal and public health and safety.

#### **4.2 Assessment of *Salvia Divinorum* for Scheduling Purposes**

##### **4.2.1 International Requirements and Trends in the Control and/or Scheduling of the Substance**

At the present time, neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and therefore do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

##### ***Australia***

In June 2002, Australia became the first country to prohibit the sale, supply, possession and use of *S. divinorum* and salvinorin A. Both *S. divinorum* and salvinorin A are listed in Schedule 9 of Australia's (Standard for the Uniform Scheduling of Drugs and Poisons) on the basis of "high potential for abuse and risk to public health and safety."<sup>3</sup> Schedule 9 is Australia's most restrictive drug schedule, and includes "substances which may be abused or misused, the

<sup>3</sup> <http://www.tga.gov.au/ndpsc/record/rr200111.pdf>

manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities.”<sup>4</sup>

### **Belgium**

A decree was passed in Belgium on October 22, 2006 which added *S. divinorum* to the list of controlled substances. This list includes substances such as psilocybin mushrooms, khat and peyote cactus.<sup>5</sup>

### **Denmark**

In 2003, Denmark added *S. divinorum* and salvinorin A to their list of “category B” controlled substances, a category which also includes psilocybin mushrooms, cocaine, amphetamine, and several others substances that are only legal for medicinal and scientific purposes. Illegal possession carries a penalty of up to two years in prison.

### **Germany**

*S. divinorum* (plant and plant parts) was added to Appendix I of the *Narcotics Act* in Germany on March 1, 2008, making it illegal to produce, traffic, or possess. The law does not specifically mention salvinorin A.

### **Italy**

On June 25, 2004, the Italian Ministry of Health issued an ordinance prohibiting the sale of *S. divinorum* and its active constituent salvinorin A. On January 11, 2005, the Ministry of Health made possession of *S. divinorum* and salvinorin A illegal by placing them in “*Tabella 1*” of the *Tabella Sostanze Stupefacenti o Psicotrope*.

### **Japan**

On November 9, 2006, the Japanese government added a group of thirty-three drugs to its list of controlled substances, including salvinorin A. The drugs are banned under a revised pharmaceutical law, under which persons involved in their illegal import, production, and sale, i.e. beyond medical treatment or research purposes, will be subject to up to five years imprisonment or a fine of up to five million yen.

### **Spain**

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<sup>4</sup> [http://www.cognitiveliberty.org/news/salvia\\_australia.htm](http://www.cognitiveliberty.org/news/salvia_australia.htm)

<sup>5</sup> <http://eldd.emcdda.europa.eu/html.cfm/index5176EN.html?pluginMethod=eldd.shownewsdetails&id=20/12/2006BELGIUM:%20New%20substances%20controlled%20include%20mCPP%20and%20khat>

On January 28, 2004, the Spanish Ministry of Health and Consumption issued an order prohibiting the sale of *S. divinorum*. The regulation went into effect on May 6, 2004 and only prohibits activities related to commerce. Possession and/or use are not considered to be criminal offences.

### ***Other Countries***

*Salvia divinorum* is illegal to possess or sell in Croatia, Latvia, Lithuania, Poland, Romania, South Korea and Sweden. In Russia it is illegal to grow or sell *S. divinorum*, but it is legal to possess it. In Estonia, Finland, Iceland and Norway, *S. divinorum* is treated as a medicinal herb and it is illegal to import it without a relevant prescription from a doctor.

### ***United States of America***

*S. divinorum* and salvinorin A are not included in the Schedules to the United States *Controlled Substances Act* although both *S. divinorum* and salvinorin A have been added to a list of chemicals "of concern" which has no legal implications. According to the National Institute for Drug Abuse, the Drug Enforcement Agency is considering classifying salvia as a Schedule I drug. This Schedule includes substances such as LSD and marijuana.

In addition, some individual states have implemented laws restricting its use, sale and/or distribution. As of July 2010, a number of states have enacted legislation placing regulatory controls on *S. divinorum* and/or salvinorin A including Delaware,<sup>(6)</sup> Georgia, Florida, Hawaii, Illinois, Kansas, Kentucky, Maryland, Mississippi, Missouri, Nebraska, North Dakota, Ohio, Oklahoma, South Dakota, Wisconsin, Virginia, California, Louisiana, Maine, North Carolina, and Tennessee. More details regarding the regulation of *S. divinorum* in these last five states are provided below.

#### ***California***

As of January 1, 2009, the sale or distribution of *S. divinorum* or salvinorin A, or any substance or material containing *S. divinorum* or salvinorin A, to any person under 18 years of age is a misdemeanor punishable by imprisonment in a county jail for not more than six months, a fine of no more than \$1,000, or both.

#### ***Louisiana***

In 2005, Louisiana passed a bill which prohibits the possession, production, manufacture and distribution of a material, compound, mixture, or preparation intended for human consumption and that contains a hallucinogenic plant. A "hallucinogenic plant" is defined as "any part or portion" of a plant on a list of forty plants, which includes *S. divinorum*.

#### ***Maine***

In Maine, *S. divinorum* and salvinorin A are regulated in the same way as tobacco products; adults eighteen years of age or over can legally purchase and use the material, but selling or providing *S. divinorum* or salvinorin A to anyone under the age of eighteen is a criminal offence. Possession by a minor is a civil violation, punishable by a fine, community service, or both.

### ***North Carolina***

On December 1, 2009, the North Carolina State Legislature brought a new law into force which made *Salvia divinorum* and salvinorin A illegal. The only legal *S. divinorum* activities are the growing for aesthetic, landscaping, or decorative purposes or university-affiliated medical or pharmacological research.

### ***Tennessee***

On July 1, 2006, Tennessee classified the deliberate production, manufacture, distribution, or possession of the active chemical ingredient in the hallucinogenic plant *S. divinorum* as a Class A misdemeanor. It is not, however, a criminal offence to possess, plant, cultivate, grow, or harvest *S. divinorum* for aesthetic, landscaping, or decorative purposes. The law also does not apply to any dosage that is legally obtainable from a retail establishment without a prescription when (and if) it is recognized by the Food and Drug Administration as a homeopathic drug.

#### **4.2.2 Chemical and/or Pharmacological Similarity to Substances Listed in the Schedules to the CDSA**

The psychoactive ingredient in *Salvia divinorum* is the neoclerodane diterpene salvinorin A.<sup>6</sup> Other plants which contain psychotropic terpenoids are *Artemisia absinthium* (wormwood) and *Cannabis sativa*.<sup>7</sup>

Unlike all other hallucinogens, salvinorin A is structurally distinct and does not interact with the serotonin-2A receptor or any other molecular target of classical hallucinogens {reference?}. Instead, the available research suggests the psychotropic effects of salvinorin A are mediated by its agonistic actions at  $\kappa$ -opioid (KOR) receptor.<sup>8</sup> Its mechanism of action is therefore unique.<sup>9</sup>

<sup>6</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage *Salvia divinorum*. *Life Sci.* 2005 Dec 22;78(5):527-31.

<sup>7</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.

<sup>8</sup> Roth BL, Baner K, Westkaemper R, Siebert D, Rice KC, Steinberg S, Ernsberger P, Rothman RB. Salvinorin A: a potent naturally occurring nonnitrogenous kappa opioid selective agonist. *Proc Natl Acad Sci U S A.* 2002 Sep 3;99(18):11934-9.

<sup>9</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

The psychoactive effects of *S. divinorum* vary in onset and duration and include the sensation of becoming an object, visions of various two-dimensional surfaces, films and membranes, revisiting places of the past (particularly childhood), perceived loss of the body and/or identity, various sensations of motion (being pulled or twisted by a force of some kind), uncontrollable hysterical laughter, and overlapping realities (perceptions of being in more than one place).<sup>10</sup> Laughter, happiness, sense of well-being and dissociative effects were deemed the most positive aspects of *S. divinorum* by users, second only to the "trip" that the drug elicits.<sup>11</sup> Depersonalization, speaking gibberish, widening of consciousness and subjective illusions of rapid movement, flying or hovering have also been reported.<sup>12</sup>

The psychotomimetic effects of *S. divinorum* closely resemble schizoid symptoms induced by lysergic acid diethylamide (LSD) or phencyclidine (PCP).<sup>13</sup> Yet, it is said to have only weak influence on the prevailing mood of the user which differentiates it from other hallucinogens such as LSD and psilocybin.<sup>14</sup> Its strong dissociative effects are often compared to those of ketamine.<sup>15</sup> Users have reported that the psychedelic effects of *S. divinorum* were most similar to those caused by psilocybin mushrooms.<sup>16</sup> However, users familiar with the effects of other hallucinogens agree that despite certain similarities to classical hallucinogens, the visions and overall experience are quite unique.<sup>17</sup>

*S. divinorum* causes an unusually high degree of sedation, weakness and fatigue, while the increased de-realization is not commonly reported for classical psychedelics.<sup>18</sup> The combination of these effects seems to correlate with that of other KOR agonists such as pentazocine.<sup>19</sup>

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<sup>10</sup> Siebert DJ. Salvia divinorum and salvinin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>11</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>12</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5 and Siebert DJ. Salvia divinorum and salvinin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>13</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5.

<sup>14</sup> Siebert DJ. Salvia divinorum and salvinin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>15</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinin A content in five Salvia divinorum herbal products. Pharmacotherapy. 2006 Sep;26(9):1268-72.

<sup>16</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>17</sup> Siebert DJ. Salvia divinorum and salvinin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6 and González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>18</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>19</sup> Arasteh K, Poudevida S, Farre M, Roset PN, Cami J. Response patterns of the Spanish version of the 49-item short form of the Addiction Research Center Inventory after the use of sedatives, stimulants, and opioids. Drug Alcohol Depend. 1999 Jun 1;55(1-2):117-25.

The onset and intensity of the effects of *Salvia divinorum* appear to be related to the route of administration. Traditional uses generally produce mild effects because the leaves are rolled and chewed or crushed and prepared as a foamy infusion whereby the salvinorin A is degraded in the gastrointestinal system before being absorbed into the bloodstream. Hence, the level of effect relates quite closely to the length of time the material spends in the mouth, with the onset of effect generally taking 5-10 minutes. The effects build over the next hour and last for another hour before they begin to subside.<sup>20</sup>

Routes of administration that avoid the hepatic first-pass effect (i.e. inhalation, intravenous, intramuscular and sublingual use) are the quickest and most intense.<sup>21</sup> Salvinorin A can be isolated from the plant to make a powder which can be vaporized and inhaled. The onset of effects felt from vaporizing salvinorin A powder occurs in about 30 seconds and effects last for about 5-10 minutes and then subside over the next 30 minutes.<sup>22</sup>

Smoking is by far the most popular method of administration<sup>23</sup> and this is accomplished by smoking the dried leaves or a concentrated extract using a pipe or bong. Dried leaves may also be fortified with a concentrated extract of salvinorin A. A concentrated extract can also be used sublingually. Neither *S. divinorum* nor salvinorin A can be injected because the powder is insoluble in water.<sup>24</sup>

#### **4.2.3 Legitimate Use of the Substance, including Therapeutic, Scientific, Industrial or Commercial Uses**

*Salvia divinorum* has traditionally been used for spiritual and medicinal purposes by the Mazatec Indians in Oaxaca, Mexico,<sup>25</sup> where an infusion of the leaves or the leaves themselves are ingested to treat gastrointestinal problems, headaches, rheumatism, anemia and swelling of the stomach.<sup>26</sup> Its main use today is, however, for its psychedelic properties in the aid of producing "mystical" or hallucinogenic experiences as part of spiritual rituals.<sup>27</sup>

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<sup>20</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>21</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.

<sup>22</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>23</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62 and Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>24</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs.* 1994 Jul-Sep;26(3):277-83.

<sup>25</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>26</sup> Munro, T. The Chemistry of *Salvia divinorum*. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

<sup>27</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage *Salvia divinorum*. *Life Sci.* 2005 Dec 22;78(5):527-31.



Although selective kappa receptor agonists have been shown to produce analgesic effects, adverse effects such as psychotomimesis, dysphoria and diuresis have been observed in studies investigating their therapeutic use.<sup>28</sup> In addition, while it has been speculated that KOR agonists may be useful in the treatment of certain psychiatric disorders including Alzheimer's disease, schizophrenia, dementia and bipolar disorder,<sup>29</sup> much more research is needed in order to substantiate these hypotheses. Similarly, another study has suggested that chemical analogues of salvinorin A may be a useful treatment for those suffering from addiction to other substances.<sup>30</sup> That said there are presently no recognized medical uses for *S. divinorum* in Canada.

Similarly, there are no known industrial or commercial uses for *S. divinorum* in Canada. Most websites offering *S. divinorum* cuttings and seeds for sale appear to do so in the context of growing the plant for "recreational" purposes, rather than out of horticultural interest or for its esthetic appeal. *S. divinorum* is ~~sometimes sold~~ <sup>also marketed</sup> as incense. However, there is no evidence that *S. divinorum* has any fragrant properties that would legitimize ~~its use as incense~~ <sup>such a use</sup>. Therefore it is believed that the marketing of this plant as an incense is a recent invention to avoid compliance and enforcement actions by Health Canada.

#### 4.2.4 Potential for Abuse and/or Addiction Liability of the Substance

Salvinorin A is a potent, selective agonist of the  $\kappa$ -opioid receptor (KOR), and in contrast to the euphoria produced by  $\mu$ -opioid receptor (MOR) agonists such as morphine, KOR agonists are negatively reinforcing and aversive. In addition, KOR agonists have analgesic properties but are not associated with respiratory depression like MOR agonists. Finally, while MOR agonists increase the release of dopamine, the activation of KOR decreases dopamine release in the nucleus accumbens.<sup>31</sup> In the case of MOR agonists, the increase of dopamine acts as a positive reinforcer. This action motivates the user to use the drug again, which could lead to drug abuse and/or addiction. For KOR agonists, this is not the case.

The aversive effects of KOR agonists suggest that the risk of addiction to *S. divinorum* is negligible. However, very few controlled scientific studies of the physical and psychotropic effects of *S. divinorum* on humans have been carried out. Therefore, it is difficult to predict with certainty its potential for addiction and abuse. In studies that have been conducted, there is conflicting information around the addiction liability of *S. divinorum* in both animals and

<sup>28</sup> Barker RL, Fawcett J, Barkin SJ. 2002. Chronic pain management with a focus on the role of newer antidepressants and centrally acting agents. In: Pain Management: A Practical Guide for Clinicians, 6th edition, Weiner RS ed. CRC Press, Boca Raton, FL. pp. 415-34 and Tidgewell et al., 2004. A facile method for the preparation of deuterium labelled salvinorin A: Biorganic & Medicinal Chemistry Letters, 14: 5099-5102.

<sup>29</sup> Sheffler DJ & Roth BL. Salvinorin A: the 'magic mint' hallucinogen finds a molecular target in the kappa opioid receptor. Trends Pharmacol Sci. 2003 Mar;24(3):107-109.

<sup>30</sup> Prisinzano TE. Natural products as tools for neuroscience: discovery and development of novel agents to treat drug abuse. J Nat Prod. 2009 Mar 27;72(3):581-7.

<sup>31</sup> Gustein HB & Akil H. Opioid Analgesics. In: Goodman and Gilman's The Pharmacological Basis of Therapeutics 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.

humans. Some users have noted that they require increasing doses of salvinorin A in order to achieve the desired effect and the stimulated cerebral KOR may act as a mechanism of tolerance.<sup>32</sup> Further studies in this area and on the mediated decrease of dopamine as well as the impact of dose on effects are also required. *in order to fully understand the addiction potential of this substance.*

While concerns for the potential of abuse were once minimal because 1 kg of dried leaves yields only 3 to 6 human doses of salvinorin A, it was discovered that vaporizing and inhaling 200-500 micrograms had profound hallucinogenic effects.<sup>33</sup> Given that only small doses of this substance are necessary to achieve the desired effects, there is a higher potential for abuse. The extraction of salvinorin A from the plant is simple, and with care, approximately 1.5 grams of pure salvinorin A per kilogram of dried leaves (8kg of fresh leaves) can be isolated. This is enough for 2000 human doses.<sup>34</sup>

#### 4.2.5 Evidence of Extent of Actual Abuse of the Substance in Canada and Internationally

In Canada, the extent of actual abuse of *Salvia divinorum* and/or salvinorin A is relatively unknown. There is, however, some data regarding the prevalence of use of *Salvia divinorum* in Canada, despite the lack of legitimate uses for this plant. Questions about the use of *S. divinorum* were included in the 2009 Ontario Student Drug Use and Health Survey, the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey.

It is difficult to determine the extent of actual abuse of *S. divinorum* in Canada or elsewhere as there appear to be inconsistencies in the literature regarding risk aversion. For example, one author states: "Many who have used salvinorin A find the experience extremely unnerving, frightening and overly intense and most have no desire to repeat the experience."<sup>35</sup> However, another study suggested that this is not the experience of all recreational users of *S. divinorum*.<sup>36</sup> Over eighty percent of users surveyed on a web-based questionnaire about their *S. divinorum* use said that they would probably or definitely use *S. divinorum* again.<sup>37</sup> Users have reported the negative effects of *S. divinorum* as: the short duration of action, lack of control over the

<sup>32</sup> Bucheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>33</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>34</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs*. 1994 Jul-Sep;26(3):277-83.

<sup>35</sup> Turner DM. *Salvinorin - The Psychedelic Essence of Salvia Divinorum*. Panther Press, San Francisco, CA 1996.

<sup>36</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62, Bucheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5, and Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs*. 1994 Jul-Sep;26(3):277-83.

<sup>37</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

experience, persisting negative effects (most often anxiety),<sup>38</sup> sweating, chills, increased diuresis, impaired vigilance,<sup>39</sup> and negative after-effects including tiredness, feeling head heavy, dizziness, physical exhaustion, and some degree of malaise or 'hangover' as they 'comedown' from the drug.<sup>40</sup>

The results from the 2009 Ontario Student Drug Use and Health Survey were published on November 18, 2009 and indicate that:

- Among all responding students in Ontario, 4.4% reported using *Salvia divinorum* at least once in the past year. In comparison, 58.2% indicated they had used alcohol, 25.6% indicated they had used cannabis and 5.0% indicated they had used hallucinogens other than LSD and PCP in the past year;
- Males (6.2%) were significantly more likely than females (2.3%) to report using *Salvia divinorum*;
- There is significant grade variation, with *Salvia divinorum* use most likely among 11<sup>th</sup> graders (8.6%) and 12<sup>th</sup> graders (8.4%); and
- There are significant regional variations, with students in Northern Ontario (9.2%) most likely to use *Salvia divinorum*.

The results of the 2008-2009 Youth Smoking Survey were published on May 31, 2010 and indicate that:

- 4.9% of students stated that they had used *S. divinorum* in the last twelve months. In comparison, 53.0% indicated they had used alcohol, 27.3% indicated they had used cannabis and 6.9% indicated they had used other hallucinogens in the last twelve months;
- 2.6% of students in Grades 7-9 and 7.0% of students in Grades 10-12 had used *S. divinorum* in the last twelve months; and
- Males (6.6%) were more likely to have used *S. divinorum* in the past twelve months compared to females (3.2%).

The scope of the previously mentioned studies did not provide for any explanations regarding differences in usage between ages, genders and regions. In this regard, it is difficult to speculate on the causality of such differences.

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<sup>38</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>39</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>40</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

The Canadian Alcohol and Drug Use Monitoring Survey specifically examined Salvia for the first time in 2009. An estimated 1.6% of Canadians, aged 15 years and older, reported that they had used salvia in their lifetime, and 0.2% reported using it in the past-year. In comparison, the prevalence of past-year cannabis use among Canadians 15 years of age and older was 10.6%. 1.2% of respondents reported using cocaine or crack in the past 12 months, 0.9% had used ecstasy and 0.7% used illicit hallucinogens.

Health Canada's Drug Analysis Services (DAS) has identified salvinorin A in a number of samples seized by law enforcement, as shown in the following table. It is, however, difficult to determine how this data reflects the extent of actual abuse of salvinorin A in Canada.

**NUMBER OF SAMPLES FOUND TO CONTAIN SALVINORIN A**

Year	Count
2006	9
2007	8
2008	4
2009	20
2010 (as of May 7)	8

The National Forensic Laboratory Information System (NFLIS) and the System to Retrieve Information from Drug Evidence (STRIDE) in the United States are Drug Enforcement Agency (DEA) databases that collect scientifically verified data on analyzed samples in state and local forensic labs as well as samples from DEA labs. The following table shows the quantity of *S. divinorum* products that were seized from 2000 through to 2009.

**ANALYZED SALVIA DIVINORUM or SALVINORIN A SEIZURES**

(Number of Items/Exhibits)

Source	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009*
NFLIS-State/Local <sup>1</sup>	0	0	0	0	1	8	12	12	70	34
STRIDE <sup>2</sup>	0	0	1	1	1	0	0	0	N/A	N/A
<b>TOTAL</b>	0	0	1	1	2	8	12	12	70	34

Data Source: NFLIS & STRIDE, 2008 data queried 11/24/08, updated 06/10/2010

<sup>1</sup> NFLIS reported seizures of *Salvia divinorum* and/or salvinorin A

<sup>2</sup> STRIDE reported items of *Salvia divinorum*.

\* Includes only January - May data in 2009.

once again it is difficult to determine how this data can be used to reflect the actual extent of abuse of S.d. & S.a. in the USA.

**4.2.6 Risk to Personal and Public Health and Safety**

The increase in both the number of enquiries from various municipalities and members of the public and the amount of media interest regarding the availability of *Salvia divinorum* in Canada may be an indication that the recreational use of *S. divinorum* as a hallucinogen is on the rise. However, there are no available statistics that indicate there has been a significant increase in *S. divinorum* use in the Canadian population and, in comparison to the use of other drugs such as

~~alcohol and cannabis, the actual use of *S. divinorum* is quite low.~~

*Infectious* The potential for harm to the user and/or other individuals is primarily related to the hallucinogenic properties of the substance. As this substance is typically smoked, there is no risk of disease transmission as is the case when a drug is injected. Users may get up and walk around without apparent awareness of their movements, behaviour or surroundings, and distinction between self and surroundings is often lost. At doses greater than 1mg of salvinorin A, out of body experiences are frequent and loss of consciousness has been reported.<sup>41</sup> There is little information regarding the social behaviours of persons under the influence of *S. divinorum* products, and what risks their activities such as operating a motorized vehicle may pose to the general public. There is also very little data regarding the toxicity, teratogenicity or other long-term effects of *S. divinorum* use.<sup>42</sup>

As far as law enforcement is concerned, the Department has only received a limited number of communications indicating concern with respect to *S. divinorum* and ~~none of these have advised that the use of *S. divinorum* poses any threat to public safety.~~ The Royal Canadian Mounted Police (RCMP) has stated that while *S. divinorum* is readily available, it has not become a popular drug in Canada, probably due to its aversive effects such as anxiety and introversion.

A handful of case reports regarding the physiological and psychotropic effects of *S. divinorum* use have been published in the academic literature. An international case report described the perceptions of a 19 year-old man after inhaling *S. divinorum* smoke. The peak psychotropic effects, including prickling of the skin, fever-like hot flashes, muscular tremor, and depersonalization, were reached in less than five minutes after inhalation of an unknown amount of smoke from burning dried leaves.<sup>43</sup> Another report involved a 15-year-old male who presented to psychiatric emergency services with acute onset of paranoia, déjà vu, blunted affect, difficulties in thought processing and slowed speech after smoking *Salvia divinorum* over an unknown period of time. During his hospitalization all symptoms improved significantly except the feeling of déjà vu. Based on this case presentation, the author suggested that the feelings of déjà vu may be a long-term effect of *S. divinorum* use.<sup>44</sup> However, given that this is the only case report in which déjà vu was associated with the use of *S. divinorum*, more reports are needed to substantiate this finding.

In addition to the above-mentioned reports, in 2006, a case was reported in the U.S. in which a 17-year-old boy committed suicide after smoking *S. divinorum* for an unknown period of time.<sup>45</sup> It should be noted that alcohol and general depression were the main confounders in this case. After this case was reported, the state of Delaware passed a law which classified *S. divinorum* as a Schedule I controlled substance along with other hallucinogenic substances.

Like many drugs of abuse, users are often unaware of the potency and adulterants in the product

<sup>41</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>42</sup> Grundmann O, Phipps SM, Zadezensky I, Butterweck V. *Salvia divinorum* and Salvinorin A: An Update on Pharmacology and Analytical Methodology. Planta Med 2007 Jun;73:1039-1046.

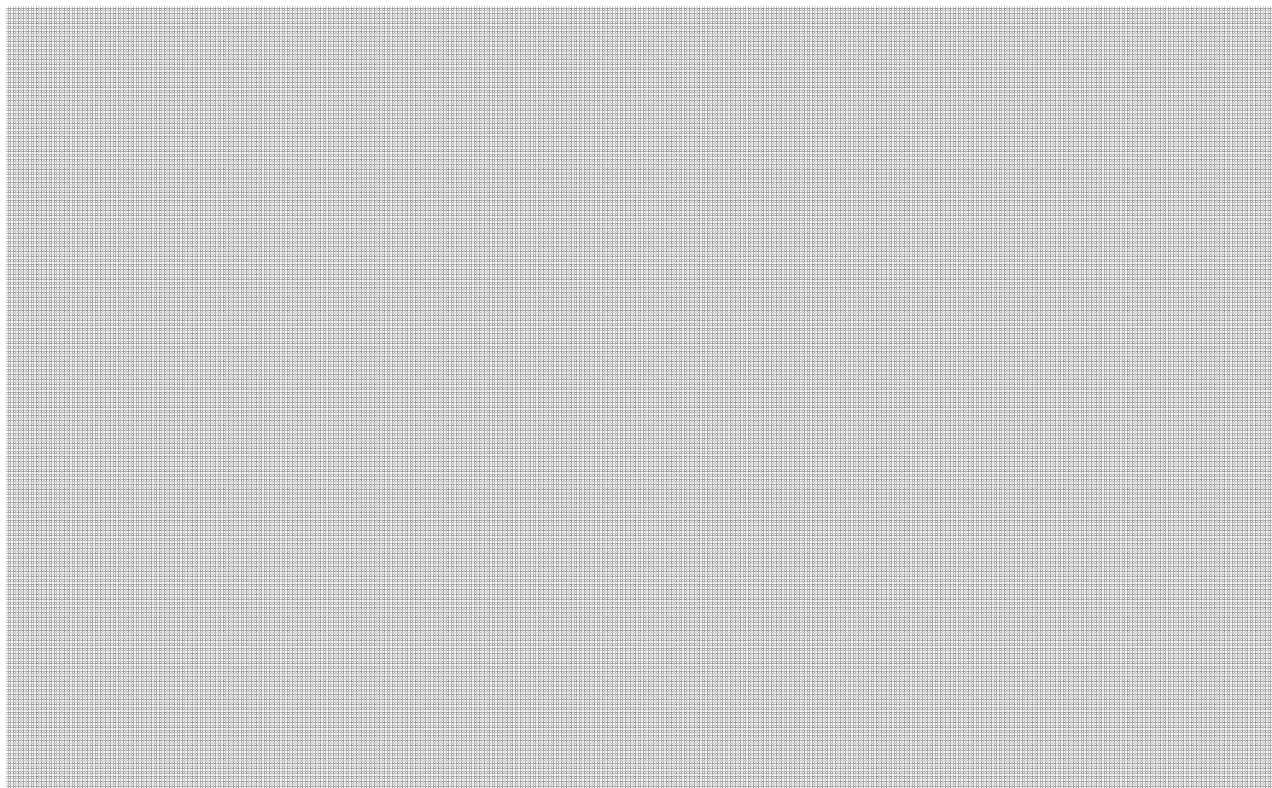
<sup>44</sup> Singh S. (2007) Adolescent salvia substance abuse. Addiction. 102, 823-824.

<sup>45</sup> <http://www.kvbc.com/Global/story.asp?S=4893692>

they purchase. A study by Wolowich *et al.* (2006)<sup>46</sup>, showed that the salvinorin A content in five out of five *S. divinorum* products was falsely indicated on the label and 4 out of 5 products contained unidentified adulterants (i.e. vitamin E, caffeine).

that Health Canada has ~~only anecdotal~~ <sup>some</sup> information about the use and abuse of *S. divinorum* in Canada ~~as well as the threat~~ <sup>as well as the</sup> *S. divinorum* may pose <sup>to the</sup> health and safety of Canadians. There are several reports of domestic adverse reactions related to the use of *S. divinorum* that have been received through the Canada Vigilance database. However, this does not reflect true incidence due to under-reporting. ~~Considering also the limited population exposure information, it is not possible to adequately characterize the risk to the general population.~~ <sup>that</sup>

## 5. ASSESSMENT OF RISKS AND BENEFITS



## 6. IDENTIFICATION AND ANALYSIS OF OPTIONS



<sup>46</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

**Page(s) 001404 to\à 001405**

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**of the Access to Information Act  
de la Loi sur l'accès à l'information**

s.21(1)(a)

s.21(1)(b)

## 7. CONSIDERATIONS

The KOR-mediated aversive and dysphoric effects of *Salvia divinorum* do not appear to be hampering its use as young adults have begun smoking the leaves and leaf extract recreationally.<sup>47</sup> It can be purchased through online botanical companies and other drug promotion sites and is often touted as a legal alternative to substances such as cannabis and mescaline.<sup>48</sup> Interestingly, after being widely available for over a decade, the drug does not appear to have had the same social impact as LSD or ecstasy.<sup>49</sup>

While there has been an increase over the past few years in the number of enquiries from various municipalities and members of the public regarding the availability of *Salvia divinorum* as a hallucinogen, ~~according to available statistics, the reported use of *S. divinorum* by young Canadians is much lower than that of alcohol or cannabis.~~ *there does not yet appear to be an increase in reported use of this substance.*

The NHPR are limited in their capacity to control the availability of *S. divinorum* in that *S. divinorum* products are often declared as incense and therefore cannot be considered unapproved natural health products. In addition, compliance and enforcement actions such as voluntary stop-sales, forfeiture, destruction, and administrative seizure, cannot be implemented unless the *marketing* labeling of the product indicates that it is to be used for human consumption and can modify an organic function.

The previous HPFB recommendation to schedule *S. divinorum* under the CDSA was likely based on a misunderstanding of the (previously-described) criteria upon which scheduling decisions are made within the Healthy Environments and Consumer Safety Branch (HECSB). In particular, it did not consider a number of factors, including potential for abuse and risk to public health and safety. The Office of Controlled Substances (OCS) was also not consulted by HPFB at the time this recommendation was made. In addition, among countries who have decided to control *S. divinorum* in some way, very little or no substantiation of the risks of *S. divinorum* upon which the decision was based are available.

<sup>47</sup> Hazelden Foundation, 2004. Drug Abuse Trends. June 2004. URL: [www.reserach.hazelden.org](http://www.reserach.hazelden.org).

<sup>48</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

<sup>49</sup> Munro, T. The Chemistry of *Salvia divinorum*. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.



Neither *Salvia divinorum* <sup>and</sup> nor salvinorin A <sup>appear to</sup> meet the criteria for scheduling a substance under the CDSA. Despite being regulated in some jurisdictions, neither the plant nor salvinorin A are scheduled under any of the UN Drug Control Conventions. *S. divinorum* and salvinorin A are not structurally or pharmacologically similar to other substances included in the schedules to the CDSA. There are also currently no legitimate therapeutic or industrial uses for *S. divinorum*. The abuse liability and potential for dependence of *S. divinorum* is not known as very few controlled scientific studies of its physical and psychotropic effects have been carried out on humans. The extent of actual abuse of *S. divinorum* is also largely unknown. Evidence of a risk to public health and safety is anecdotal in nature and not quantified in any way as there is a lack of information regarding abuse in Canada.

## 8. RECOMMENDATIONS

## 9. CONSULTATIONS

The Drug Analysis Services (DAS) was contacted in order to provide any data available regarding the identification of salvinorin A in samples submitted by law enforcement.

The Royal Canadian Mounted Police (RCMP) was contacted in order to establish their views with respect to *S. divinorum* use in Canada. The RCMP advised that ~~though *S. divinorum* is readily available, it does not appear to pose a threat to public safety.~~ <sup>and ~~priority~~ law enforcement has no means to prevent its sale.</sup>

OCS has received a number of correspondences from Canada Border Services Agency (CBSA) officers concerning a lack of information regarding the status of *S. divinorum* and how the plant should be treated at the border. CBSA officers have also expressed concern regarding the plant's hallucinogenic properties. At present, only shipments of *S. divinorum* that are represented as health products that modify organic functions can be refused for import under the NHPR.

OCS brought *S. divinorum* and salvinorin A to the Controlled Substances Scheduling Working Group (CSS-WG) in August 2010 to discuss the possibility of regulatory control of these substances. The CSS-WG recommended that both *S. divinorum* and salvinorin A be included under Schedule III to the CDSA.

## 10. IMPLEMENTATION AND EVALUATION

**Page(s) 001408 to\à 001408**

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# Issue Analysis Summary

DRAFT

## Scheduling *Salvia Divinorum* and/or Salvinorin A under the CDSA

Regulatory Policy Division  
Office of Controlled Substances  
Controlled Substances and Tobacco and Directorate

October 22, 2010

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### 1. APPROVALS

This Issue Analysis Summary is approved.

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Jocelyn Kula, A/Director  
Office of Controlled Substances  
Controlled Substances and Tobacco Directorate

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[DD/MM/2010]

### 2. ISSUE

Health Canada has received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *S. divinorum* and/or its main active ingredient salvinorin A, neither of which are currently regulated under the *Controlled Drugs and Substances Act* (CDSA). These requests are further to reports from scientific and media sources suggesting that *S. divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has also noted an

ongoing media interest regarding the availability of *S. divinorum* in Canada.

### 3. PURPOSE

To assess *Salvia divinorum* and/or salvinorin A against the criteria for the addition of a substance to one of the Schedules to the CDSA, and determine whether one or both substances should be regulated as controlled substances in Canada.

### 4. CONTEXT

*Salvia divinorum* is a species of sage which belongs to the mint family, and which is found in the form of dried leaves, extract and plant cuttings. Also known as "diviner's sage", the plant is known to induce illusions and hallucinations when chewed or smoked. Salvinorin A, the psychoactive ingredient in *S. divinorum* (also referred to chemically as a neoclerodane diterpene) is found primarily in the leaves, and to a lesser extent in the stem.<sup>1</sup>

*S. divinorum* is widely touted as a "legal" hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs among adolescents and young adults.<sup>2</sup> While very little is known about how and where *S. divinorum* is sold in Canada, it is suspected that it is mainly purchased over the Internet and/or bought at head shops or alternative life style stores, etc. *S. divinorum* cuttings are also available from a number of garden supply companies.

The use of *S. divinorum* as a psychotropic agent first came to Health Canada's attention in 2002. In 2004, Health Canada received four adverse drug reaction (ADR) reports associated with the use of *S. divinorum* as a hallucinogen, with three being considered non-serious (requiring no medical attention) and the fourth being considered serious (medical intervention was required). The serious ADR report involved the concomitant use of alcohol in a person diagnosed with Attention Deficit Disorder.

Further to the receipt of the aforementioned ADRs, the Marketed Health Products Directorate (MHPD) and the Natural Health Products Directorate (NHPD) of the Health Products and Food Branch (HPFB) prepared an issue analysis summary (IAS), which recommended that *S. divinorum* and its active ingredient salvinorin A be regulated as controlled substances. This recommendation was maintained when the IAS was updated in November 2006.

Later, in December 2005, MHPD and NHPD prepared a Signal Assessment (SA) (updated in June 2007) that eventually led to the preparation of a Health Risk Assessment (HRA), which concluded that *S. divinorum* or salvinorin A-containing health products would constitute a Type

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<sup>1</sup> U.S. Department of Justice Drug Enforcement Administration. 2002. Drugs and Chemicals of Concern: *Salvia Divinorum* (salvinorin A, divinorin A) URL:

[http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm) Nov 2008

<sup>2</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.

II Health Risk according to the Health Hazard Classification of the Recall Policy of the Health Products and Food Branch Inspectorate (HBFBI). Such a risk is defined as “a situation in which the use of, or exposure to, a product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote”.

Further to an Assistant Deputy Minister (ADM) discussion in April 2007, the Drug Strategy and Controlled Substances Directorate (DSCSD) organized a meeting with MHPD, NHPD and HPFBI to discuss *S. divinorum*. HPFBI was to determine appropriate compliance activities regarding *S. divinorum* and consult with the Canada Border Services Agency (CBSA) regarding the movement of products containing *S. divinorum* into and out of Canada.

On September 13, 2007, a further meeting between DSCSD, MHPD, NHPD and HPFBI led to the conclusion that DSCSD would conduct a scheduling assessment of *S. divinorum* in order to explore the possibility of scheduling this substance under the CDSA.

In September 2008, the Director Generals of DSCSD, MHPD, TPD and the HPFBI agreed that media lines and an “It’s Your Health” article on *S. divinorum* would be prepared.

#### **4.1 Relevant Legislative Frameworks in Canada**

##### **4.1.1 Food and Drug Regulations (under the Food and Drugs Act)**

The *Food and Drug Regulations* (F&DR) serve to ensure the safety, efficacy, and quality of health products offered for sale in Canada, including drugs and medical devices. Prior to being given market authorization, a manufacturer must present substantive scientific evidence that their product is safe, efficacious and of high quality. For drugs, Health Canada reviews this information carefully and, if the review is satisfactory, a Notice of Compliance (NOC) is issued and appropriate Drug Identification Numbers (DINs) are assigned.

A “drug” is defined under the F&DR as any substance or mixture of substances manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
- (b) restoration, correction or modification of organic functions in human beings or animals, or
- (c) disinfection in premises in which food is manufactured, prepared or kept;

As no products containing *S. divinorum* or its extracts have been reviewed and approved by Health Canada as of October 2010, it is illegal to market *S. divinorum* when it is represented as a drug.

#### 4.1.2 Natural Health Products Regulations (under the Food and Drugs Act)

The *Natural Health Products Regulations* (NHPR) aim to provide Canadians with ready access to natural health products (NHPs) that are safe, effective, and of high quality, while respecting freedom of choice and philosophical and cultural diversity. The NHPR require that all licensed products display a Natural Product Number (NPN), or, in the case of a homeopathic medicine, a Drug Identification Number - Homeopathic Medicine (DIN-HM), on their labels. These numbers are issued once a product is authorized for sale in Canada further to the submission of a product license application in which the applicant attests to all of the conditions set out in a *natural health product monograph* prepared and published by the Natural Health Products Directorate or submission of a product license application that provides sufficient evidence of quality, safety and efficacy that is assessed and approved by NHPD by the non-compendial route. The NHPR also require that all manufacturers, packagers, labelers, and importers be licensed which in turn requires the presence of procedures respecting distribution records, product recalls, product handling, storage and delivery, and all other aspects of Good Manufacturing Practices as set out in the NHPR.

The definition of an NHP under the NHPR has both a function and substance component. The function component refers to those substances that are manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
- (b) restoring or correcting organic functions in humans; or
- (c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

The substance component refers to the requirement that all of the medicinal ingredients of an NHP must be substances set out in Schedule 1 to the NHPR, which is a list of included substances. Included substances are those substances that are traditional or homeopathic medicines, and of which none of the ingredients are substances set out in Schedule 2, which is a list of excluded substances. Excluded substances include any substance listed on Schedules I to V of the CDSA. Section 2(2) of the NHPR excludes those substances (except homeopathic medicines) whose sale is required to be pursuant to a prescription as per Section C.01.043 of the F&DR. As per section 93(1)(b)(vi) of the NHPR, every natural health product must be labeled with its authorized recommended use or purpose. In the case of *S. divinorum*, it is generally marketed for its hallucinogenic properties which are considered a modification of an organic function. Therefore products that contain *S. divinorum* and are manufactured, sold or represented for use as a hallucinogen meet the definition of an NHP.

As of October 2010, no products containing *S. divinorum* have been reviewed and approved by

Health Canada and no NPNs or DIN-HMs have been issued. Therefore sales of *S. divinorum* are illegal under the NHPR if it is represented for use as a hallucinogen or if other health claims such as with regard to modifying organic functions are made.

#### **4.1.3 Controlled Drugs and Substances Act and its Regulations**

The CDSA provides a legislative framework for the control of substances that can alter mental processes and that may produce harm to the health of an individual or to society when diverted or misused. Except as authorized under its regulations, activities such as possession, possession for the purposes of trafficking, trafficking, importation, exportation, possession for the purposes of exportation and production of controlled substances are prohibited under the CDSA.

The substances regulated under the CDSA are grouped into eight Schedules, and each Schedule is associated with particular offences and penalties as described in Part I of the CDSA.

In determining whether a substance should be regulated as a controlled substance, and into which Schedule of the CDSA it should be placed, Health Canada considers the following factors:

- International requirements and trends in the control and/or scheduling;
- Chemical and/or pharmacological similarity to substances listed in the Schedules to the CDSA;
- Legitimate use of the substance, including therapeutic, scientific, industrial or commercial uses;
- Potential for abuse and/or addiction liability;
- Evidence of extent of actual abuse of the substance in Canada and internationally; and
- Risk to personal and public health and safety.

#### **4.2 Assessment of *Salvia Divinorum* for Scheduling Purposes**

##### **4.2.1 International Requirements and Trends in the Control and/or Scheduling**

At the present time, neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and therefore do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

##### ***Australia***

In June 2002, Australia became the first country to prohibit the sale, supply, possession and use of *S. divinorum* and salvinorin A. Both *S. divinorum* and salvinorin A are listed in Schedule 9 of Australia's *Standard for the Uniform Scheduling of Drugs and Poisons* on the basis of "high potential for abuse and risk to public health and safety."<sup>3</sup> Schedule 9 is Australia's most restrictive drug schedule, and includes "substances which may be abused or misused, the

<sup>3</sup> <http://www.tga.gov.au/ndpsc/record/rr200111.pdf>

manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities.”<sup>4</sup>

### ***Belgium***

A decree was passed in Belgium on October 22, 2006 which added *S. divinorum* to the list of controlled substances. This list includes substances such as psilocybin mushrooms, khat and peyote cactus.<sup>5</sup>

### ***Denmark***

In 2003, Denmark added *S. divinorum* and salvinorin A to their list of “category B” controlled substances, a category which also includes psilocybin mushrooms, cocaine, amphetamine, and several others substances that are only legal for medicinal and scientific purposes. Illegal possession carries a penalty of up to two years in prison.

### ***Germany***

*S. divinorum* (plant and plant parts) was added to Appendix I of the *Narcotics Act* in Germany on March 1, 2008, making it illegal to produce, traffic, or possess. The law does not specifically mention salvinorin A.

### ***Italy***

On June 25, 2004, the Italian Ministry of Health issued an ordinance prohibiting the sale of *S. divinorum* and its active constituent salvinorin A. On January 11, 2005, the Ministry of Health made possession of *S. divinorum* and salvinorin A illegal by placing them in “*Tabella I*” of the *Tabelle Sostanze Stupefacenti o Psicotrope*.

### ***Japan***

On November 9, 2006, the Japanese government added a group of thirty-three drugs to its list of controlled substances, including salvinorin A. The drugs are banned under a revised pharmaceutical law, under which persons involved in their illegal import, production, and sale, i.e. beyond medical treatment or research purposes, will be subject to up to five years imprisonment or a fine of up to five million yen.

### ***Spain***

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<sup>4</sup> [http://www.cognitiveliberty.org/news/salvia\\_australia.htm](http://www.cognitiveliberty.org/news/salvia_australia.htm)

<sup>5</sup> <http://eldd.emcdda.europa.eu/html.cfm/index5176EN.html?pluginMethod=eldd.shownewsdetails&id=20/12/2006BELGIUM:%20New%20substances%20controlled%20include%20mCPP%20and%20khat>



On January 28, 2004, the Spanish Ministry of Health and Consumption issued an order prohibiting the sale of *S. divinorum*. The regulation went into effect on May 6, 2004 and only prohibits activities related to commerce. Possession and/or use are not considered to be criminal offences.

### ***Other Countries***

*Salvia divinorum* is illegal to possess or sell in Croatia, Latvia, Lithuania, Poland, Romania, South Korea and Sweden. In Russia it is illegal to grow or sell *S. divinorum*, but it is legal to possess it. In Estonia, Finland, Iceland and Norway, *S. divinorum* is treated as a medicinal herb and it is illegal to import it without a relevant prescription from a doctor.

### ***United States of America***

*S. divinorum* and salvinorin A are not included in the Schedules to the United States *Controlled Substances Act* although both *S. divinorum* and salvinorin A have been added to a list of chemicals "of concern" which has no legal implications. According to the National Institute for Drug Abuse, the Drug Enforcement Agency is considering classifying salvia as a Schedule I drug. This Schedule includes substances such as LSD and marijuana.

In addition, some individual states have implemented laws restricting its use, sale and/or distribution. As of July 2010, a number of states have enacted legislation placing regulatory controls on *S. divinorum* and/or salvinorin A including Delaware, Georgia, Florida, Hawaii, Illinois, Kansas, Kentucky, Maryland, Mississippi, Missouri, Nebraska, North Dakota, Ohio, Oklahoma, South Dakota, Wisconsin, Virginia, California, Louisiana, Maine, North Carolina, and Tennessee. More details regarding the regulation of *S. divinorum* in these last five states are provided below.

#### ***California***

As of January 1, 2009, the sale or distribution of *S. divinorum* or salvinorin A, or any substance or material containing *S. divinorum* or salvinorin A, to any person under 18 years of age is a misdemeanor punishable by imprisonment in a county jail for not more than six months, a fine of no more than \$1,000, or both.

#### ***Louisiana***

In 2005, Louisiana passed a bill which prohibits the possession, production, manufacture and distribution of a material, compound, mixture, or preparation intended for human consumption and that contains a hallucinogenic plant. A "hallucinogenic plant" is defined as "any part or portion" of a plant on a list of forty plants, which includes *S. divinorum*.

#### ***Maine***

In Maine, *S. divinorum* and salvinorin A are regulated in the same way as tobacco products; adults eighteen years of age or over can legally purchase and use the material, but selling or providing *S. divinorum* or salvinorin A to anyone under the age of eighteen is a criminal offence. Possession by a minor is a civil violation, punishable by a fine, community service, or both.

### ***North Carolina***

On December 1, 2009, the North Carolina State Legislature brought a new law into force which made *Salvia divinorum* and salvinorin A illegal. The only legal *S. divinorum* activities are the growing for aesthetic, landscaping, or decorative purposes or university-affiliated medical or pharmacological research.

### ***Tennessee***

On July 1, 2006, Tennessee classified the deliberate production, manufacture, distribution, or possession of the active chemical ingredient in the hallucinogenic plant *S. divinorum* as a Class A misdemeanor. It is not, however, a criminal offence to possess, plant, cultivate, grow, or harvest *S. divinorum* for aesthetic, landscaping, or decorative purposes. The law also does not apply to any dosage that is legally obtainable from a retail establishment without a prescription when (and if) it is recognized by the Food and Drug Administration as a homeopathic drug.

## **4.2.2 Chemical and/or Pharmacological Similarity to Substances Listed in the Schedules to the CDSA**

The psychoactive ingredient in *Salvia divinorum* is the neoclerodane diterpene salvinorin A.<sup>6</sup> Other plants which contain psychotropic terpenoids are *Artemisia absinthium* (wormwood) and *Cannabis sativa*.<sup>7</sup>

Unlike all other hallucinogens, salvinorin A is structurally distinct and does not interact with the serotonin-2A receptor or any other molecular target of classical hallucinogens.<sup>8</sup> Instead, the available research suggests the psychotropic effects of salvinorin A are mediated by its agonistic actions at the  $\kappa$ -opioid (KOR) receptor.<sup>9</sup> Its mechanism of action is therefore unique.<sup>10</sup>

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<sup>6</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage *Salvia divinorum*. *Life Sci.* 2005 Dec 22;78(5):527-31.

<sup>7</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.

<sup>8</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.

<sup>9</sup> Roth BL, Baner K, Westkaemper R, Siebert D, Rice KC, Steinberg S, Ernsberger P, Rothman RB. Salvinorin A: a potent naturally occurring nonnitrogenous kappa opioid selective agonist. *Proc Natl Acad Sci U S A.* 2002 Sep 3;99(18):11934-9.

The psychoactive effects of *S. divinorum* vary in onset and duration and include the sensation of becoming an object, visions of various two-dimensional surfaces, films and membranes, revisiting places of the past (particularly childhood), perceived loss of the body and/or identity, various sensations of motion (being pulled or twisted by a force of some kind), uncontrollable hysterical laughter, and overlapping realities (perceptions of being in more than one place).<sup>11</sup> Laughter, happiness, sense of well-being and dissociative effects were deemed the most positive aspects of *S. divinorum* by users, second only to the "trip" that the drug elicits.<sup>12</sup> Depersonalization, speaking gibberish, widening of consciousness and subjective illusions of rapid movement, flying or hovering have also been reported.<sup>13</sup>

The psychotomimetic effects of *S. divinorum* closely resemble schizoid symptoms induced by lysergic acid diethylamide (LSD) or phencyclidine (PCP).<sup>14</sup> Yet, it is said to have only weak influence on the prevailing mood of the user which differentiates it from other hallucinogens such as LSD and psilocybin.<sup>15</sup> Its strong dissociative effects are often compared to those of ketamine.<sup>16</sup> Users have reported that the psychedelic effects of *S. divinorum* were most similar to those caused by psilocybin mushrooms.<sup>17</sup> However, users familiar with the effects of other hallucinogens agree that despite certain similarities to classical hallucinogens, the visions and overall experience are quite unique.<sup>18</sup>

*S. divinorum* causes an unusually high degree of sedation, weakness and fatigue, while the increased de-realization is not commonly reported for classical psychedelics.<sup>19</sup> The combination

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<sup>10</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>11</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>12</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>13</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5 and Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>14</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5.

<sup>15</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>16</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five Salvia divinorum herbal products. Pharmacotherapy. 2006 Sep;26(9):1268-72.

<sup>17</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>18</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6 and González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>19</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

of these effects seems to correlate with that of other KOR agonists such as pentazocine.<sup>20</sup>

The onset and intensity of the effects of *Salvia divinorum* appear to be related to the route of administration. Traditional uses generally produce mild effects because the leaves are rolled and chewed or crushed and prepared as a foamy infusion whereby the salvinorin A is degraded in the gastrointestinal system before being absorbed into the bloodstream. Hence, the level of effect relates quite closely to the length of time the material spends in the mouth, with the onset of effect generally taking 5-10 minutes. The effects build over the next hour and last for another hour before they begin to subside.<sup>21</sup>

Routes of administration that avoid the hepatic first-pass effect (i.e. inhalation, intravenous, intramuscular and sublingual use) are the quickest and most intense.<sup>22</sup> Salvinorin A can be isolated from the plant to make a powder which can be vaporized and inhaled. The onset of effects felt from vaporizing salvinorin A powder occurs in about 30 seconds and effects last for about 5-10 minutes and then subside over the next 30 minutes.<sup>23</sup>

Smoking is by far the most popular method of administration<sup>24</sup> and this is accomplished by smoking the dried leaves or a concentrated extract using a pipe or bong. Dried leaves may also be fortified with a concentrated extract of salvinorin A. A concentrated extract can also be used sublingually. Neither *S. divinorum* nor salvinorin A can be injected because the powder is insoluble in water.<sup>25</sup>

#### 4.2.3 Legitimate Use of the Substance, including Therapeutic, Scientific, Industrial or Commercial Uses

*Salvia divinorum* has traditionally been used for spiritual and medicinal purposes by the Mazatec Indians in Oaxaca, Mexico,<sup>26</sup> where an infusion of the leaves or the leaves themselves are ingested to treat gastrointestinal problems, headaches, rheumatism, anemia and swelling of the

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<sup>20</sup> Arasteh K, Poudevida S, Farre M, Roset PN, Cami J. Response patterns of the Spanish version of the 49-item short form of the Addiction Research Center Inventory after the use of sedatives, stimulants, and opioids. *Drug Alcohol Depend.* 1999 Jun 1;55(1-2):117-25.

<sup>21</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>22</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.

<sup>23</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>24</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62 and Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>25</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs.* 1994 Jul-Sep;26(3):277-83.

<sup>26</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

stomach.<sup>27</sup> Its main use today is, however, for its psychedelic properties in the aid of producing “mystical” or hallucinogenic experiences as part of spiritual rituals.<sup>28</sup>

Although selective kappa receptor agonists have been shown to produce analgesic effects, adverse effects such as psychotomimesis, dysphoria and diuresis have been observed in studies investigating their therapeutic use.<sup>29</sup> In addition, while it has been speculated that KOR agonists may be useful in the treatment of certain psychiatric disorders including Alzheimer’s disease, schizophrenia, dementia and bipolar disorder,<sup>30</sup> much more research is needed in order to substantiate these hypotheses. Similarly, another study has suggested that chemical analogues of salvinorin A may be a useful treatment for those suffering from addiction to other substances.<sup>31</sup> That said there are presently no recognized medical uses for *S. divinorum* in Canada.

Similarly, there are no known industrial or commercial uses for *S. divinorum* in Canada. Most websites offering *S. divinorum* cuttings and seeds for sale appear to do so in the context of growing the plant for “recreational” purposes, rather than out of horticultural interest or for its esthetic appeal. *S. divinorum* is also marketed as incense. However, there is no evidence that *S. divinorum* has any fragrant properties that would legitimize such a use. Therefore it is believed that the marketing of this plant as an incense is a recent invention to avoid compliance and enforcement actions by Health Canada.

#### 4.2.4 Potential for Abuse and/or Addiction Liability

Salvinorin A is a potent, selective agonist of the  $\kappa$ -opioid receptor (KOR), and in contrast to the euphoria produced by  $\mu$ -opioid receptor (MOR) agonists such as morphine, KOR agonists are negatively reinforcing and aversive. In addition, KOR agonists have analgesic properties but are not associated with respiratory depression like MOR agonists. Finally, while MOR agonists increase the release of dopamine, the activation of KOR decreases dopamine release in the nucleus accumbens.<sup>32</sup> In the case of MOR agonists, the increase of dopamine acts as a positive reinforcer. This action motivates the user to use the drug again, which could lead to drug abuse and/or addiction. For KOR agonists, this is not the case.

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<sup>27</sup> Munro, T. The Chemistry of *Salvia divinorum*. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

<sup>28</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage *Salvia divinorum*. *Life Sci.* 2005 Dec 22;78(5):527-31.

<sup>29</sup> Barker RL, Fawcett J, Barkin SJ. 2002. Chronic pain management with a focus on the role of newer antidepressants and centrally acting agents. In: *Pain Management: A Practical Guide for Clinicians*, 6th edition, Weiner RS ed. CRC Press, Boca Raton, FL. pp. 415-34 and Tidgewell et al., 2004. A facile method for the preparation of deuterium labelled salvinorin A: *Biorganic & Medicinal Chemistry Letters*, 14: 5099-5102.

<sup>30</sup> Sheffler DJ & Roth BL. Salvinorin A: the ‘magic mint’ hallucinogen finds a molecular target in the kappa opioid receptor. *Trends Pharmacol Sci.* 2003 Mar;24(3):107-109.

<sup>31</sup> Prisinzano TE. Natural products as tools for neuroscience: discovery and development of novel agents to treat drug abuse. *J Nat Prod.* 2009 Mar 27;72(3):581-7.

<sup>32</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman’s The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.

The aversive effects of KOR agonists suggest that the risk of addiction to *S. divinorum* is negligible. However, very few controlled scientific studies of the physical and psychotropic effects of *S. divinorum* on humans have been carried out. Therefore, it is difficult to predict with certainty its potential for addiction and abuse. In studies that have been conducted, there is conflicting information around the addiction liability of *S. divinorum* in both animals and humans. Some users have noted that they require increasing doses of salvinorin A in order to achieve the desired effect and the stimulated cerebral KOR may act as a mechanism of tolerance.<sup>33</sup> Further studies in this area and on the KOR mediated decrease of dopamine are also required in order to fully understand the addiction potential of this substance.

While concerns for the potential of abuse were once minimal because 1 kg of dried leaves yields only 3 to 6 human doses of salvinorin A, it was discovered that vaporizing and inhaling 200-500 micrograms had profound hallucinogenic effects.<sup>34</sup> Given that only small doses of this substance are necessary to achieve the desired effects, there is a higher potential for abuse. The extraction of salvinorin A from the plant is simple, and with care, approximately 1.5 grams of pure salvinorin A per kilogram of dried leaves (8kg of fresh leaves) can be isolated. This is enough for 2000 human doses.<sup>35</sup>

#### 4.2.5 Evidence of Extent of Actual Abuse of the Substance in Canada and Internationally

In Canada, the extent of actual abuse of *Salvia divinorum* and/or salvinorin A is relatively unknown. There is, however, some data regarding the prevalence of use of *Salvia divinorum* in Canada, despite the lack of legitimate uses for this plant. Questions about the use of *S. divinorum* were included in the 2009 Ontario Student Drug Use and Health Survey, the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey.

It is difficult to determine the extent of actual abuse of *S. divinorum* in Canada or elsewhere as there appear to be inconsistencies in the literature regarding risk aversion. For example, one author states: "Many who have used salvinorin A find the experience extremely unnerving, frightening and overly intense and most have no desire to repeat the experience."<sup>36</sup> However, another study suggested that this is not the experience of all recreational users of *S. divinorum*.<sup>37</sup>

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<sup>33</sup> Bucheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>34</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>35</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs*. 1994 Jul-Sep;26(3):277-83.

<sup>36</sup> Turner DM. *Salvinorin - The Psychedelic Essence of Salvia Divinorum*. Panther Press, San Francisco, CA 1996.

<sup>37</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62, Bucheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5, and Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs*. 1994 Jul-Sep;26(3):277-83.

Over eighty percent of users surveyed on a web-based questionnaire about their *S. divinorum* use said that they would probably or definitely use *S. divinorum* again.<sup>38</sup> Users have reported the negative effects of *S. divinorum* as: the short duration of action, lack of control over the experience, persisting negative effects (most often anxiety),<sup>39</sup> sweating, chills, increased diuresis, impaired vigilance,<sup>40</sup> and negative after-effects including tiredness, feeling head heavy, dizziness, physical exhaustion, and some degree of malaise or 'hangover' as they 'comedown' from the drug.<sup>41</sup>

The results from the 2009 Ontario Student Drug Use and Health Survey were published on November 18, 2009 and indicate that:

- Among all responding students in Ontario, 4.4% reported using *Salvia divinorum* at least once in the past year. In comparison, 58.2% indicated they had used alcohol, 25.6% indicated they had used cannabis and 5.0% indicated they had used hallucinogens other than LSD and PCP in the past year;
- Males (6.2%) were significantly more likely than females (2.3%) to report using *Salvia divinorum*;
- There is significant grade variation, with *Salvia divinorum* use most likely among 11<sup>th</sup> graders (8.6%) and 12<sup>th</sup> graders (8.4%); and
- There are significant regional variations, with students in Northern Ontario (9.2%) most likely to use *Salvia divinorum*.

The results of the 2008-2009 Youth Smoking Survey were published on May 31, 2010 and indicate that:

- 4.9% of students stated that they had used *S. divinorum* in the last twelve months. In comparison, 53.0% indicated they had used alcohol, 27.3% indicated they had used cannabis and 6.9% indicated they had used other hallucinogens in the last twelve months;
- 2.6% of students in Grades 7-9 and 7.0% of students in Grades 10-12 had used *S. divinorum* in the last twelve months; and

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<sup>38</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>39</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>40</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>41</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

- Males (6.6%) were more likely to have used *S. divinorum* in the past twelve months compared to females (3.2%).

The scope of the previously mentioned studies did not provide for any explanations regarding differences in usage between ages, genders and regions. In this regard, it is difficult to speculate on the causality of such differences.

The Canadian Alcohol and Drug Use Monitoring Survey specifically examined salvia for the first time in 2009. An estimated 1.6% of Canadians, aged 15 years and older, reported that they had used salvia in their lifetime, and 0.2% reported using it in the past-year. In comparison, the prevalence of past-year cannabis use among Canadians 15 years of age and older was 10.6%. 1.2% of respondents reported using cocaine or crack in the past 12 months, 0.9% had used ecstasy and 0.7% used illicit hallucinogens.

Health Canada's Drug Analysis Services (DAS) has identified salvinorin A in a number of samples seized by law enforcement, as shown in the following table. It is, however, difficult to determine how this data reflects the extent of actual abuse of salvinorin A in Canada.

**NUMBER OF SAMPLES FOUND TO CONTAIN SALVINORIN A**

Year	Count
2006	9
2007	8
2008	4
2009	20
2010 (as of May 7)	8

The National Forensic Laboratory Information System (NFLIS) and the System to Retrieve Information from Drug Evidence (STRIDE) in the United States are Drug Enforcement Agency (DEA) databases that collect scientifically verified data on analyzed samples in state and local forensic labs as well as samples from DEA labs. The following table shows the quantity of *S. divinorum* products that were seized from 2000 through to 2009.

**ANALYZED SALVIA DIVINORUM or SALVINORIN A SEIZURES**

(Number of Items/Exhibits)

Source	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009*
NFLIS-State/Local <sup>1</sup>	0	0	0	0	1	8	12	12	70	34
STRIDE <sup>2</sup>	0	0	1	1	1	0	0	0	N/A	N/A
<b>TOTAL</b>	0	0	1	1	2	8	12	12	70	34

Data Source: NFLIS & STRIDE, 2008 data queried 11/24/08, updated 06/10/2010

<sup>1</sup> NFLIS reported seizures of *Salvia divinorum* and/or salvinorin A

<sup>2</sup> STRIDE reported items of *Salvia divinorum*.

\* Includes only January – May data in 2009.

Once again, it is difficult to determine how this data can be used to reflect the actual extent of



abuse of *S. divinorum* and salvinorin A in the United States.

#### **4.2.6 Risk to Personal and Public Health and Safety**

The increase in both the number of enquiries from various municipalities and members of the public and the amount of media interest regarding the availability of *Salvia divinorum* in Canada may be an indication that the recreational use of *S. divinorum* as a hallucinogen is on the rise. However, there are no available statistics that indicate there has been a significant increase in *S. divinorum* use in the Canadian population.

The potential for harm to the user and/or other individuals is primarily related to the hallucinogenic properties of the substance. As this substance is typically smoked, there is no risk of infectious disease transmission as is the case when a drug is injected. Users may get up and walk around without apparent awareness of their movements, behaviour or surroundings, and distinction between self and surroundings is often lost. At doses greater than 1mg of salvinorin A, out of body experiences are frequent and loss of consciousness has been reported.<sup>42</sup> There is little information regarding the social behaviours of persons under the influence of *S. divinorum* products, and what risks their activities such as operating a motorized vehicle may pose to the general public. There is also very little data regarding the toxicity, teratogenicity or other long-term effects of *S. divinorum* use.<sup>43</sup>

As far as law enforcement is concerned, the Department has only received a limited number of communications indicating concern with respect to *S. divinorum*. The Royal Canadian Mounted Police (RCMP) has stated that while *S. divinorum* is readily available, it has not become a popular drug in Canada, probably due to its aversive effects such as anxiety and introversion.

A handful of case reports regarding the physiological and psychotropic effects of *S. divinorum* use have been published in the academic literature. An international case report described the perceptions of a 19 year-old man after inhaling *S. divinorum* smoke. The peak psychotropic effects, including prickling of the skin, fever-like hot flashes, muscular tremor, and depersonalization, were reached in less than five minutes after inhalation of an unknown amount of smoke from burning dried leaves.<sup>44</sup> Another report involved a 15-year-old male who presented to psychiatric emergency services with acute onset of paranoia, déjà vu, blunted affect, difficulties in thought processing and slowed speech after smoking *Salvia divinorum* over an unknown period of time. During his hospitalization all symptoms improved significantly except the feeling of déjà vu. Based on this case presentation, the author suggested that the feelings of déjà vu may be a long-term effect of *S. divinorum* use.<sup>45</sup> However, given that this is the only case report in which déjà vu was associated with the use of *S. divinorum*, more reports are needed to substantiate this finding.

In addition to the above-mentioned reports, in 2006, a case was reported in the U.S. in which a

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<sup>42</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>43</sup> Grundmann O, Phipps SM, Zadezensky I, Butterweck V. *Salvia divinorum* and Salvinorin A: An Update on Pharmacology and Analytical Methodology. *Planta Med* 2007 Jun;73:1039-1046.

<sup>45</sup> Singh S. (2007) Adolescent salvia substance abuse. *Addiction.* 102, 823-824.

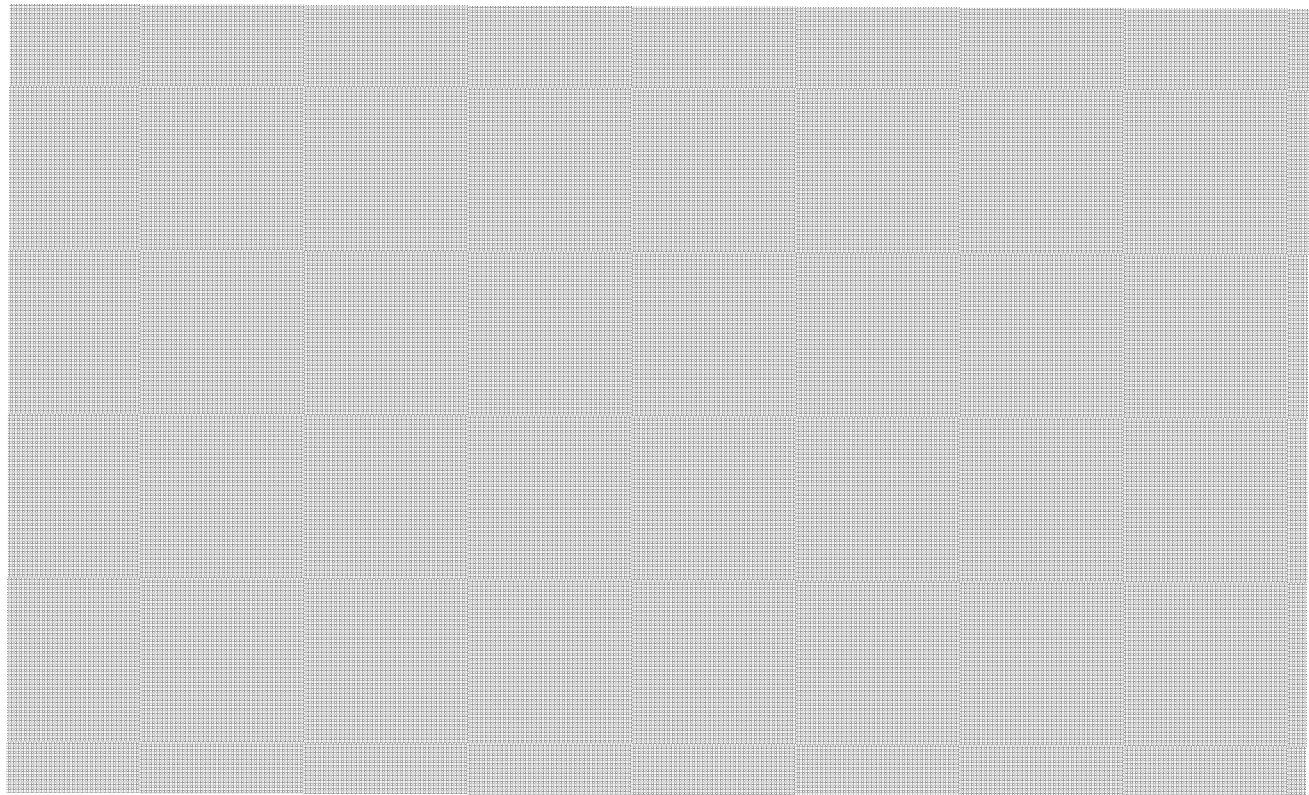
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s.21(1)(b)

17-year-old boy committed suicide after smoking *S. divinorum* for an unknown period of time.<sup>46</sup> It should be noted that alcohol and general depression were the main confounders in this case. After this case was reported, the state of Delaware passed a law which classified *S. divinorum* as a Schedule I controlled substance along with other hallucinogenic substances.

Like many drugs of abuse, users are often unaware of the potency and adulterants in the product they purchase. A study by Wolowich *et al.* (2006), showed that the salvinorin A content in five out of five *S. divinorum* products was falsely indicated on the label and 4 out of 5 products contained unidentified adulterants (i.e. vitamin E, caffeine).<sup>47</sup>

Health Canada has some information about the use and abuse of *S. divinorum* in Canada that indicate that *S. divinorum* may pose a risk to the health and safety of Canadians. There are several reports of domestic adverse reactions related to the use of *S. divinorum* that have been received through the Canada Vigilance database. However, this does not reflect true incidence due to under-reporting.

## 5. ASSESSMENT OF RISKS AND BENEFITS



## 6. IDENTIFICATION AND ANALYSIS OF OPTIONS



<sup>46</sup> <http://www.kvbc.com/Global/story.asp?S=4893692>

<sup>47</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

**Page(s) 001425 to\à 001426**

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est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**

s.21(1)(a)

s.21(1)(b)

## 7. CONSIDERATIONS

The KOR-mediated aversive and dysphoric effects of *Salvia divinorum* do not appear to be hampering its use as young adults have begun smoking the leaves and leaf extract recreationally.<sup>48</sup> It can be purchased through online botanical companies and other drug promotion sites and is often touted as a legal alternative to substances such as cannabis and mescaline.<sup>49</sup> Interestingly, after being widely available for over a decade, the drug does not appear to have had the same social impact as LSD or ecstasy.<sup>50</sup>

While there has been an increase over the past few years in the number of enquiries from various municipalities and members of the public regarding the availability of *Salvia divinorum* as a hallucinogen, there does not appear to be a significant increase in the reported use of this substance.

The NHPR are limited in their capacity to control the availability of *S. divinorum* in that *S. divinorum* products are often declared as incense and therefore cannot be considered unapproved natural health products. In addition, compliance and enforcement actions such as voluntary stop-sales, forfeiture, destruction, and administrative seizure, cannot be implemented unless the marketing of the product indicates that it is to be used for human consumption and can modify an organic function.

*Salvia divinorum* and salvinorin A meet the criteria for scheduling a substance under the CDSA. While neither the plant nor salvinorin A are scheduled under any of the UN Drug Control Conventions, a number of countries and American states have taken steps to control the distribution and use of these substances. *S. divinorum* and salvinorin A are pharmacologically similar to other substances included in Schedule III to the CDSA, such as LSD and psilocybin. There are also currently no legitimate therapeutic, commercial or industrial uses for *S. divinorum*.

<sup>48</sup> Hazelden Foundation, 2004. Drug Abuse Trends. June 2004. URL: [www.research.hazelden.org](http://www.research.hazelden.org).

<sup>49</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

<sup>50</sup> Munro, T. The Chemistry of *Salvia divinorum*. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

s.21(1)(a)

s.21(1)(b)

While the potential for physical dependence of *S. divinorum* appears to be low, there is a significant potential for its abuse as a 'legal' hallucinogen. There is very little information with regards to the long-term effects of *S. divinorum* use. There is also evidence of abuse, particularly by Canadian youth and adolescents, and potential for risk to public health and safety.

## 8. RECOMMENDATIONS

## 9. CONSULTATIONS

The Drug Analysis Services (DAS) was contacted in order to provide any data available regarding the identification of salvinorin A in samples submitted by law enforcement.

The Royal Canadian Mounted Police (RCMP) was contacted in order to establish their views with respect to *S. divinorum* use in Canada. The RCMP advised that *S. divinorum* is readily available and law enforcement agencies have no legal means to prevent its sale.

OCS has received a number of correspondences from Canada Border Services Agency (CBSA) officers concerning a lack of information regarding the status of *S. divinorum* and how the plant should be treated at the border. CBSA officers have also expressed concern regarding the plant's hallucinogenic properties. At present, only shipments of *S. divinorum* that are represented as health products that modify organic functions can be refused for import under the NHPR.

OCS brought *S. divinorum* and salvinorin A to the Controlled Substances Scheduling Working Group (CSS-WG) in August 2010 to discuss the possibility of regulatory control of these substances. The CSS-WG recommended that both *S. divinorum* and salvinorin A be included under Schedule III to the CDSA.

## 10. IMPLEMENTATION AND EVALUATION

**Page(s) 001429 to\à 001429**

**Is(Are) exempted pursuant to section(s)  
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**21(1)(a), 21(1)(b)**

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# Issue Analysis Summary

DRAFT

## Scheduling *Salvia Divinorum* and/or Salvinorin A under the CDSA

Regulatory Policy Division  
Office of Controlled Substances  
Controlled Substances and Tobacco and Directorate

October 22, 2010

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8. RECOMMENDATION(S)
9. CONSULTATIONS
10. IMPLEMENTATION AND EVALUATION

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### 1. APPROVALS

This Issue Analysis Summary is approved.

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Jocelyn Kula, A/Director  
Office of Controlled Substances  
Controlled Substances and Tobacco Directorate

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[DD/MM/2010]

### 2. ISSUE

Health Canada has received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *S. divinorum* and/or its main active ingredient salvinorin A, neither of which are currently regulated under the *Controlled Drugs and Substances Act* (CDSA). These requests are further to reports from scientific and media sources suggesting that *S. divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has also noted an

ongoing media interest regarding the availability of *S. divinorum* in Canada.

### 3. PURPOSE

To assess *Salvia divinorum* and/or salvinorin A against the criteria for the addition of a substance to one of the Schedules to the CDSA, and determine whether one or both substances should be regulated as controlled substances in Canada.

→ this suggests they are different "substances"?

### 4. CONTEXT

*Salvia divinorum* is a species of sage which belongs to the <sup>called</sup> mint family, and which is found in the form of dried leaves, extract and plant cuttings. Also known as "diviner's sage", the plant is known to induce illusions and hallucinations when chewed or smoked. Salvinorin A, the psychoactive ingredient in *S. divinorum* (also referred to chemically as a neoclerodane diterpene) is found primarily in the leaves, and to a lesser extent in the stem.<sup>1</sup>

*S. divinorum* is widely touted as a "legal" hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs among adolescents and young adults.<sup>2</sup> While very little is known about how and where *S. divinorum* is sold in Canada, it is suspected that it is mainly purchased over the Internet and/or bought at head shops or alternative life style stores, etc. *S. divinorum* cuttings are also available from a number of garden supply companies.

The use of *S. divinorum* as a psychotropic agent first came to Health Canada's attention in 2002. In 2004, Health Canada received four adverse drug reaction (ADR) reports associated with the use of *S. divinorum* as a hallucinogen, with three being considered non-serious (requiring no medical attention) and the fourth being considered serious (medical intervention was required). The serious ADR report involved the concomitant use of alcohol in a person diagnosed with Attention Deficit Disorder.

Further to the receipt of the aforementioned ADRs, the Marketed Health Products Directorate (MHPD) and the Natural Health Products Directorate (NHPD) of the Health Products and Food Branch (HPFB) prepared an issue analysis summary (IAS), which recommended that *S. divinorum* and its active ingredient salvinorin A be regulated as controlled substances. This recommendation was maintained when the IAS was updated in November 2006.

check in put initials in parentheses

Later, in December 2005, MHPD and NHPD prepared a Signal Assessment (SA) (updated in June 2007) that eventually led to the preparation of a Health Risk Assessment (HRA), which concluded that *S. divinorum* or salvinorin A-containing health products would constitute a Type

<sup>1</sup> U.S. Department of Justice Drug Enforcement Administration. 2002. Drugs and Chemicals of Concern: Salvia Divinorum (salvinorin A, divinorin A) URL:

[http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm) Nov 2008

<sup>2</sup> Dennehy CE, Tsurounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.



II Health Risk according to the Health Hazard Classification of the Recall Policy of the Health Products and Food Branch Inspectorate (HBFBI). Such a risk is defined as “a situation in which the use of, or exposure to, a product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote”.

Further to an Assistant Deputy Minister (ADM) discussion in April 2007, the Drug Strategy and Controlled Substances Directorate (DSCSD) organized a meeting with MHPD, NHPD and HPFBI to discuss *S. divinorum*. HPFBI was to determine appropriate compliance activities regarding *S. divinorum* and consult with the Canada Border Services Agency (CBSA) regarding the movement of products containing *S. divinorum* into and out of Canada.

On September 13, 2007, a further meeting between DSCSD, MHPD, NHPD and HPFBI led to the conclusion that DSCSD would conduct a scheduling assessment of *S. divinorum* in order to explore the possibility of scheduling this substance under the CDSA.

In September 2008, the Director Generals of DSCSD, MHPD, TPD and the HPFBI agreed that media lines and an “It’s Your Health” article on *S. divinorum* would be prepared.

#### **4.1 Relevant Legislative Frameworks in Canada**

##### **4.1.1 Food and Drug Regulations (under the Food and Drugs Act)**

The *Food and Drug Regulations* (F&DR) serve to ensure the safety, efficacy, and quality of health products offered for sale in Canada, including drugs and medical devices. Prior to being given market authorization, a manufacturer must present substantive scientific evidence that their product is safe, efficacious and of high quality. For drugs, Health Canada reviews this information carefully and, if the review is satisfactory, a Notice of Compliance (NOC) is issued and appropriate Drug Identification Numbers (DINs) are assigned.

A “drug” is defined under the F&DR as any substance or mixture of substances manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
- (b) restoration, correction or modification of organic functions in human beings or animals, or
- (c) disinfection in premises in which food is manufactured, prepared or kept;

As no products containing *S. divinorum* or its extracts have been reviewed and approved by Health Canada as of October 2010, it is illegal to market *S. divinorum* when it is represented as a drug.

#### 4.1.2 Natural Health Products Regulations (under the Food and Drugs Act)

The *Natural Health Products Regulations* (NHPR) aim to provide Canadians with ready access to natural health products (NHPs) that are safe, effective, and of high quality, while respecting freedom of choice and philosophical and cultural diversity. The NHPR require that all licensed products display a Natural Product Number (NPN), or, in the case of a homeopathic medicine, a Drug Identification Number - Homeopathic Medicine (DIN-HM), on their labels. These numbers are issued once a product is authorized for sale in Canada further to the submission of a product license application in which the applicant attests to all of the conditions set out in a natural health product monograph prepared and published by the Natural Health Products Directorate or submission of a product license application that provides sufficient evidence of quality, safety and efficacy that is assessed and approved by NHPD by the non-compendial route. The NHPR also require that all manufacturers, packagers, labelers, and importers be licensed which in turn requires the presence of procedures respecting distribution records, product recalls, product handling, storage and delivery, and all other aspects of Good Manufacturing Practices as set out in the NHPR.

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actual title?

The definition of an NHP under the NHPR has both a function and substance component. The function component refers to those substances that are manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
- (b) restoring or correcting organic functions in humans; or
- (c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

The substance component refers to the requirement that all of the medicinal ingredients of an NHP must be substances set out in Schedule 1 to the NHPR, which is a list of included substances. Included substances are those substances that are traditional or homeopathic medicines, and of which none of the ingredients are substances set out in Schedule 2, which is a list of excluded substances. Excluded substances include any substance listed on Schedules I to V of the CDSA. Section 2(2) of the NHPR excludes those substances (except homeopathic medicines) whose sale is required to be pursuant to a prescription as per Section C.01.043 of the F&DR. As per section 93(1)(b)(vi) of the NHPR, every natural health product must be labeled with its authorized recommended use or purpose. In the case of *S. divinorum*, it is generally marketed for its hallucinogenic properties which are considered a modification of an organic function. Therefore products that contain *S. divinorum* and are manufactured, sold or represented for use as a hallucinogen meet the definition of an NHP.

As of October 2010, no products containing *S. divinorum* have been reviewed and approved by

for such products (2)

Health Canada and no NPNs or DIN-HMs have been issued. Therefore sales of *S. divinorum* are illegal under the NHPR if it is represented for use as a hallucinogen or if other health claims such as with regard to modifying organic functions are made.  
regarding the modification of

#### 4.1.3 Controlled Drugs and Substances Act and its Regulations

The CDSA provides a legislative framework for the control of substances that can alter mental processes and that may produce harm to the health of an individual or to society when diverted or misused. Except as authorized under its regulations, activities such as possession, possession for the purposes of trafficking, trafficking, importation, exportation, possession for the purposes of exportation and production of controlled substances are prohibited under the CDSA.

The substances regulated under the CDSA are grouped into ~~eight~~ Schedules, and each Schedule is associated with particular offences and penalties as described in Part I of the CDSA.

In determining whether a substance should be regulated as a controlled substance, and into which Schedule of the CDSA it should be placed, Health Canada considers the following factors:  
a number of → including:

- International requirements and trends in ~~the~~ control and/or scheduling;
- Chemical and/or pharmacological similarity to substances listed in the Schedules to the CDSA;
- Legitimate use of the substance, including therapeutic, scientific, industrial or commercial uses;
- Potential for abuse and/or addiction liability;
- Evidence of extent of actual abuse of the substance in Canada and internationally; and
- Risk to personal and public health and safety.

#### 4.2 **Assessment of *Salvia Divinorum* for Scheduling Purposes**

##### 4.2.1 International Requirements and Trends in the Control and/or Scheduling

At the present time, neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and therefore do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

##### ***Australia***

In June 2002, Australia became the first country to prohibit the sale, supply, possession and use of *S. divinorum* and salvinorin A. Both *S. divinorum* and salvinorin A are listed in Schedule 9 of Australia's *Standard for the Uniform Scheduling of Drugs and Poisons* on the basis of "high potential for abuse and risk to public health and safety."<sup>3</sup> Schedule 9 is Australia's most restrictive drug schedule, and includes "substances which may be abused or misused, the

<sup>3</sup> <http://www.tga.gov.au/ndpsc/record/rr200111.pdf>

manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities.”<sup>4</sup>

### **Belgium**

A decree was passed in Belgium on October 22, 2006 which added *S. divinorum* to the list of controlled substances. This list includes substances such as psilocybin mushrooms, khat and peyote cactus.<sup>5</sup>

### **Denmark**

In 2003, Denmark added *S. divinorum* and salvinorin A to their list of “category B” controlled substances, a category which also includes psilocybin mushrooms, cocaine, amphetamine, and several others substances that are only legal for medicinal and scientific purposes. Illegal possession carries a penalty of up to two years in prison.

### **Germany**

*S. divinorum* (plant and plant parts) was added to Appendix I of the *Narcotics Act* in Germany on March 1, 2008, making it illegal to produce, traffic, or possess. The law does not specifically mention salvinorin A.

### **Italy**

On June 25, 2004, the Italian Ministry of Health issued an ordinance prohibiting the sale of *S. divinorum* and its active constituent salvinorin A. On January 11, 2005, the Ministry of Health made possession of *S. divinorum* and salvinorin A illegal by placing them in “*Tabella I*” of the *Tabella Sostanze Stupefacenti o Psicotrope*.

### **Japan**

On November 9, 2006, the Japanese government added a group of thirty-three drugs to its list of controlled substances, including salvinorin A. The drugs are banned under a revised pharmaceutical law, under which persons involved in their illegal import, production, and sale, i.e. beyond medical treatment or research purposes, will be subject to up to five years imprisonment or a fine of up to five million yen.

### **Spain**

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<sup>4</sup> [http://www.cognitiveliberty.org/news/salvia\\_australia.htm](http://www.cognitiveliberty.org/news/salvia_australia.htm)

<sup>5</sup> <http://eidd.emcdda.europa.eu/html.cfm/index5176EN.html?pluginMethod=eidd.shownewsdetails&id=20/12/2006BELGIUM:%20New%20substances%20controlled%20include%20mCPP%20and%20khat>

On January 28, 2004, the Spanish Ministry of Health and Consumption issued an order prohibiting the sale of *S. divinorum*. The regulation went into effect on May 6, 2004 and only prohibits activities related to commerce. Possession and/or use are not considered to be criminal offences.

### **Other Countries**

*Salvia divinorum* is illegal to possess or sell in Croatia, Latvia, Lithuania, Poland, Romania, South Korea and Sweden. In Russia it is illegal to grow or sell *S. divinorum*, but it is legal to possess it. In Estonia, Finland, Iceland and Norway, *S. divinorum* is treated as a medicinal herb and it is illegal to import it without a relevant prescription from a doctor.

### **United States of America**

*S. divinorum* and salvinorin A are not included in the Schedules to the United States *Controlled Substances Act* although both *S. divinorum* and salvinorin A have been added to a list of chemicals "of concern" which has no legal implications. According to the National Institute for Drug Abuse, the Drug Enforcement Agency is considering classifying salvia as a Schedule I drug. This Schedule includes substances such as LSD and marijuana.

In addition, some individual states have implemented laws restricting its use, sale and/or distribution. As of July 2010, a number of states have enacted legislation placing regulatory controls on *S. divinorum* and/or salvinorin A including Delaware, Georgia, Florida, Hawaii, Illinois, Kansas, Kentucky, Maryland, Mississippi, Missouri, Nebraska, North Dakota, Ohio, Oklahoma, South Dakota, Wisconsin, Virginia, California, Louisiana, Maine, North Carolina, and Tennessee. More details regarding the regulation of *S. divinorum* in these last five states are provided below.

by way of example ...

#### **California**

As of January 1, 2009, the sale or distribution of *S. divinorum* or salvinorin A, or any substance or material containing *S. divinorum* or salvinorin A, to any person under 18 years of age is a misdemeanor punishable by imprisonment in a county jail for not more than six months, a fine of no more than \$1,000, or both.

#### **Louisiana**

In 2005, Louisiana passed a bill which prohibits the possession, production, manufacture and distribution of a material, compound, mixture, or preparation intended for human consumption and that contains a hallucinogenic plant. A "hallucinogenic plant" is defined as "any part or portion" of a plant on a list of forty plants, which includes *S. divinorum*.

#### **Maine**

/ Q: Any particular reason we focus on those 5 five.

In Maine, *S. divinorum* and salvinorin A are regulated in the same way as tobacco products; adults eighteen years of age or over can legally purchase and use the material, but selling or providing *S. divinorum* or salvinorin A to anyone under the age of eighteen is a criminal offence. Possession by a minor is a civil violation, punishable by a fine, community service, or both.

### ***North Carolina***

On December 1, 2009, the North Carolina State Legislature brought a new law into force which made *Salvia divinorum* and salvinorin A illegal. The only legal *S. divinorum* activities are the growing for aesthetic, landscaping, or decorative purposes or university-affiliated medical or pharmacological research.

### ***Tennessee***

On July 1, 2006, Tennessee classified the deliberate production, manufacture, distribution, or possession of the active chemical ingredient in the hallucinogenic plant *S. divinorum* as a Class A misdemeanor. It is not, however, a criminal offence to possess, plant, cultivate, grow, or harvest *S. divinorum* for aesthetic, landscaping, or decorative purposes. The law also does not apply to any dosage that is legally obtainable from a retail establishment without a prescription when (and if) it is recognized by the Food and Drug Administration as a homeopathic drug.

#### **4.2.2 Chemical and/or Pharmacological Similarity to Substances Listed in the Schedules to the CDSA**

The psychoactive ingredient in *Salvia divinorum* is the neoclerodane diterpene salvinorin A.<sup>6</sup> Other plants which contain psychotropic terpenoids are *Artemisia absinthium* (wormwood) and *Cannabis sativa*.<sup>7</sup>

Unlike all other hallucinogens, salvinorin A is structurally distinct and does not interact with the serotonin-2A receptor or any other molecular target of classical hallucinogens.<sup>8</sup> Instead, the available research suggests the psychotropic effects of salvinorin A are mediated by its agonistic actions at the  $\kappa$ -opioid (KOR) receptor.<sup>9</sup> Its mechanism of action is therefore unique.<sup>10</sup>

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<sup>6</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage *Salvia divinorum*. *Life Sci.* 2005 Dec 22;78(5):527-31.

<sup>7</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.

<sup>8</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.

<sup>9</sup> Roth BL, Baner K, Westkaemper R, Siebert D, Rice KC, Steinberg S, Ernsberger P, Rothman RB. Salvinorin A: a potent naturally occurring nonnitrogenous kappa opioid selective agonist. *Proc Natl Acad Sci U S A.* 2002 Sep 3;99(18):11934-9.

The psychoactive effects of *S. divinorum* vary in onset and duration and include the sensation of becoming an object, visions of various two-dimensional surfaces, films and membranes, revisiting places of the past (particularly childhood), perceived loss of the body and/or identity, various sensations of motion (being pulled or twisted by a force of some kind), uncontrollable hysterical laughter, and overlapping realities (perceptions of being in more than one place).<sup>11</sup> Laughter, happiness, sense of well-being and dissociative effects were deemed the most positive aspects of *S. divinorum* by users, second only to the "trip" that the drug elicits.<sup>12</sup> Depersonalization, speaking gibberish, widening of consciousness and subjective illusions of rapid movement, flying or hovering have also been reported.<sup>13</sup>

The psychotomimetic effects of *S. divinorum* closely resemble schizoid symptoms induced by lysergic acid diethylamide (LSD) or phencyclidine (PCP).<sup>14</sup> Yet, it is said to have only weak influence on the prevailing mood of the user which differentiates it from other hallucinogens such as LSD and psilocybin.<sup>15</sup> Its strong dissociative effects are often compared to those of ketamine.<sup>16</sup> Users have reported that the psychedelic effects of *S. divinorum* were most similar to those caused by psilocybin mushrooms.<sup>17</sup> However, users familiar with the effects of other hallucinogens agree that despite certain similarities to classical hallucinogens, the visions and overall experience are quite unique.<sup>18</sup>

*S. divinorum* causes an unusually high degree of sedation, weakness and fatigue, while the increased de-realization is not commonly reported for classical psychedelics.<sup>19</sup> The combination

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<sup>10</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>11</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>12</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>13</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5 and Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>14</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5.

<sup>15</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>16</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five Salvia divinorum herbal products. Pharmacotherapy. 2006 Sep;26(9):1268-72.

<sup>17</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>18</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6 and González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>19</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

of these effects seems to correlate with that of other KOR agonists such as pentazocine.<sup>20</sup>

The onset and intensity of the effects of *Salvia divinorum* appear to be related to the route of administration. Traditional uses generally produce mild effects because the leaves are rolled and chewed or crushed and prepared as a foamy infusion whereby the salvinorin A is degraded in the gastrointestinal system before being absorbed into the bloodstream. Hence, the level of effect relates quite closely to the length of time the material spends in the mouth, with the onset of effect generally taking 5-10 minutes. The effects build over the next hour and last for another hour before they begin to subside.<sup>21</sup>

Routes of administration that avoid the hepatic first-pass effect (i.e. inhalation, intravenous, intramuscular and sublingual use) are the quickest and most intense.<sup>22</sup> Salvinorin A can be isolated from the plant to make a powder which can be vaporized and inhaled. The onset of effects felt from vaporizing salvinorin A powder occurs in about 30 seconds and effects last for about 5-10 minutes and then subside over the next 30 minutes.<sup>23</sup>

Smoking is by far the most popular method of administration<sup>24</sup> and this is accomplished by smoking the dried leaves or a concentrated extract using a pipe or bong. Dried leaves may also be fortified with a concentrated extract of salvinorin A. A concentrated extract can also be used sublingually. Neither *S. divinorum* nor salvinorin A can be injected because the powder is insoluble in water.<sup>25</sup>

#### 4.2.3 Legitimate Use of the Substance, including Therapeutic, Scientific, Industrial or Commercial Uses

*Salvia divinorum* has traditionally been used for spiritual and medicinal purposes by the Mazatec Indians in Oaxaca, Mexico,<sup>26</sup> where an infusion of the leaves or the leaves themselves are ingested to treat gastrointestinal problems, headaches, rheumatism, anemia and swelling of the

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<sup>20</sup> Arasteh K, Poudevida S, Farre M, Roset PN, Cami J. Response patterns of the Spanish version of the 49-item short form of the Addiction Research Center Inventory after the use of sedatives, stimulants, and opioids. *Drug Alcohol Depend.* 1999 Jun 1;55(1-2):117-25.

<sup>21</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>22</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.

<sup>23</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>24</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62 and Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>25</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs.* 1994 Jul-Sep;26(3):277-83.

<sup>26</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.



stomach.<sup>27</sup> Its main use today is, however, for its psychedelic properties in the aid of producing “mystical” or hallucinogenic experiences as part of spiritual rituals.<sup>28</sup>

Although selective kappa receptor agonists have been shown to produce analgesic effects, adverse effects such as psychotomimesis, dysphoria and diuresis have been observed in studies investigating their therapeutic use.<sup>29</sup> In addition, while it has been speculated that KOR agonists may be useful in the treatment of certain psychiatric disorders including Alzheimer’s disease, schizophrenia, dementia and bipolar disorder,<sup>30</sup> much more research is needed in order to substantiate these hypotheses. Similarly, another study has suggested that chemical analogues of salvinorin A may be a useful treatment for those suffering from addiction to other substances.<sup>31</sup> That said there are presently no recognized medical uses for *S. divinorum* in Canada.

Similarly, there are no known industrial or commercial uses for *S. divinorum* in Canada. Most websites offering *S. divinorum* cuttings and seeds for sale appear to do so in the context of growing the plant for “recreational” purposes, rather than out of horticultural interest or for its esthetic appeal. *S. divinorum* is also marketed as incense. However, there is no evidence that *S. divinorum* has any fragrant properties that would legitimize such a use. Therefore it is believed that the marketing of this plant as an incense is a recent invention to avoid compliance and enforcement actions by Health Canada.

#### 4.2.4 Potential for Abuse and/or Addiction Liability

Salvinorin A is a potent, selective agonist of the  $\kappa$ -opioid receptor (KOR), and in contrast to the euphoria produced by  $\mu$ -opioid receptor (MOR) agonists such as morphine, KOR agonists are negatively reinforcing and aversive. In addition, KOR agonists have analgesic properties but are not associated with respiratory depression like MOR agonists. Finally, while MOR agonists increase the release of dopamine, the activation of KOR decreases dopamine release in the nucleus accumbens.<sup>32</sup> In the case of MOR agonists, the increase of dopamine acts as a positive reinforcer. This action motivates the user to use the drug again, which could lead to drug abuse and/or addiction. For KOR agonists, this is not the case.

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<sup>27</sup> Munro, T. The Chemistry of *Salvia divinorum*. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

<sup>28</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage *Salvia divinorum*. *Life Sci.* 2005 Dec 22;78(5):527-31.

<sup>29</sup> Barker RL, Fawcett J, Barkin SJ. 2002. Chronic pain management with a focus on the role of newer antidepressants and centrally acting agents. In: *Pain Management: A Practical Guide for Clinicians*, 6th edition, Weiner RS ed. CRC Press, Boca Raton, FL. pp. 415-34 and Tidgewell et al., 2004. A facile method for the preparation of deuterium labelled salvinorin A: *Biorganic & Medicinal Chemistry Letters*, 14: 5099-5102.

<sup>30</sup> Sheffler DJ & Roth BL. Salvinorin A: the ‘magic mint’ hallucinogen finds a molecular target in the kappa opioid receptor. *Trends Pharmacol Sci.* 2003 Mar;24(3):107-109.

<sup>31</sup> Prisinzano TE. Natural products as tools for neuroscience: discovery and development of novel agents to treat drug abuse. *J Nat Prod.* 2009 Mar 27;72(3):581-7.

<sup>32</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman’s The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.

The aversive effects of KOR agonists suggest that the risk of addiction to *S. divinorum* is negligible. However, very few controlled scientific studies of the physical and psychotropic effects of *S. divinorum* on humans have been carried out. Therefore, it is difficult to predict with certainty its potential for addiction and abuse. In studies that have been conducted, there is conflicting information around the addiction liability of *S. divinorum* in both animals and humans. Some users have noted that they require increasing doses of salvinorin A in order to achieve the desired effect and the stimulated cerebral KOR may act as a mechanism of tolerance.<sup>33</sup> Further studies in this area and on the KOR mediated decrease of dopamine are also required in order to fully understand the addiction potential of this substance.

While concerns for the potential of abuse were once minimal because 1 kg of dried leaves yields only 3 to 6 human doses of salvinorin A, it was discovered that vaporizing and inhaling 200-500 micrograms had profound hallucinogenic effects.<sup>34</sup> Given that only small doses of this substance are necessary to achieve the desired effects, there is a higher potential for abuse. The extraction of salvinorin A from the plant is simple, and with care, approximately 1.5 grams of pure salvinorin A per kilogram of dried leaves (8kg of fresh leaves) can be isolated. This is enough for 2000 human doses.<sup>35</sup>

#### 4.2.5 Evidence of Extent of Actual Abuse of the Substance in Canada and Internationally

In Canada, the extent of actual abuse of *Salvia divinorum* and/or salvinorin A is relatively unknown. There is, however, some data regarding the prevalence of use of *Salvia divinorum* in Canada, despite the lack of legitimate uses for this plant. Questions about the use of *S. divinorum* were included in the 2009 Ontario Student Drug Use and Health Survey, the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey.

It is difficult to determine the extent of actual abuse of *S. divinorum* in Canada or elsewhere as there appear to be inconsistencies in the literature regarding risk aversion. For example, one author states: "Many who have used salvinorin A find the experience extremely unnerving, frightening and overly intense and most have no desire to repeat the experience."<sup>36</sup> However, another study suggested that this is not the experience of all recreational users of *S. divinorum*.<sup>37</sup>

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<sup>33</sup> Bucheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>34</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>35</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs*. 1994 Jul-Sep;26(3):277-83.

<sup>36</sup> Turner DM. *Salvinorin - The Psychedelic Essence of Salvia Divinorum*. Panther Press, San Francisco, CA 1996.

<sup>37</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62, Bucheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5, and Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs*. 1994 Jul-Sep;26(3):277-83.

Over eighty percent of users surveyed on a web-based questionnaire about their *S. divinorum* use said that they would probably or definitely use *S. divinorum* again.<sup>38</sup> Users have reported the negative effects of *S. divinorum* as: the short duration of action, lack of control over the experience, persisting negative effects (most often anxiety),<sup>39</sup> sweating, chills, increased diuresis, impaired vigilance,<sup>40</sup> and negative after-effects including tiredness, feeling head heavy, dizziness, physical exhaustion, and some degree of malaise or 'hangover' as they 'comedown' from the drug.<sup>41</sup>

The results from the 2009 Ontario Student Drug Use and Health Survey were published on November 18, 2009 and indicate that:

- Among all responding students in Ontario, 4.4% reported using *Salvia divinorum* at least once in the past year. In comparison, 58.2% indicated they had used alcohol, 25.6% indicated they had used cannabis and 5.0% indicated they had used hallucinogens other than LSD and PCP in the past year;
- Males (6.2%) were significantly more likely than females (2.3%) to report using *Salvia divinorum*;
- There is significant grade variation, with *Salvia divinorum* use most likely among 11<sup>th</sup> graders (8.6%) and 12<sup>th</sup> graders (8.4%); and
- There are significant regional variations, with students in Northern Ontario (9.2%) most likely to use *Salvia divinorum*.

The results of the 2008-2009 Youth Smoking Survey were published on May 31, 2010 and indicate that:

- 4.9% of students stated that they had used *S. divinorum* in the last twelve months. In comparison, 53.0% indicated they had used alcohol, 27.3% indicated they had used cannabis and 6.9% indicated they had used other hallucinogens in the last twelve months;
- 2.6% of students in Grades 7-9 and 7.0% of students in Grades 10-12 had used *S. divinorum* in the last twelve months; and

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<sup>38</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>39</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>40</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>41</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

- Males (6.6%) were more likely to have used *S. divinorum* in the past twelve months compared to females (3.2%).

The scope of the previously mentioned studies did not provide for any explanations regarding differences in usage between ages, genders and regions. In this regard, it is difficult to speculate on the causality of such differences.

The Canadian Alcohol and Drug Use Monitoring Survey specifically examined salvia for the first time in 2009. An estimated 1.6% of Canadians, aged 15 years and older, reported that they had used salvia in their lifetime, and 0.2% reported using it in the past-year. In comparison, the prevalence of past-year cannabis use among Canadians 15 years of age and older was 10.6%. 1.2% of respondents reported using cocaine or crack in the past 12 months, 0.9% had used ecstasy and 0.7% used illicit hallucinogens.

Health Canada's Drug Analysis Services (DAS) has identified salvinorin A in a number of samples seized by law enforcement, as shown in the following table. It is, however, difficult to determine how this data reflects the extent of actual abuse of salvinorin A in Canada.

**NUMBER OF SAMPLES FOUND TO CONTAIN SALVINORIN A**

Year	Count
2006	9
2007	8
2008	4
2009	20
2010 (as of May 7)	8

The National Forensic Laboratory Information System (NFLIS) and the System to Retrieve Information from Drug Evidence (STRIDE) in the United States are Drug Enforcement Agency (DEA) databases that collect scientifically verified data on analyzed samples in state and local forensic labs as well as samples from DEA labs. The following table shows the quantity of *S. divinorum* products that were seized from 2000 through to 2009.

**ANALYZED SALVIA DIVINORUM or SALVINORIN A SEIZURES**

(Number of Items/Exhibits)

Source	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009*
NFLIS-State/Local <sup>1</sup>	0	0	0	0	1	8	12	12	70	34
STRIDE <sup>2</sup>	0	0	1	1	1	0	0	0	N/A	N/A
<b>TOTAL</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>1</b>	<b>2</b>	<b>8</b>	<b>12</b>	<b>12</b>	<b>70</b>	<b>34</b>

Data Source: NFLIS & STRIDE, 2008 data queried 11/24/08, updated 06/10/2010

<sup>1</sup> NFLIS reported seizures of *Salvia divinorum* and/or salvinorin A

<sup>2</sup> STRIDE reported items of *Salvia divinorum*.

\* Includes only January – May data in 2009.

Once again, it is difficult to determine how this data can be used to reflect the actual extent of

abuse of *S. divinorum* and salvinorin A in the United States.

#### 4.2.6 Risk to Personal and Public Health and Safety

The increase in both the number of enquiries from various municipalities and members of the public and the amount of media interest regarding the availability of *Salvia divinorum* in Canada may be an indication that the recreational use of *S. divinorum* as a hallucinogen is on the rise. However, there are no available statistics that indicate there has been a significant increase in *S. divinorum* use in the Canadian population.

The potential for harm to the user and/or other individuals is primarily related to the hallucinogenic properties of the substance. As this substance is typically smoked, there is no risk of infectious disease transmission as is the case when a drug is injected. Users may get up and walk around without apparent awareness of their movements, behaviour or surroundings, and distinction between self and surroundings is often lost. At doses greater than 1mg of salvinorin A, out of body experiences are frequent and loss of consciousness has been reported.<sup>42</sup> There is little information regarding the social behaviours of persons under the influence of *S. divinorum* products, and what risks their activities such as operating a motorized vehicle may pose to the general public. There is also very little data regarding the toxicity, teratogenicity or other long-term effects of *S. divinorum* use.<sup>43</sup>

As far as law enforcement is concerned, the Department has only received a limited number of communications indicating concern with respect to *S. divinorum*. The Royal Canadian Mounted Police (RCMP) has stated that while *S. divinorum* is readily available, it has not become a popular drug in Canada, probably due to its aversive effects such as anxiety and introversion.

A handful of case reports regarding the physiological and psychotropic effects of *S. divinorum* use have been published in the academic literature. An international case report described the perceptions of a 19 year-old man after inhaling *S. divinorum* smoke. The peak psychotropic effects, including prickling of the skin, fever-like hot flashes, muscular tremor, and depersonalization, were reached in less than five minutes after inhalation of an unknown amount of smoke from burning dried leaves.<sup>44</sup> Another report involved a 15-year-old male who presented to psychiatric emergency services with acute onset of paranoia, déjà vu, blunted affect, difficulties in thought processing and slowed speech after smoking *Salvia divinorum* over an unknown period of time. During his hospitalization all symptoms improved significantly except the feeling of déjà vu. Based on this case presentation, the author suggested that the feelings of déjà vu may be a long-term effect of *S. divinorum* use.<sup>45</sup> However, given that this is the only case report in which déjà vu was associated with the use of *S. divinorum*, more reports are needed to substantiate this finding.

In addition to the above-mentioned reports, in 2006, a case was reported in the U.S. in which a

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<sup>42</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>43</sup> Grundmann O, Phipps SM, Zadezensky I, Butterweck V. *Salvia divinorum* and Salvinorin A: An Update on Pharmacology and Analytical Methodology. *Planta Med* 2007 Jun;73:1039-1046.

<sup>45</sup> Singh S. (2007) Adolescent salvia substance abuse. *Addiction.* 102, 823-824.

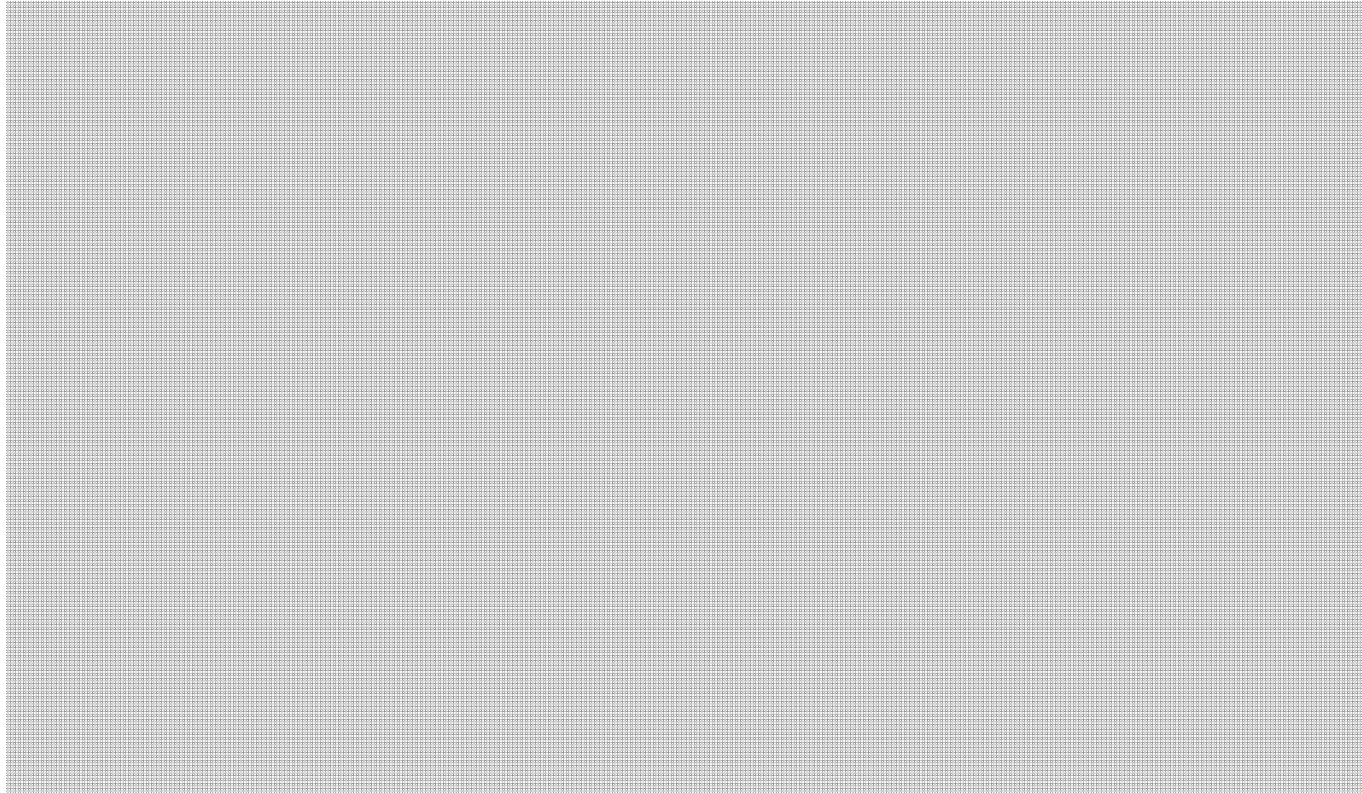
17-year-old boy committed suicide after smoking *S. divinorum* for an unknown period of time.<sup>46</sup> It should be noted that alcohol and general depression were the main confounders in this case. After this case was reported, the state of Delaware passed a law which classified *S. divinorum* as a Schedule I controlled substance along with other hallucinogenic substances.

Like many drugs of abuse, users are often unaware of the potency and adulterants in the product they purchase. A study by Wolowich *et al.* (2006), showed that the salvinorin A content in five out of five *S. divinorum* products was falsely indicated on the label and 4 out of 5 products contained unidentified adulterants (i.e. vitamin E, caffeine).<sup>47</sup>

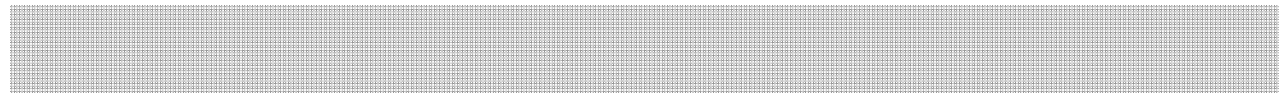
specific?

Health Canada has some information about the use and abuse of *S. divinorum* in Canada that indicate that *S. divinorum* may pose a risk to the health and safety of Canadians. There are several reports of domestic adverse reactions related to the use of *S. divinorum* that have been received through the Canada Vigilance database. However, this does not reflect true incidence due to under-reporting.

## 5. ASSESSMENT OF RISKS AND BENEFITS



## 6. IDENTIFICATION AND ANALYSIS OF OPTIONS



<sup>46</sup> <http://www.kvbc.com/Global/story.asp?S=4893692>

<sup>47</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

**Page(s) 001446 to\à 001447**

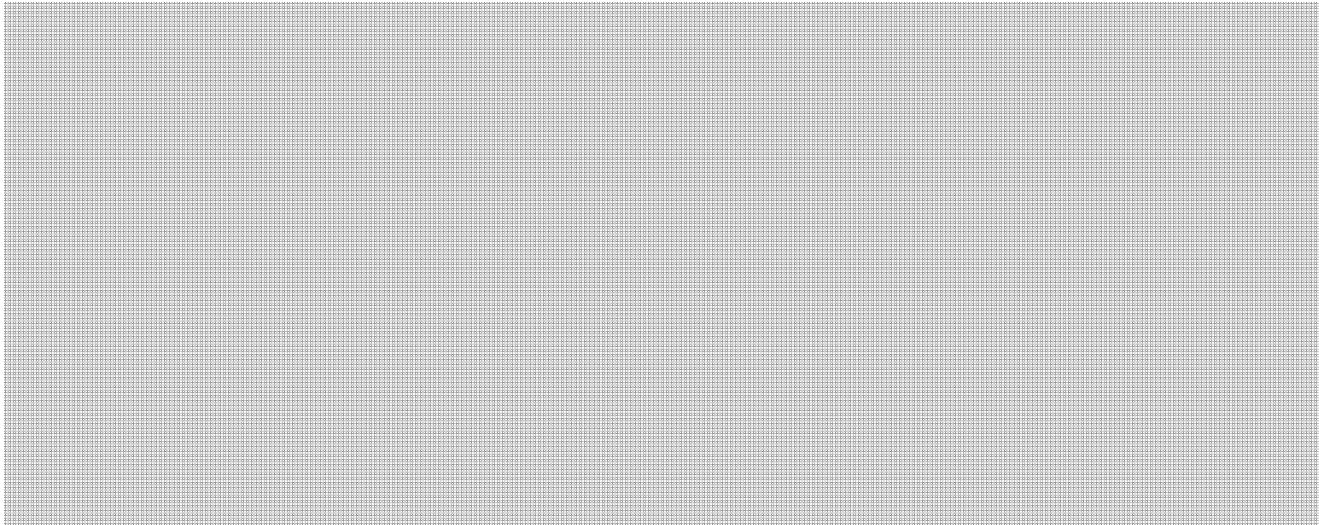
**Is(Are) exempted pursuant to section(s)  
est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**

s.21(1)(a)

s.21(1)(b)



## 7. CONSIDERATIONS

*Dature r*  
*Fin*  
The KOR-mediated aversive and dysphoric effects of *Salvia divinorum* do not appear to be hampering its use as young adults have begun smoking the leaves and leaf extract recreationally.<sup>48</sup> It can be purchased through online botanical companies and other drug promotion sites and is often touted as a legal alternative to substances such as cannabis and mescaline.<sup>49</sup> Interestingly, after being widely available for over a decade, the drug does not appear to have had the same social impact as LSD or ecstasy.<sup>50</sup>

While there has been an increase over the past few years in the number of enquiries from various municipalities and members of the public regarding the availability of *Salvia divinorum* as a hallucinogen, there does not appear to be a significant increase in the reported use of this substance.

The NHPR are limited in their capacity to control the availability of *S. divinorum* in that *S. divinorum* products are often declared as incense and therefore cannot be considered unapproved natural health products. In addition, compliance and enforcement actions such as voluntary stop-sales, forfeiture, destruction, and administrative seizure, cannot be implemented unless the marketing of the product indicates that it is to be used for human consumption and can modify an organic function.

*Salvia divinorum* and salvinorin A meet the criteria for scheduling a substance under the CDSA. While neither the plant nor salvinorin A are scheduled under any of the UN Drug Control Conventions, a number of countries and American states have taken steps to control the distribution and use of these substances. *S. divinorum* and salvinorin A are pharmacologically similar to other substances included in Schedule III to the CDSA, such as LSD and psilocybin. There are also currently no legitimate therapeutic, commercial or industrial uses for *S. divinorum*.

<sup>48</sup> Hazelden Foundation, 2004. Drug Abuse Trends. June 2004. URL: [www.research.hazelden.org](http://www.research.hazelden.org).

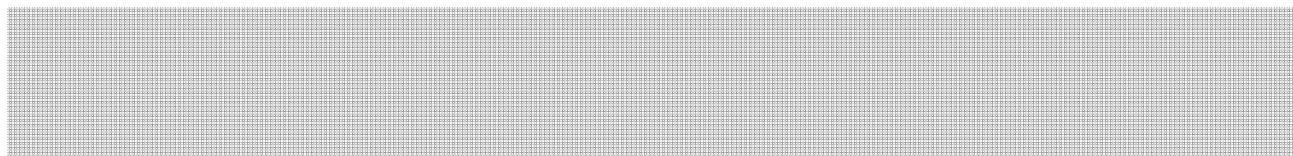
<sup>49</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

<sup>50</sup> Munro, T. The Chemistry of *Salvia divinorum*. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.



While the potential for physical dependence of *S. divinorum* appears to be low, there is a significant potential for its abuse as a 'legal' hallucinogen. There is very little information with regards to the long-term effects of *S. divinorum* use. There is also evidence of abuse, particularly by Canadian youth and adolescents, and potential for risk to public health and safety.

## 8. RECOMMENDATIONS



## 9. CONSULTATIONS

The Drug Analysis Services (DAS) was contacted in order to provide any data available regarding the identification of salvinorin A in samples submitted by law enforcement.

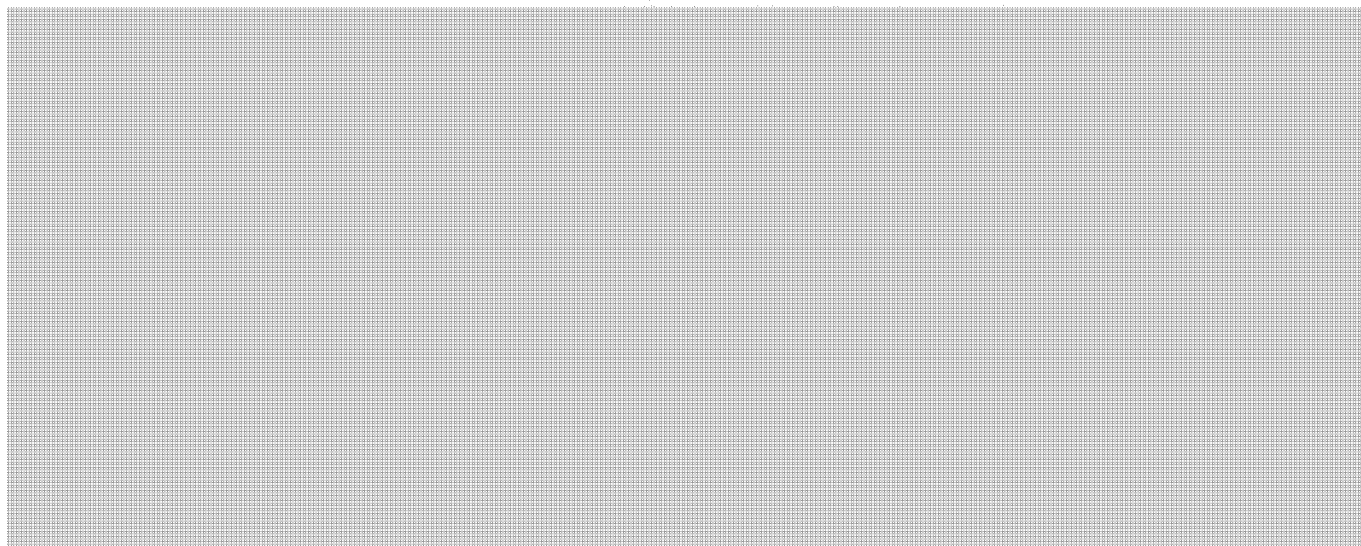
The Royal Canadian Mounted Police (RCMP) was contacted in order to establish their views with respect to *S. divinorum* use in Canada. The RCMP advised that *S. divinorum* is readily available and law enforcement agencies have no legal means to prevent its sale.

OCS has received a number of correspondences from Canada Border Services Agency (CBSA) officers concerning a lack of information regarding the status of *S. divinorum* and how the plant should be treated at the border. CBSA officers have also expressed concern regarding the plant's hallucinogenic properties. At present, only shipments of *S. divinorum* that are represented as health products that modify organic functions can be refused for import under the NHPR.

OCS brought *S. divinorum* and salvinorin A to the Controlled Substances Scheduling Working Group (CSS-WG) in August 2010 to discuss the possibility of regulatory control of these substances. The CSS-WG recommended that both *S. divinorum* and salvinorin A be included under Schedule III to the CDSA.

?  
← August?  
new section?

## 10. IMPLEMENTATION AND EVALUATION



**Page(s) 001450 to\à 001450**

**Is(Are) exempted pursuant to section(s)  
est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**

**Page(s) 001451 to\à 001451**

**Is(Are) exempted pursuant to section(s)  
est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**



Re: Salvia

Suzanne Desjardins to: Tiana Branch

2010-10-22 04:02 PM

Cc: Tiffany Thornton, Allison Vadneau, Denis Arsenault, Stephanie Chandler

deadline is short, but let's try it.

thanks

Suzanne

Tiana Branch

Bonjour Suzanne, We understand your concern...

2010-10-22 03:51:04 PM

From: Tiana Branch/HC-SC/GC/CA  
To: Suzanne Desjardins/HC-SC/GC/CA@HWC  
Cc: Tiffany Thornton/HC-SC/GC/CA@HWC, Allison Vadneau/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2010-10-22 03:51 PM  
Subject: Re: Salvia

Bonjour Suzanne,

We understand your concern and propose that an updated draft IAS be provided to CSS-WG members by close of business on Monday in preparation for discussion at the WG meeting. All major changes will be highlighted in this draft, in order to facilitate easier review.

We would then request that WG members provide comments by Thursday at noon. This plan would enable us to keep our commitment to provide Jocelyn with a draft IAS by Friday October 29th. Do you concur with this proposal?

Tiana

Suzanne Desjardins Hi, Since the changes to the IAS will be signifi...

2010-10-22 03:35:40 PM

From: Suzanne Desjardins/HC-SC/GC/CA  
To: Tiffany Thornton/HC-SC/GC/CA@HWC  
Cc: Allison Vadneau/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC, Tiana Branch/HC-SC/GC/CA@HWC  
Date: 2010-10-22 03:35 PM  
Subject: Re: Salvia

Hi,

Since the changes to the IAS will be significant compared to the previous version, I would like to give the WG the opportunity to comment on it and not just provide it to the WG for information. The WG should be comfortable with the version that will be moved forward.

Thanks

Suzanne

Tiffany Thornton Hi Tiana, I think that will be fine. Suzanne, could...

2010-10-22 02:51:44 PM

From: Tiffany Thornton/HC-SC/GC/CA  
To: Tiana Branch/HC-SC/GC/CA@HWC  
Cc: Stephanie Chandler/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC, Allison Vadneau/HC-SC/GC/CA@HWC  
Date: 2010-10-22 02:51 PM  
Subject: Salvia

Hi Tiana,

I think that will be fine. Suzanne, could you please let me know if you are okay with this? I think the Agenda currently reflects this so it does not need to be changed.

Can you give me an idea of when you might be sending out the revised docs pertaining to the EAC for circulation to the CSS-WG before the meeting on Wednesday?

Thanks,

----- Forwarded by Tiffany Thornton/HC-SC/GC/CA on 2010-10-22 02:47 PM -----

From: Tiana Branch/HC-SC/GC/CA  
To: Tiffany Thornton/HC-SC/GC/CA@HWC, Allison Vadneau/HC-SC/GC/CA@HWC  
Cc: Stephanie Chandler/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2010-10-22 01:34 PM  
Subject: Salvia

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Hi Tiffany/Allison,

As discussed, RPD is in the process of updating the IAS on Salvia and have committed to providing a revised draft to Jocelyn by the end of the month. Therefore, we will not have sufficient time to provide to CSS-WG in advance. We simply want to confirm that Suzanne would be okay with us providing the updated IAS to CSS-WG for information following Jocelyn's review.

Pls advise if there are any concerns.

Much appreciated,  
Tiana



**Re: CSS-WG - Updated Salvia IAS**   
Tiffany Thornton to: Stephanie Chandler  
Cc: Allison Vadneau

2010-10-25 02:23 PM

Okay will circulate to the CSS-WG for their review.

Thanks,  
Tiffany

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Stephanie Chandler Hi Tiffany and Allison, Here is the updated draf... 2010-10-25 02:22:27 PM

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From: Stephanie Chandler/HC-SC/GC/CA  
To: Tiffany Thornton/HC-SC/GC/CA@HWC, Allison Vadneau/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC, Tiana Branch/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC  
Date: 2010-10-25 02:22 PM  
Subject: CSS-WG - Updated Salvia IAS

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Hi Tiffany and Allison,

Here is the updated draft of the Salvia IAS.



Draft Salvia Divinorum IAS\_Oct 25 2010.doc

Please note that the sections of the IAS that have been subject to major changes have been highlighted to facilitate easier review.

Regards,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
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# Issue Analysis Summary

DRAFT

## Scheduling *Salvia Divinorum* and/or Salvinorin A under the CDSA

Regulatory Policy Division  
Office of Controlled Substances  
Controlled Substances and Tobacco and Directorate

October 25, 2010

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### 1. APPROVALS

This Issue Analysis Summary is approved.

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Jocelyn Kula, A/Director  
Office of Controlled Substances  
Controlled Substances and Tobacco Directorate

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[DD/MM/2010]

### 2. ISSUE

Health Canada has received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *S. divinorum* and/or its main active ingredient salvinorin A, neither of which are currently regulated under the *Controlled Drugs and Substances Act* (CDSA). These requests are further to reports from scientific and media sources suggesting that *S. divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has also noted an

ongoing media interest regarding the availability of *S. divinorum* in Canada.

### 3. PURPOSE

To assess *Salvia divinorum* and/or salvinorin A against the criteria for the addition of a substance to one of the Schedules to the CDSA, and determine whether these substances should be regulated as controlled substances in Canada.

### 4. CONTEXT

*Salvia divinorum* is a species of sage which belongs to the mint family, and which is found in the form of dried leaves, extract and plant cuttings. Also known as "diviner's sage", the plant is known to induce illusions and hallucinations when chewed or smoked. Salvinorin A, the psychoactive ingredient in *S. divinorum* (also referred to chemically as a neoclerodane diterpene) is found primarily in the leaves, and to a lesser extent in the stem.<sup>1</sup>

*S. divinorum* is widely touted as a "legal" hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs among adolescents and young adults.<sup>2</sup> While very little is known about how and where *S. divinorum* is sold in Canada, it is suspected that it is mainly purchased over the Internet and/or bought at head shops or alternative life style stores, etc. *S. divinorum* cuttings are also available from a number of garden supply companies.

The use of *S. divinorum* as a psychotropic agent first came to Health Canada's attention in 2002. In 2004, Health Canada received four adverse drug reaction (ADR) reports associated with the use of *S. divinorum* as a hallucinogen, with three being considered non-serious (requiring no medical attention) and the fourth being considered serious (medical intervention was required). The serious ADR report involved the concomitant use of alcohol in a person diagnosed with Attention Deficit Disorder.

Further to the receipt of the aforementioned ADRs, the Marketed Health Products Directorate (MHPD) and the Natural Health Products Directorate (NHPD) of the Health Products and Food Branch (HPFB) prepared an issue analysis summary (IAS) in November 2005, which recommended that *S. divinorum* and its active ingredient salvinorin A be regulated as controlled substances. This recommendation was maintained when the IAS was updated in November 2006.

Later, in December 2005, MHPD and NHPD prepared a Signal Assessment (SA) (updated in June 2007) that eventually led to the preparation of a Health Risk Assessment (HRA), which

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<sup>1</sup> U.S. Department of Justice Drug Enforcement Administration. 2002. Drugs and Chemicals of Concern: *Salvia Divinorum* (salvinorin A, divinorin A) URL:

[http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm) Nov 2008

<sup>2</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.



concluded that *S. divinorum* or salvinorin A-containing health products would constitute a Type II Health Risk according to the Health Hazard Classification of the Recall Policy of the Health Products and Food Branch Inspectorate (HBFBI). Such a risk is defined as “a situation in which the use of, or exposure to, a product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote”.

Further to an Assistant Deputy Minister (ADM) discussion in April 2007, the Drug Strategy and Controlled Substances Directorate (DSCSD) organized a meeting with MHPD, NHPD and HPFBI to discuss *S. divinorum*. HPFBI was to determine appropriate compliance activities regarding *S. divinorum* and consult with the Canada Border Services Agency (CBSA) regarding the movement of products containing *S. divinorum* into and out of Canada.

On September 13, 2007, a further meeting between DSCSD, MHPD, NHPD and HPFBI led to the conclusion that DSCSD would conduct a scheduling assessment of *S. divinorum* in order to explore the possibility of scheduling this substance under the CDSA.

In September 2008, the Director Generals of DSCSD, MHPD, TPD and the HPFBI agreed that media lines and an “It’s Your Health” article on *S. divinorum* would be prepared.

#### **4.1 Relevant Legislative Frameworks in Canada**

##### **4.1.1 Food and Drug Regulations (under the Food and Drugs Act)**

The *Food and Drug Regulations* (F&DR) serve to ensure the safety, efficacy, and quality of health products offered for sale in Canada, including drugs and medical devices. Prior to being given market authorization, a manufacturer must present substantive scientific evidence that their product is safe, efficacious and of high quality. For drugs, Health Canada reviews this information carefully and, if the review is satisfactory, a Notice of Compliance (NOC) is issued and appropriate Drug Identification Numbers (DINs) are assigned.

A “drug” is defined under the F&DR as any substance or mixture of substances manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
- (b) restoration, correction or modification of organic functions in human beings or animals, or
- (c) disinfection in premises in which food is manufactured, prepared or kept;

As no products containing *S. divinorum* or its extracts have been reviewed and approved by Health Canada as of October 2010, it is illegal to market *S. divinorum* when it is represented as a drug.

#### 4.1.2 Natural Health Products Regulations (under the Food and Drugs Act)

The *Natural Health Products Regulations* (NHPR) aim to provide Canadians with ready access to natural health products (NHPs) that are safe, effective, and of high quality, while respecting freedom of choice and philosophical and cultural diversity. The NHPR require that all licensed products display a Natural Product Number (NPN), or, in the case of a homeopathic medicine, a Drug Identification Number - Homeopathic Medicine (DIN-HM), on their labels. These numbers are issued once a product is authorized for sale in Canada further to the submission of a product license application in which the applicant attests to all of the conditions set out in a natural health product monograph prepared and published by the Natural Health Products Directorate or submission of a product license application that provides sufficient evidence of quality, safety and efficacy that is assessed and approved by NHPD by the non-compendial route. The NHPR also require that all manufacturers, packagers, labelers, and importers be licensed which in turn requires the presence of procedures respecting distribution records, product recalls, product handling, storage and delivery, and all other aspects of Good Manufacturing Practices as set out in the NHPR.

The definition of an NHP under the NHPR has both a function and substance component. The function component refers to those substances that are manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
- (b) restoring or correcting organic functions in humans; or
- (c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

The substance component refers to the requirement that all of the medicinal ingredients of an NHP must be substances set out in Schedule 1 to the NHPR, which is a list of included substances. Included substances are those substances that are traditional or homeopathic medicines, and of which none of the ingredients are substances set out in Schedule 2, which is a list of excluded substances. Excluded substances include any substance listed on Schedules I to V of the CDSA. Section 2(2) of the NHPR excludes those substances (except homeopathic medicines) whose sale is required to be pursuant to a prescription as per Section C.01.043 of the F&DR. As per section 93(1)(b)(vi) of the NHPR, every natural health product must be labeled with its authorized recommended use or purpose. In the case of *S. divinorum*, it is generally marketed for its hallucinogenic properties which are considered a modification of an organic function. Therefore products that contain *S. divinorum* and are manufactured, sold or represented for use as a hallucinogen meet the definition of an NHP.

As of October 2010, no products containing *S. divinorum* have been reviewed and approved by Health Canada and no NPNs or DIN-HMs have been issued for such products. Therefore sales of *S. divinorum* are illegal under the NHPR if it is represented for use as a hallucinogen or if other health claims regarding the modification of organic functions are made.

#### **4.1.3 Controlled Drugs and Substances Act and its Regulations**

The CDSA provides a legislative framework for the control of substances that can alter mental processes and that may produce harm to the health of an individual or to society when diverted or misused. Except as authorized under its regulations, activities such as possession, possession for the purposes of trafficking, trafficking, importation, exportation, possession for the purposes of exportation and production of controlled substances are prohibited under the CDSA.

The substances regulated under the CDSA are grouped into eight Schedules, and each Schedule is associated with particular offences and penalties as described in Part I of the CDSA.

In determining whether a substance should be regulated as a controlled substance, and into which Schedule of the CDSA it should be placed, Health Canada considers a number of factors including:

- International requirements and trends in the control and/or scheduling;
- Chemical and/or pharmacological similarity to substances listed in the Schedules to the CDSA;
- Legitimate use of the substance, including therapeutic, scientific, industrial or commercial uses;
- Potential for abuse and/or addiction liability;
- Evidence of extent of actual abuse of the substance in Canada and internationally; and
- Risk to personal and public health and safety.

#### **4.2 Assessment of *Salvia Divinorum* for Scheduling Purposes**

##### **4.2.1 International Requirements and Trends in the Control and/or Scheduling**

At the present time, neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and therefore do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

##### ***Australia***

In June 2002, Australia became the first country to prohibit the sale, supply, possession and use of *S. divinorum* and salvinorin A. Both *S. divinorum* and salvinorin A are listed in Schedule 9 of Australia's *Standard for the Uniform Scheduling of Drugs and Poisons* on the basis of "high

potential for abuse and risk to public health and safety.”<sup>3</sup> Schedule 9 is Australia’s most restrictive drug schedule, and includes “substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities.”<sup>4</sup>

### ***Belgium***

A decree was passed in Belgium on October 22, 2006 which added *S. divinorum* to the list of controlled substances. This list includes substances such as psilocybin mushrooms, khat and peyote cactus.<sup>5</sup>

### ***Denmark***

In 2003, Denmark added *S. divinorum* and salvinorin A to their list of “category B” controlled substances, a category which also includes psilocybin mushrooms, cocaine, amphetamine, and several others substances that are only legal for medicinal and scientific purposes. Illegal possession carries a penalty of up to two years in prison.

### ***Germany***

*S. divinorum* (plant and plant parts) was added to Appendix I of the *Narcotics Act* in Germany on March 1, 2008, making it illegal to produce, traffic, or possess. The law does not specifically mention salvinorin A.

### ***Italy***

On June 25, 2004, the Italian Ministry of Health issued an ordinance prohibiting the sale of *S. divinorum* and its active constituent salvinorin A. On January 11, 2005, the Ministry of Health made possession of *S. divinorum* and salvinorin A illegal by placing them in “*Tabella I*” of the *Tabella Sostanze Stupefacenti o Psicotrope*.

### ***Japan***

On November 9, 2006, the Japanese government added a group of thirty-three drugs to its list of controlled substances, including salvinorin A. The drugs are banned under a revised pharmaceutical law, under which persons involved in their illegal import, production, and sale, i.e. beyond medical treatment or research purposes, will be subject to up to five years imprisonment or a fine of up to five million yen.

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<sup>3</sup> <http://www.tga.gov.au/ndpsc/record/rr2001111.pdf>

<sup>4</sup> [http://www.cognitiveliberty.org/news/salvia\\_australia.htm](http://www.cognitiveliberty.org/news/salvia_australia.htm)

<sup>5</sup>

## ***Spain***

On January 28, 2004, the Spanish Ministry of Health and Consumption issued an order prohibiting the sale of *S. divinorum*. The regulation went into effect on May 6, 2004 and only prohibits activities related to commerce. Possession and/or use are not considered to be criminal offences.

## ***Other Countries***

*Salvia divinorum* is illegal to possess or sell in Croatia, Latvia, Lithuania, Poland, Romania, South Korea and Sweden. In Russia it is illegal to grow or sell *S. divinorum*, but it is legal to possess it. In Estonia, Finland, Iceland and Norway, *S. divinorum* is treated as a medicinal herb and it is illegal to import it without a relevant prescription from a doctor.

## ***United States of America***

*S. divinorum* and salvinorin A are not included in the Schedules to the United States *Controlled Substances Act* although both *S. divinorum* and salvinorin A have been added to a list of chemicals "of concern" which has no legal implications. According to the National Institute for Drug Abuse, the Drug Enforcement Agency is considering classifying salvia as a Schedule I drug. This Schedule includes substances such as LSD and marijuana.

In addition, some individual states have implemented laws restricting its use, sale and/or distribution. As of July 2010, a number of states have enacted legislation placing regulatory controls on *S. divinorum* and/or salvinorin A including Delaware, Georgia, Florida, Hawaii, Illinois, Kansas, Kentucky, Maryland, Mississippi, Missouri, Nebraska, North Dakota, Ohio, Oklahoma, South Dakota, Wisconsin, Virginia, California, Louisiana, Maine, North Carolina, and Tennessee. By way of example, additional details regarding the regulation of *S. divinorum* in these last five states are provided below.

### ***California***

As of January 1, 2009, the sale or distribution of *S. divinorum* or salvinorin A, or any substance or material containing *S. divinorum* or salvinorin A, to any person under 18 years of age is a misdemeanor punishable by imprisonment in a county jail for not more than six months, a fine of no more than \$1,000, or both.

### ***Louisiana***

In 2005, Louisiana passed a bill which prohibits the possession, production, manufacture and distribution of a material, compound, mixture, or preparation intended for human consumption and that contains a hallucinogenic plant. A "hallucinogenic plant" is defined as "any part or portion" of a plant on a list of forty plants, which includes *S.*

*divinorum*.

### **Maine**

In Maine, *S. divinorum* and salvinorin A are regulated in the same way as tobacco products; adults eighteen years of age or over can legally purchase and use the material, but selling or providing *S. divinorum* or salvinorin A to anyone under the age of eighteen is a criminal offence. Possession by a minor is a civil violation, punishable by a fine, community service, or both.

### **North Carolina**

On December 1, 2009, the North Carolina State Legislature brought a new law into force which made *Salvia divinorum* and salvinorin A illegal. The only legal *S. divinorum* activities are the growing for aesthetic, landscaping, or decorative purposes or university-affiliated medical or pharmacological research.

### **Tennessee**

On July 1, 2006, Tennessee classified the deliberate production, manufacture, distribution, or possession of the active chemical ingredient in the hallucinogenic plant *S. divinorum* as a Class A misdemeanor. It is not, however, a criminal offence to possess, plant, cultivate, grow, or harvest *S. divinorum* for aesthetic, landscaping, or decorative purposes. The law also does not apply to any dosage that is legally obtainable from a retail establishment without a prescription when (and if) it is recognized by the Food and Drug Administration as a homeopathic drug.

#### **4.2.2 Chemical and/or Pharmacological Similarity to Substances Listed in the Schedules to the CDSA**

The psychoactive ingredient in *Salvia divinorum* is the neoclerodane diterpene salvinorin A.<sup>6</sup> Other plants which contain psychotropic terpenoids are *Artemisia absinthium* (wormwood) and *Cannabis sativa*.<sup>7</sup>

Unlike all other hallucinogens, salvinorin A is structurally distinct and does not interact with the serotonin-2A receptor or any other molecular target of classical hallucinogens.<sup>8</sup> Instead, the

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<sup>6</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage *Salvia divinorum*. Life Sci. 2005 Dec 22;78(5):527-31.

<sup>7</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. Pharmacotherapy. 2006 Sep;26(9):1268-72.

<sup>8</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. Pharmacotherapy. 2006 Sep;26(9):1268-72.

available research suggests the psychotropic effects of salvinorin A are mediated by its agonistic actions at the  $\kappa$ -opioid (KOR) receptor.<sup>9</sup> Its mechanism of action is therefore unique.<sup>10</sup>

The psychoactive effects of *S. divinorum* vary in onset and duration and include the sensation of becoming an object, visions of various two-dimensional surfaces, films and membranes, revisiting places of the past (particularly childhood), perceived loss of the body and/or identity, various sensations of motion (being pulled or twisted by a force of some kind), uncontrollable hysterical laughter, and overlapping realities (perceptions of being in more than one place).<sup>11</sup> Laughter, happiness, sense of well-being and dissociative effects were deemed the most positive aspects of *S. divinorum* by users, second only to the "trip" that the drug elicits.<sup>12</sup> Depersonalization, speaking gibberish, widening of consciousness and subjective illusions of rapid movement, flying or hovering have also been reported.<sup>13</sup>

The psychotomimetic effects of *S. divinorum* closely resemble schizoid symptoms induced by lysergic acid diethylamide (LSD) or phencyclidine (PCP).<sup>14</sup> Yet, it is said to have only weak influence on the prevailing mood of the user which differentiates it from other hallucinogens such as LSD and psilocybin.<sup>15</sup> Its strong dissociative effects are often compared to those of ketamine.<sup>16</sup> Users have reported that the psychedelic effects of *S. divinorum* were most similar to those caused by psilocybin mushrooms.<sup>17</sup> However, users familiar with the effects of other hallucinogens agree that despite certain similarities to classical hallucinogens, the visions and overall experience are quite unique.<sup>18</sup>

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<sup>9</sup> Roth BL, Baner K, Westkaemper R, Siebert D, Rice KC, Steinberg S, Ernsberger P, Rothman RB. Salvinorin A: a potent naturally occurring nonnitrogenous kappa opioid selective agonist. *Proc Natl Acad Sci U S A*. 2002 Sep 3;99(18):11934-9.

<sup>10</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>11</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>12</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>13</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5 and Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>14</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>15</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>16</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

<sup>17</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>18</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6 and González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

*S. divinorum* causes an unusually high degree of sedation, weakness and fatigue, while the increased de-realization is not commonly reported for classical psychedelics.<sup>19</sup> The combination of these effects seems to correlate with that of other KOR agonists such as pentazocine.<sup>20</sup>

The onset and intensity of the effects of *Salvia divinorum* appear to be related to the route of administration. Traditional uses generally produce mild effects because the leaves are rolled and chewed or crushed and prepared as a foamy infusion whereby the salvinorin A is degraded in the gastrointestinal system before being absorbed into the bloodstream. Hence, the level of effect relates quite closely to the length of time the material spends in the mouth, with the onset of effect generally taking 5-10 minutes. The effects build over the next hour and last for another hour before they begin to subside.<sup>21</sup>

Routes of administration that avoid the hepatic first-pass effect (i.e. inhalation, intravenous, intramuscular and sublingual use) are the quickest and most intense.<sup>22</sup> Salvinorin A can be isolated from the plant to make a powder which can be vaporized and inhaled. The onset of effects felt from vaporizing salvinorin A powder occurs in about 30 seconds and effects last for about 5-10 minutes and then subside over the next 30 minutes.<sup>23</sup>

Smoking is by far the most popular method of administration<sup>24</sup> and this is accomplished by smoking the dried leaves or a concentrated extract using a pipe or bong. Dried leaves may also be fortified with a concentrated extract of salvinorin A. A concentrated extract can also be used sublingually. Neither *S. divinorum* nor salvinorin A can be injected because the powder is insoluble in water.<sup>25</sup>

#### 4.2.3 Legitimate Use of the Substance, including Therapeutic, Scientific, Industrial or Commercial Uses

*Salvia divinorum* has traditionally been used for spiritual and medicinal purposes by the Mazatec

<sup>19</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>20</sup> Arasteh K, Poudevida S, Farre M, Roset PN, Cami J. Response patterns of the Spanish version of the 49-item short form of the Addiction Research Center Inventory after the use of sedatives, stimulants, and opioids. *Drug Alcohol Depend.* 1999 Jun 1;55(1-2):117-25.

<sup>21</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>22</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.

<sup>23</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>24</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62 and Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>25</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs.* 1994 Jul-Sep;26(3):277-83.



Indians in Oaxaca, Mexico,<sup>26</sup> where an infusion of the leaves or the leaves themselves are ingested to treat gastrointestinal problems, headaches, rheumatism, anemia and swelling of the stomach.<sup>27</sup> Its main use today is, however, for its psychedelic properties in the aid of producing “mystical” or hallucinogenic experiences as part of spiritual rituals.<sup>28</sup>

Although selective kappa receptor agonists have been shown to produce analgesic effects, adverse effects such as psychotomimesis, dysphoria and diuresis have been observed in studies investigating their therapeutic use.<sup>29</sup> In addition, while it has been speculated that KOR agonists may be useful in the treatment of certain psychiatric disorders including Alzheimer’s disease, schizophrenia, dementia and bipolar disorder,<sup>30</sup> much more research is needed in order to substantiate these hypotheses. Similarly, another study has suggested that chemical analogues of salvinorin A may be a useful treatment for those suffering from addiction to other substances.<sup>31</sup> That said there are presently no recognized medical uses for *S. divinorum* in Canada.

Similarly, there are no known industrial or commercial uses for *S. divinorum* in Canada. Most websites offering *S. divinorum* cuttings and seeds for sale appear to do so in the context of growing the plant for “recreational” purposes, rather than out of horticultural interest or for its esthetic appeal. *S. divinorum* is also marketed as incense. However, there is no evidence that *S. divinorum* has any fragrant properties that would legitimize such a use. Therefore it is believed that the marketing of this plant as an incense is a recent invention to avoid compliance and enforcement actions by Health Canada.

#### 4.2.4 Potential for Abuse and/or Addiction Liability

Salvinorin A is a potent, selective agonist of the  $\kappa$ -opioid receptor (KOR), and in contrast to the euphoria produced by  $\mu$ -opioid receptor (MOR) agonists such as morphine, KOR agonists are negatively reinforcing and aversive. In addition, KOR agonists have analgesic properties but are not associated with respiratory depression like MOR agonists. Finally, while MOR agonists increase the release of dopamine, the activation of KOR decreases dopamine release in the

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<sup>26</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>27</sup> Munro, T. The Chemistry of *Salvia divinorum*. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

<sup>28</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage *Salvia divinorum*. *Life Sci.* 2005 Dec 22;78(5):527-31.

<sup>29</sup> Barker RL, Fawcett J, Barkin SJ. 2002. Chronic pain management with a focus on the role of newer antidepressants and centrally acting agents. In: *Pain Management: A Practical Guide for Clinicians*, 6th edition, Weiner RS ed. CRC Press, Boca Raton, FL. pp. 415-34 and Tidgewell et al., 2004. A facile method for the preparation of deuterium labelled salvinorin A: *Biorganic & Medicinal Chemistry Letters*, 14: 5099-5102.

<sup>30</sup> Sheffler DJ & Roth BL. Salvinorin A: the ‘magic mint’ hallucinogen finds a molecular target in the kappa opioid receptor. *Trends Pharmacol Sci.* 2003 Mar;24(3):107-109.

<sup>31</sup> Prisinzano TE. Natural products as tools for neuroscience: discovery and development of novel agents to treat drug abuse. *J Nat Prod.* 2009 Mar 27;72(3):581-7.

nucleus accumbens.<sup>32</sup> In the case of MOR agonists, the increase of dopamine acts as a positive reinforcer. This action motivates the user to use the drug again, which could lead to drug abuse and/or addiction. For KOR agonists, this is not the case.

The aversive effects of KOR agonists suggest that the risk of addiction to *S. divinorum* is negligible. However, very few controlled scientific studies of the physical and psychotropic effects of *S. divinorum* on humans have been carried out. Therefore, it is difficult to predict with certainty its potential for addiction and abuse. In studies that have been conducted, there is conflicting information around the addiction liability of *S. divinorum* in both animals and humans. Some users have noted that they require increasing doses of salvinorin A in order to achieve the desired effect and the stimulated cerebral KOR may act as a mechanism of tolerance.<sup>33</sup> Further studies in this area and on the KOR mediated decrease of dopamine are also required in order to fully understand the addiction potential of this substance.

While concerns for the potential of abuse were once minimal because 1 kg of dried leaves yields only 3 to 6 human doses of salvinorin A, it was discovered that vaporizing and inhaling 200-500 micrograms had profound hallucinogenic effects.<sup>34</sup> Given that only small doses of this substance are necessary to achieve the desired effects, there is a higher potential for abuse. The extraction of salvinorin A from the plant is simple, and with care, approximately 1.5 grams of pure salvinorin A per kilogram of dried leaves (8kg of fresh leaves) can be isolated. This is enough for 2000 human doses.<sup>35</sup>

#### 4.2.5 Evidence of Extent of Actual Abuse of the Substance in Canada and Internationally

In Canada, the extent of actual abuse of *Salvia divinorum* and/or salvinorin A is relatively unknown. There is, however, some data regarding the prevalence of use of *Salvia divinorum* in Canada, despite the lack of legitimate uses for this plant. Questions about the use of *S. divinorum* were included in the 2009 Ontario Student Drug Use and Health Survey, the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey.

It is difficult to determine the extent of actual abuse of *S. divinorum* in Canada or elsewhere as there appear to be inconsistencies in the literature regarding risk aversion. For example, one author states: "Many who have used salvinorin A find the experience extremely unnerving, frightening and overly intense and most have no desire to repeat the experience."<sup>36</sup> However,

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<sup>32</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.

<sup>33</sup> Bucheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>34</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>35</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs*. 1994 Jul-Sep;26(3):277-83.

<sup>36</sup> Turner DM. *Salvinorin - The Psychedelic Essence of Salvia Divinorum*. Panther Press, San Francisco, CA 1996.

another study suggested that this is not the experience of all recreational users of *S. divinorum*.<sup>37</sup> Over eighty percent of users surveyed on a web-based questionnaire about their *S. divinorum* use said that they would probably or definitely use *S. divinorum* again.<sup>38</sup> Users have reported the negative effects of *S. divinorum* as: the short duration of action, lack of control over the experience, persisting negative effects (most often anxiety),<sup>39</sup> sweating, chills, increased diuresis, impaired vigilance,<sup>40</sup> and negative after-effects including tiredness, feeling head heavy, dizziness, physical exhaustion, and some degree of malaise or 'hangover' as they 'comedown' from the drug.<sup>41</sup>

The results from the 2009 Ontario Student Drug Use and Health Survey were published on November 18, 2009 and indicate that:

- Among all responding students in Ontario, 4.4% reported using *Salvia divinorum* at least once in the past year. In comparison, 58.2% indicated they had used alcohol, 25.6% indicated they had used cannabis and 5.0% indicated they had used hallucinogens other than LSD and PCP in the past year;
- Males (6.2%) were significantly more likely than females (2.3%) to report using *Salvia divinorum*;
- There is significant grade variation, with *Salvia divinorum* use most likely among 11<sup>th</sup>

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<sup>37</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62, Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry.* 2005 Jan;38(1):1-5, and Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs.* 1994 Jul-Sep;26(3):277-83.

<sup>38</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>39</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>40</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry.* 2005 Jan;38(1):1-5.

<sup>41</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

- graders (8.6%) and 12<sup>th</sup> graders (8.4%); and
- There are significant regional variations, with students in Northern Ontario (9.2%) most likely to use *Salvia divinorum*.

The results of the 2008-2009 Youth Smoking Survey were published on May 31, 2010 and indicate that:

- 4.9% of students stated that they had used *S. divinorum* in the last twelve months. In comparison, 53.0% indicated they had used alcohol, 27.3% indicated they had used cannabis and 6.9% indicated they had used other hallucinogens in the last twelve months;
- 2.6% of students in Grades 7-9 and 7.0% of students in Grades 10-12 had used *S. divinorum* in the last twelve months; and
- Males (6.6%) were more likely to have used *S. divinorum* in the past twelve months compared to females (3.2%).

The scope of the previously mentioned studies did not provide for any explanations regarding differences in usage between ages, genders and regions. In this regard, it is difficult to speculate on the causality of such differences.

The Canadian Alcohol and Drug Use Monitoring Survey specifically examined salvia for the first time in 2009. An estimated 1.6% of Canadians, aged 15 years and older, reported that they had used salvia in their lifetime, and 0.2% reported using it in the past-year. In comparison, the prevalence of past-year cannabis use among Canadians 15 years of age and older was 10.6%. 1.2% of respondents reported using cocaine or crack in the past 12 months, 0.9% had used ecstasy and 0.7% used illicit hallucinogens.

Health Canada's Drug Analysis Services (DAS) has identified salvinorin A in a number of samples seized by law enforcement, as shown in the following table. It is, however, difficult to determine how this data reflects the extent of actual abuse of salvinorin A in Canada.

**NUMBER OF SAMPLES FOUND TO CONTAIN SALVINORIN A**

Year	Count
2006	9
2007	8
2008	4
2009	20
2010 (as of May 7)	8

The National Forensic Laboratory Information System (NFLIS) and the System to Retrieve Information from Drug Evidence (STRIDE) in the United States are Drug Enforcement Agency (DEA) databases that collect scientifically verified data on analyzed samples in state and local forensic labs as well as samples from DEA labs. The following table shows the quantity of *S. divinorum* products that were seized from 2000 through to 2009.

**ANALYZED SALVIA DIVINORUM or SALVINORIN A SEIZURES**

(Number of Items/Exhibits)

Source	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009*
NFLIS-State/Local <sup>1</sup>	0	0	0	0	1	8	12	12	70	34
STRIDE <sup>2</sup>	0	0	1	1	1	0	0	0	N/A	N/A
<b>TOTAL</b>	0	0	1	1	2	8	12	12	70	34

Data Source: NFLIS & STRIDE, 2008 data queried 11/24/08, updated 06/10/2010

<sup>1</sup> NFLIS reported seizures of *Salvia divinorum* and/or salvinorin A

<sup>2</sup> STRIDE reported items of *Salvia divinorum*.

\* Includes only January – May data in 2009.

Once again, it is difficult to determine how this data can be used to reflect the actual extent of abuse of *S. divinorum* and salvinorin A in the United States.

#### 4.2.6 Risk to Personal and Public Health and Safety

The increase in both the number of enquiries from various municipalities and members of the public and the amount of media interest regarding the availability of *Salvia divinorum* in Canada may be an indication that the recreational use of *S. divinorum* as a hallucinogen is on the rise. However, there are no available statistics that indicate there has been a significant increase in *S. divinorum* use in the Canadian population.

The potential for harm to the user and/or other individuals is primarily related to the hallucinogenic properties of the substance. As this substance is typically smoked, there is no risk of infectious disease transmission as is the case when a drug is injected. Users may get up and walk around without apparent awareness of their movements, behaviour or surroundings, and distinction between self and surroundings is often lost. At doses greater than 1mg of salvinorin A, out of body experiences are frequent and loss of consciousness has been reported.<sup>42</sup> There is little information regarding the social behaviours of persons under the influence of *S. divinorum* products, and what risks their activities such as operating a motorized vehicle may pose to the general public. There is also very little data regarding the toxicity, teratogenicity or other long-term effects of *S. divinorum* use.<sup>43</sup>

As far as law enforcement is concerned, the Department has only received a limited number of communications indicating concern with respect to *S. divinorum*. The Royal Canadian Mounted Police (RCMP) has stated that while *S. divinorum* is readily available, it has not become a popular drug in Canada, probably due to its aversive effects such as anxiety and introversion.

A handful of case reports regarding the physiological and psychotropic effects of *S. divinorum* use have been published in the academic literature. An international case report described the perceptions of a 19 year-old man after inhaling *S. divinorum* smoke. The peak psychotropic effects, including prickling of the skin, fever-like hot flashes, muscular tremor, and depersonalization, were reached in less than five minutes after inhalation of an unknown amount

<sup>42</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>43</sup> Grundmann O, Phipps SM, Zadezensky I, Butterweck V. *Salvia divinorum* and Salvinorin A: An Update on Pharmacology and Analytical Methodology. Planta Med 2007 Jun;73:1039-1046.

s.21(1)(a)

s.21(1)(b)

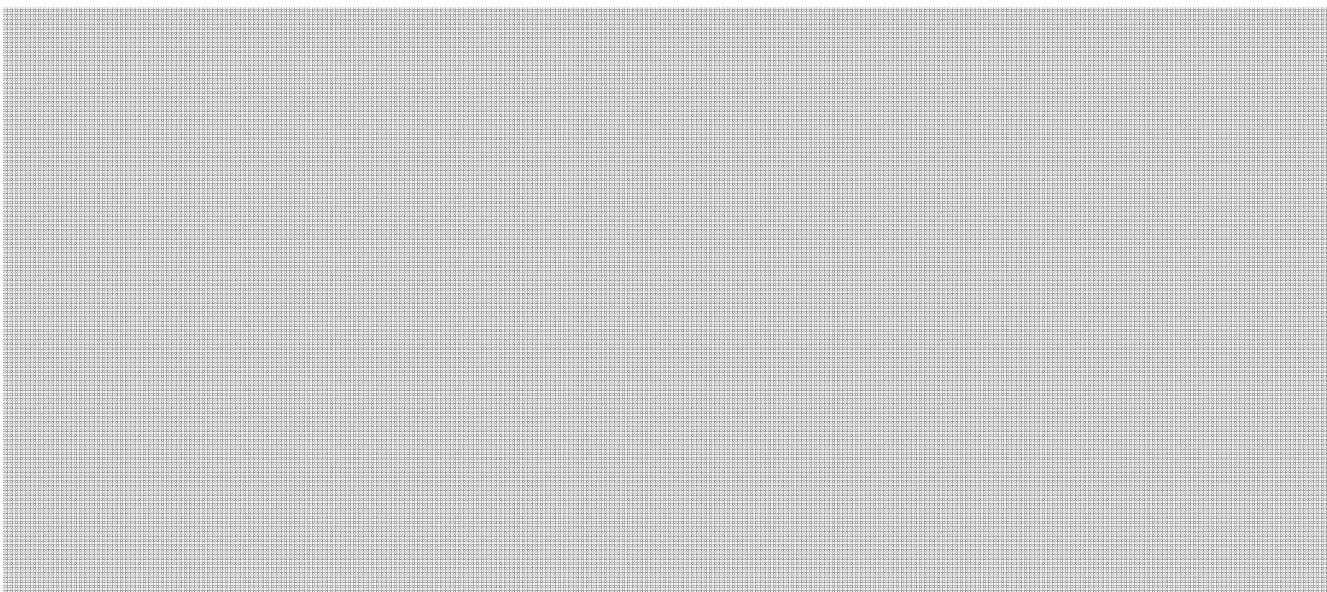
of smoke from burning dried leaves.<sup>44</sup> Another report involved a 15-year-old male who presented to psychiatric emergency services with acute onset of paranoia, déjà vu, blunted affect, difficulties in thought processing and slowed speech after smoking *Salvia divinorum* over an unknown period of time. During his hospitalization all symptoms improved significantly except the feeling of déjà vu. Based on this case presentation, the author suggested that the feelings of déjà vu may be a long-term effect of *S. divinorum* use.<sup>45</sup> However, given that this is the only case report in which déjà vu was associated with the use of *S. divinorum*, more reports are needed to substantiate this finding.

In addition to the above-mentioned reports, in 2006, a case was reported in the U.S. in which a 17-year-old boy committed suicide after smoking *S. divinorum* for an unknown period of time.<sup>46</sup> It should be noted that alcohol and general depression were the main confounders in this case. After this case was reported, the state of Delaware passed a law which classified *S. divinorum* as a Schedule I controlled substance along with other hallucinogenic substances.

Like many drugs of abuse, users are often unaware of the potency and adulterants in the product they purchase. A study by Wolowich *et al.* (2006), showed that the salvinorin A content in five out of five *S. divinorum* products was falsely indicated on the label and 4 out of 5 products contained unidentified adulterants (i.e. vitamin E, caffeine).<sup>47</sup>

Information found in scientific literature about the use and abuse of *S. divinorum* indicates that *S. divinorum* may pose a risk to the health and safety of Canadians. There are several reports of domestic adverse reactions related to the use of *S. divinorum* that have been received through the Canada Vigilance database. However, this does not reflect true incidence due to under-reporting.

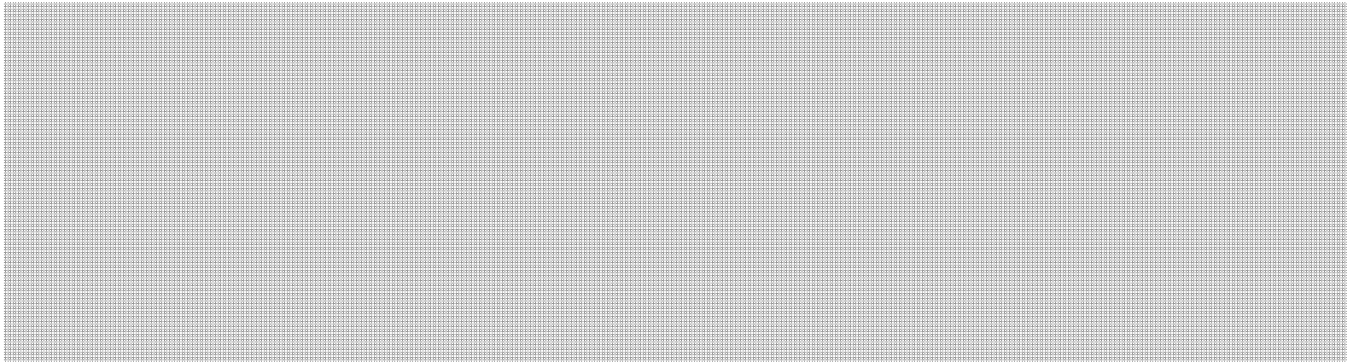
## 5. ASSESSMENT OF RISKS AND BENEFITS



<sup>45</sup> Singh S. (2007) Adolescent salvia substance abuse. *Addiction*. 102, 823-824.

<sup>46</sup> <http://www.kvbc.com/Global/story.asp?S=4893692>

<sup>47</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.



**6. IDENTIFICATION AND ANALYSIS OF OPTIONS**



**Page(s) 001472 to\à 001472**

**Is(Are) exempted pursuant to section(s)  
est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**



s.21(1)(a)

s.21(1)(b)

## 7. CONSIDERATIONS

The KOR-mediated aversive and dysphoric effects of *Salvia divinorum* do not appear to be hampering its use as young adults have begun smoking the leaves and leaf extract recreationally.<sup>49</sup> It can be purchased through online botanical companies and other drug promotion sites and is often touted as a legal alternative to substances such as cannabis and mescaline.<sup>50</sup> Interestingly, after being widely available for over a decade, the drug does not appear to have had the same social impact as LSD or ecstasy.<sup>51</sup>

While there has been an increase over the past few years in the number of enquiries from various municipalities and members of the public regarding the availability of *Salvia divinorum* as a hallucinogen, there does not appear to be a significant increase in the reported use of this substance.

The NHPR are limited in their capacity to control the availability of *S. divinorum* in that *S. divinorum* products are often declared as incense and therefore cannot be considered unapproved natural health products. In addition, compliance and enforcement actions such as voluntary stop-

<sup>49</sup> Hazelden Foundation, 2004. Drug Abuse Trends. June 2004. URL: [www.research.hazelden.org](http://www.research.hazelden.org).

<sup>50</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

<sup>51</sup> Munro, T. The Chemistry of *Salvia divinorum*. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

s.21(1)(a)

s.21(1)(b)

sales, forfeiture, destruction, and administrative seizure, cannot be implemented unless the marketing of the product indicates that it is to be used for human consumption and can modify an organic function.

*Salvia divinorum* and salvinorin A meet the criteria for scheduling a substance under the CDSA. While neither the plant nor salvinorin A are scheduled under any of the UN Drug Control Conventions, a number of countries and American states have taken steps to control the distribution and use of these substances. *S. divinorum* and salvinorin A are pharmacologically similar to other substances included in Schedule III to the CDSA, such as LSD and psilocybin. There are also currently no legitimate therapeutic, commercial or industrial uses for *S. divinorum*. While the potential for physical dependence of *S. divinorum* appears to be low, there is a significant potential for its abuse as a 'legal' hallucinogen. There is very little information with regards to the long-term effects of *S. divinorum* use. There is also evidence of abuse, particularly by Canadian youth and adolescents, and potential for risk to public health and safety.

## 8. RECOMMENDATIONS

## 9. CONSULTATIONS

The Drug Analysis Services (DAS) was contacted in order to provide any data available regarding the identification of salvinorin A in samples submitted by law enforcement.

The Royal Canadian Mounted Police (RCMP) was contacted in order to establish their views with respect to *S. divinorum* use in Canada. The RCMP advised that *S. divinorum* is readily available and law enforcement agencies have no legal means to prevent its sale.

OCS has received a number of correspondences from Canada Border Services Agency (CBSA) officers concerning a lack of information regarding the status of *S. divinorum* and how the plant should be treated at the border. CBSA officers have also expressed concern regarding the plant's hallucinogenic properties. At present, only shipments of *S. divinorum* that are represented as health products that modify organic functions can be refused for import under the NHPR.

OCS brought *S. divinorum* and salvinorin A to the Controlled Substances Scheduling Working Group (CSS-WG) in August 2010 to discuss the possibility of regulatory control of these substances. The CSS-WG recommended that both *S. divinorum* and salvinorin A be included under Schedule III to the CDSA.

## 10. IMPLEMENTATION AND EVALUATION


**Page(s) 001475 to\à 001475**

**Is(Are) exempted pursuant to section(s)  
est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**



**Re: Salvia IAS - revised**   
Daniel Galarneau to: Stephanie Chandler  
Cc: Denis Arsenault  
This message is digitally signed.

2010-10-25 10:57 AM

I have just gone through it quickly (yellow highlight) and checked the Jimson reference and I am ok with it.

*Daniel Galarneau*

Head, Regulatory Affairs Section – Chef, Section de la réglementation  
Office of Controlled Substances -- Bureau des substances contrôlées  
Controlled Substances and Tobacco Directorate – Direction des substances contrôlées et de la lutte au tabagisme  
Healthy Environments and Consumer Safety Branch -- Direction Générale de la Santé Environnementale et de la  
Sécurité des Consommateurs  
Tel: (613) 946-6521  
Fax: (613) 946-4224

Stephanie Chandler Hi Denis, I have included the revisions suggest... 2010-10-25 10:37:56 AM

From: Stephanie Chandler/HC-SC/GC/CA  
To: Denis Arsenault/HC-SC/GC/CA@HWC  
Cc: Daniel Galarneau/HC-SC/GC/CA@HWC  
Date: 2010-10-25 10:37 AM  
Subject: Salvia IAS - revised

Hi Denis,

I have included the revisions suggested by you and Daniel in the draft IAS below.  
[attachment "Draft Salvia Divinorum IAS\_Oct 25 2010.doc" deleted by Daniel Galarneau/HC-SC/GC/CA]

Would you like a chance to review it before I forward to Tiffany in the CSS-WG?

Regards,

Stephanie



**CSS-WG Meeting: October 27: Salvia IAS for review**

Suzanne Desjardins, Tanja Kalajdzic, Denis Arsenault, Robin Marles, Stephanie

**Tiffany Thornton** to: Chandler, Hanan Abramovici, Colette Strnad, 2010-10-25 02:32 PM  
Bruna Brands, Courtney Smith, Tiana Branch, Irshad Mulla

Cc: Isabel Shanahan, Laura Cooney, Valence Nebie, Allison Vadneau, Collin Pinto, Evelyn Soo, Jocelyn Kula

Please review attached document and bring your feedback on Wednesday.

Thanks!  
Tiffany



Draft Salvia Divinorum IAS\_Oct 25 2010.doc

--- Forwarded by Tiffany Thornton/HC-SC/GC/CA on 2010-10-25 02:27 PM ---

From: Tiffany Thornton/HC-SC/GC/CA  
Suzanne Desjardins/HC-SC/GC/CA@HWC, Tanja Kalajdzic/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, Robin Marles/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC, Hanan Abramovici/HC-SC/GC/CA@HWC, Collin Pinto/HC-SC/GC/CA@HWC, Colette Strnad/HC-SC/GC/CA@HWC, Bruna Brands/HC-SC/GC/CA@HWC, Evelyn Soo/HC-SC/GC/CA@HWC, Courtney Smith/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Tiana Branch/HC-SC/GC/CA@HWC  
Cc: Isabel Shanahan/HC-SC/GC/CA@HWC, Laura Cooney/HC-SC/GC/CA@HWC, Valence Nebie/HC-SC/GC/CA@HWC, Allison Vadneau/HC-SC/GC/CA@HWC  
Date: 2010-10-22 03:31 PM  
Subject: CSS-WG Meeting: October 27

Please find attached the documents for review (correspond to item #4 on the agenda) prior to the meeting on Wednesday October 27th from 10:30am-12pm.



CDSASched Deck-CSS-WG\_Oct272010.ppt



DraftProcessMap\_General\_Oct2010.doc

Also, I will be away starting Tuesday (October 26th) so if you require anything related to the meeting please contact allison.vadneau@hc-sc.gc.ca (946-3738).

Thanks very much!  
Tiffany

--- Forwarded by Tiffany Thornton/HC-SC/GC/CA on 2010-10-22 03:18 PM ---

**CSS-WG Meeting**



**2010-10-27 Wed 10:30 AM - 12:00 PM**

Location: 123 Slater, RM 405A

Colette Strnad/HC-SC/GC/CA@HWC, Collin Pinto/HC-SC/GC/CA@HWC, Courtney Smith/HC-SC/GC/CA@HWC, Evelyn Soo/HC-SC/GC/CA@HWC, Hanan

Required:	Abramovici/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Robin Marles/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC, Tanja Kalajdzic/HC-SC/GC/CA@HWC, Tiana Branch/HC-SC/GC/CA@HWC
Optional:	Isabel Shanahan/HC-SC/GC/CA@HWC, Laura Cooney/HC-SC/GC/CA@HWC, Valence Nebie/HC-SC/GC/CA@HWC

#### Description

Here is the draft agenda for Wednesday October 27th from 10:30 to 12pm in Rm 405A, 123 Slater. The meeting is a few weeks later due to scheduling conflicts. If you have any other items you would like to contribute please let me know.

Thanks,  
Tiffany

#### Draft Agenda

- 1- Members' introduction
- 2- Approval of Agenda
- 3 - Approval of ROD from August 2010  
-recommendation on scheduling Salvia
- 4- Update on CDSA Scheduling Process  
- ADM briefing (Jocelyn)
- 5- Update  
- updates on any emerging issues relevant to the WG's activities
- 6- Next steps i.e next meeting scheduled for October 13th

#### August 2010 ROD:



CSS-WG Aug 2010 Meeting RODt.doc

# Issue Analysis Summary

DRAFT

## Scheduling *Salvia Divinorum* and/or Salvinorin A under the CDSA

Regulatory Policy Division  
Office of Controlled Substances  
Controlled Substances and Tobacco and Directorate

October 25, 2010

### CONTENTS

1. APPROVALS
2. ISSUE
3. PURPOSE
4. CONTEXT
5. ASSESSMENT OF RISKS AND BENEFITS
6. IDENTIFICATION AND ANALYSIS OF OPTIONS
7. CONSIDERATIONS
8. RECOMMENDATION(S)
9. CONSULTATIONS
10. IMPLEMENTATION AND EVALUATION

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### 1. APPROVALS

This Issue Analysis Summary is approved.

---

Jocelyn Kula, A/Director  
Office of Controlled Substances  
Controlled Substances and Tobacco Directorate

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[DD/MM/2010]

### 2. ISSUE

Health Canada has received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *S. divinorum* and/or its main active ingredient salvinorin A, neither of which are currently regulated under the *Controlled Drugs and Substances Act* (CDSA). These requests are further to reports from scientific and media sources suggesting that *S. divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has also noted an

ongoing media interest regarding the availability of *S. divinorum* in Canada.

### 3. PURPOSE

To assess *Salvia divinorum* and/or salvinorin A against the criteria for the addition of a substance to one of the Schedules to the CDSA, and determine whether these substances should be regulated as controlled substances in Canada.

### 4. CONTEXT

*Salvia divinorum* is a species of sage which belongs to the mint family, and which is found in the form of dried leaves, extract and plant cuttings. Also called "diviner's sage", the plant is known to induce illusions and hallucinations when chewed or smoked. Salvinorin A, the psychoactive ingredient in *S. divinorum* (also referred to chemically as a neoclerodane diterpene) is found primarily in the leaves, and to a lesser extent in the stem.<sup>1</sup>

*S. divinorum* is widely touted as a "legal" hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs among adolescents and young adults.<sup>2</sup> While very little is known about how and where *S. divinorum* is sold in Canada, it is suspected that it is mainly purchased over the Internet and/or bought at head shops or alternative life style stores, etc. *S. divinorum* cuttings are also available from a number of garden supply companies.

The use of *S. divinorum* as a psychotropic agent first came to Health Canada's attention in 2002. In 2004, Health Canada received four adverse drug reaction (ADR) reports associated with the use of *S. divinorum* as a hallucinogen, with three being considered non-serious (requiring no medical attention) and the fourth being considered serious (medical intervention was required). The serious ADR report involved the concomitant use of alcohol in a person diagnosed with Attention Deficit Disorder.

Further to the receipt of the aforementioned ADRs, the Marketed Health Products Directorate (MHPD) and the Natural Health Products Directorate (NHPD) of the Health Products and Food Branch (HPFB) prepared an issue analysis summary (IAS) in November 2005, which recommended that *S. divinorum* and its active ingredient salvinorin A be regulated as controlled substances. This recommendation was maintained when the IAS was updated in November 2006.

Later, in December 2005, MHPD and NHPD prepared a Signal Assessment (SA) (updated in June 2007) that eventually led to the preparation of a Health Risk Assessment (HRA), which

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<sup>1</sup> U.S. Department of Justice Drug Enforcement Administration. 2002. Drugs and Chemicals of Concern: Salvia Divinorum (salvinorin A, divinorin A) URL:

[http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm) Nov 2008

<sup>2</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.



concluded that *S. divinorum* or salvinorin A-containing health products would constitute a Type II Health Risk according to the Health Hazard Classification of the Recall Policy of the Health Products and Food Branch Inspectorate (HBFBI). Such a risk is defined as “a situation in which the use of, or exposure to, a product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote”.

Further to an Assistant Deputy Minister (ADM) discussion in April 2007, the Drug Strategy and Controlled Substances Directorate (DSCSD) organized a meeting with MHPD, NHPD and HPFBI to discuss *S. divinorum*. HPFBI was to determine appropriate compliance activities regarding *S. divinorum* and consult with the Canada Border Services Agency (CBSA) regarding the movement of products containing *S. divinorum* into and out of Canada.

On September 13, 2007, a further meeting between DSCSD, MHPD, NHPD and HPFBI led to the conclusion that DSCSD would conduct a scheduling assessment of *S. divinorum* in order to explore the possibility of scheduling this substance under the CDSA.

In September 2008, the Director Generals of DSCSD, MHPD, TPD and the HPFBI agreed that media lines and an “It’s Your Health” article on *S. divinorum* would be prepared.

#### **4.1 Relevant Legislative Frameworks in Canada**

##### **4.1.1 Food and Drug Regulations (under the Food and Drugs Act)**

The *Food and Drug Regulations* (F&DR) serve to ensure the safety, efficacy, and quality of health products offered for sale in Canada, including drugs and medical devices. Prior to being given market authorization, a manufacturer must present substantive scientific evidence that their product is safe, efficacious and of high quality. For drugs, Health Canada reviews this information carefully and, if the review is satisfactory, a Notice of Compliance (NOC) is issued and appropriate Drug Identification Numbers (DINs) are assigned.

A “drug” is defined under the F&DR as any substance or mixture of substances manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
- (b) restoration, correction or modification of organic functions in human beings or animals, or
- (c) disinfection in premises in which food is manufactured, prepared or kept;

As no products containing *S. divinorum* or its extracts have been reviewed and approved by Health Canada as of October 2010, it is illegal to market *S. divinorum* when it is represented as a drug.

#### 4.1.2 Natural Health Products Regulations (under the Food and Drugs Act)

The *Natural Health Products Regulations* (NHPR) aim to provide Canadians with ready access to natural health products (NHPs) that are safe, effective, and of high quality, while respecting freedom of choice and philosophical and cultural diversity. The NHPR require that all licensed products display a Natural Product Number (NPN), or, in the case of a homeopathic medicine, a Drug Identification Number - Homeopathic Medicine (DIN-HM), on their labels. These numbers are issued once a product is authorized for sale in Canada further to the submission of a product license application in which the applicant attests to all of the conditions set out in a natural health product monograph prepared and published by the Natural Health Products Directorate or submission of a product license application that provides sufficient evidence of quality, safety and efficacy that is assessed and approved by NHPD by the non-compendial route. The NHPR also require that all manufacturers, packagers, labelers, and importers be licensed which in turn requires the presence of procedures respecting distribution records, product recalls, product handling, storage and delivery, and all other aspects of Good Manufacturing Practices as set out in the NHPR.

The definition of an NHP under the NHPR has both a function and substance component. The function component refers to those substances that are manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
- (b) restoring or correcting organic functions in humans; or
- (c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

The substance component refers to the requirement that all of the medicinal ingredients of an NHP must be substances set out in Schedule 1 to the NHPR, which is a list of included substances. Included substances are those substances that are traditional or homeopathic medicines, and of which none of the ingredients are substances set out in Schedule 2, which is a list of excluded substances. Excluded substances include any substance listed on Schedules I to V of the CDSA. Section 2(2) of the NHPR excludes those substances (except homeopathic medicines) whose sale is required to be pursuant to a prescription as per Section C.01.043 of the F&DR. As per section 93(1)(b)(vi) of the NHPR, every natural health product must be labeled with its authorized recommended use or purpose. In the case of *S. divinorum*, it is generally marketed for its hallucinogenic properties which are considered a modification of an organic function. Therefore products that contain *S. divinorum* and are manufactured, sold or represented for use as a hallucinogen meet the definition of an NHP.

As of October 2010, no products containing *S. divinorum* have been reviewed and approved by Health Canada and no NPNs or DIN-HMs have been issued for such products. Therefore sales of *S. divinorum* are illegal under the NHPR if it is represented for use as a hallucinogen or if other health claims regarding the modification of organic functions are made.

#### **4.1.3 Controlled Drugs and Substances Act and its Regulations**

The CDSA provides a legislative framework for the control of substances that can alter mental processes and that may produce harm to the health of an individual or to society when diverted or misused. Except as authorized under its regulations, activities such as possession, possession for the purposes of trafficking, trafficking, importation, exportation, possession for the purposes of exportation and production of controlled substances are prohibited under the CDSA.

The substances regulated under the CDSA are grouped into eight Schedules, and each Schedule is associated with particular offences and penalties as described in Part I of the CDSA.

In determining whether a substance should be regulated as a controlled substance, and into which Schedule of the CDSA it should be placed, Health Canada considers a number of factors including:

- International requirements and trends in the control and/or scheduling;
- Chemical and/or pharmacological similarity to substances listed in the Schedules to the CDSA;
- Legitimate use of the substance, including therapeutic, scientific, industrial or commercial uses;
- Potential for abuse and/or addiction liability;
- Evidence of extent of actual abuse of the substance in Canada and internationally; and
- Risk to personal and public health and safety.

#### **4.2 Assessment of *Salvia Divinorum* for Scheduling Purposes**

##### **4.2.1 International Requirements and Trends in the Control and/or Scheduling**

At the present time, neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and therefore do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

##### ***Australia***

In June 2002, Australia became the first country to prohibit the sale, supply, possession and use of *S. divinorum* and salvinorin A. Both *S. divinorum* and salvinorin A are listed in Schedule 9 of Australia's *Standard for the Uniform Scheduling of Drugs and Poisons* on the basis of "high

potential for abuse and risk to public health and safety.”<sup>3</sup> Schedule 9 is Australia’s most restrictive drug schedule, and includes “substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities.”<sup>4</sup>

### ***Belgium***

A decree was passed in Belgium on October 22, 2006 which added *S. divinorum* to the list of controlled substances. This list includes substances such as psilocybin mushrooms, khat and peyote cactus.<sup>5</sup>

### ***Denmark***

In 2003, Denmark added *S. divinorum* and salvinorin A to their list of “category B” controlled substances, a category which also includes psilocybin mushrooms, cocaine, amphetamine, and several others substances that are only legal for medicinal and scientific purposes. Illegal possession carries a penalty of up to two years in prison.

### ***Germany***

*S. divinorum* (plant and plant parts) was added to Appendix I of the *Narcotics Act* in Germany on March 1, 2008, making it illegal to produce, traffic, or possess. The law does not specifically mention salvinorin A.

### ***Italy***

On June 25, 2004, the Italian Ministry of Health issued an ordinance prohibiting the sale of *S. divinorum* and its active constituent salvinorin A. On January 11, 2005, the Ministry of Health made possession of *S. divinorum* and salvinorin A illegal by placing them in “*Tabella I*” of the *Tabella Sostanze Stupefacenti o Psicotrope*.

### ***Japan***

On November 9, 2006, the Japanese government added a group of thirty-three drugs to its list of controlled substances, including salvinorin A. The drugs are banned under a revised pharmaceutical law, under which persons involved in their illegal import, production, and sale, i.e. beyond medical treatment or research purposes, will be subject to up to five years imprisonment or a fine of up to five million yen.

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<sup>3</sup> <http://www.tga.gov.au/ndpsc/record/rr200111.pdf>

<sup>4</sup> [http://www.cognitiveliberty.org/news/salvia\\_australia.htm](http://www.cognitiveliberty.org/news/salvia_australia.htm)

<sup>5</sup>

<http://eldd.emcdda.europa.eu/html.cfm/index5176EN.html?pluginMethod=eldd.shownewsdetails&id=20/12/2006BELGIUM:%20New%20substances%20controlled%20include%20mCPP%20and%20khat>

### ***Spain***

On January 28, 2004, the Spanish Ministry of Health and Consumption issued an order prohibiting the sale of *S. divinorum*. The regulation went into effect on May 6, 2004 and only prohibits activities related to commerce. Possession and/or use are not considered to be criminal offences.

### ***Other Countries***

*Salvia divinorum* is illegal to possess or sell in Croatia, Latvia, Lithuania, Poland, Romania, South Korea and Sweden. In Russia it is illegal to grow or sell *S. divinorum*, but it is legal to possess it. In Estonia, Finland, Iceland and Norway, *S. divinorum* is treated as a medicinal herb and it is illegal to import it without a relevant prescription from a doctor.

### ***United States of America***

*S. divinorum* and salvinorin A are not included in the Schedules to the United States *Controlled Substances Act* although both *S. divinorum* and salvinorin A have been added to a list of chemicals "of concern" which has no legal implications. According to the National Institute for Drug Abuse, the Drug Enforcement Agency is considering classifying salvia as a Schedule I drug. This Schedule includes substances such as LSD and marijuana.

In addition, some individual states have implemented laws restricting its use, sale and/or distribution. As of July 2010, a number of states have enacted legislation placing regulatory controls on *S. divinorum* and/or salvinorin A including Delaware, Georgia, Florida, Hawaii, Illinois, Kansas, Kentucky, Maryland, Mississippi, Missouri, Nebraska, North Dakota, Ohio, Oklahoma, South Dakota, Wisconsin, Virginia, California, Louisiana, Maine, North Carolina, and Tennessee. By way of example, additional details regarding the regulation of *S. divinorum* in these last five states are provided below.

#### ***California***

As of January 1, 2009, the sale or distribution of *S. divinorum* or salvinorin A, or any substance or material containing *S. divinorum* or salvinorin A, to any person under 18 years of age is a misdemeanor punishable by imprisonment in a county jail for not more than six months, a fine of no more than \$1,000, or both.

#### ***Louisiana***

In 2005, Louisiana passed a bill which prohibits the possession, production, manufacture and distribution of a material, compound, mixture, or preparation intended for human consumption and that contains a hallucinogenic plant. A "hallucinogenic plant" is defined as "any part or portion" of a plant on a list of forty plants, which includes *S.*

*divinorum*.

### **Maine**

In Maine, *S. divinorum* and salvinorin A are regulated in the same way as tobacco products; adults eighteen years of age or over can legally purchase and use the material, but selling or providing *S. divinorum* or salvinorin A to anyone under the age of eighteen is a criminal offence. Possession by a minor is a civil violation, punishable by a fine, community service, or both.

### **North Carolina**

On December 1, 2009, the North Carolina State Legislature brought a new law into force which made *Salvia divinorum* and salvinorin A illegal. The only legal *S. divinorum* activities are the growing for aesthetic, landscaping, or decorative purposes or university-affiliated medical or pharmacological research.

### **Tennessee**

On July 1, 2006, Tennessee classified the deliberate production, manufacture, distribution, or possession of the active chemical ingredient in the hallucinogenic plant *S. divinorum* as a Class A misdemeanor. It is not, however, a criminal offence to possess, plant, cultivate, grow, or harvest *S. divinorum* for aesthetic, landscaping, or decorative purposes. The law also does not apply to any dosage that is legally obtainable from a retail establishment without a prescription when (and if) it is recognized by the Food and Drug Administration as a homeopathic drug.

#### **4.2.2 Chemical and/or Pharmacological Similarity to Substances Listed in the Schedules to the CDSA**

The psychoactive ingredient in *Salvia divinorum* is the neoclerodane diterpene salvinorin A.<sup>6</sup> Other plants which contain psychotropic terpenoids are *Artemisia absinthium* (wormwood) and *Cannabis sativa*.<sup>7</sup>

Unlike all other hallucinogens, salvinorin A is structurally distinct and does not interact with the serotonin-2A receptor or any other molecular target of classical hallucinogens.<sup>8</sup> Instead, the

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<sup>6</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage *Salvia divinorum*. Life Sci. 2005 Dec 22;78(5):527-31.

<sup>7</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. Pharmacotherapy. 2006 Sep;26(9):1268-72.

<sup>8</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. Pharmacotherapy. 2006 Sep;26(9):1268-72.

available research suggests the psychotropic effects of salvinorin A are mediated by its agonistic actions at the  $\kappa$ -opioid (KOR) receptor.<sup>9</sup> Its mechanism of action is therefore unique.<sup>10</sup>

The psychoactive effects of *S. divinorum* vary in onset and duration and include the sensation of becoming an object, visions of various two-dimensional surfaces, films and membranes, revisiting places of the past (particularly childhood), perceived loss of the body and/or identity, various sensations of motion (being pulled or twisted by a force of some kind), uncontrollable hysterical laughter, and overlapping realities (perceptions of being in more than one place).<sup>11</sup> Laughter, happiness, sense of well-being and dissociative effects were deemed the most positive aspects of *S. divinorum* by users, second only to the "trip" that the drug elicits.<sup>12</sup> Depersonalization, speaking gibberish, widening of consciousness and subjective illusions of rapid movement, flying or hovering have also been reported.<sup>13</sup>

The psychotomimetic effects of *S. divinorum* closely resemble schizoid symptoms induced by lysergic acid diethylamide (LSD) or phencyclidine (PCP).<sup>14</sup> Yet, it is said to have only weak influence on the prevailing mood of the user which differentiates it from other hallucinogens such as LSD and psilocybin.<sup>15</sup> Its strong dissociative effects are often compared to those of ketamine.<sup>16</sup> Users have reported that the psychedelic effects of *S. divinorum* were most similar to those caused by psilocybin mushrooms.<sup>17</sup> However, users familiar with the effects of other hallucinogens agree that despite certain similarities to classical hallucinogens, the visions and overall experience are quite unique.<sup>18</sup>

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<sup>9</sup> Roth BL, Baner K, Westkaemper R, Siebert D, Rice KC, Steinberg S, Ernsberger P, Rothman RB. Salvinorin A: a potent naturally occurring nonnitrogenous kappa opioid selective agonist. *Proc Natl Acad Sci U S A*. 2002 Sep 3;99(18):11934-9.

<sup>10</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>11</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>12</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>13</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5 and Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>14</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>15</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>16</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

<sup>17</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>18</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6 and González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

*S. divinorum* causes an unusually high degree of sedation, weakness and fatigue, while the increased de-realization is not commonly reported for classical psychedelics.<sup>19</sup> The combination of these effects seems to correlate with that of other KOR agonists such as pentazocine.<sup>20</sup>

The onset and intensity of the effects of *Salvia divinorum* appear to be related to the route of administration. Traditional uses generally produce mild effects because the leaves are rolled and chewed or crushed and prepared as a foamy infusion whereby the salvinorin A is degraded in the gastrointestinal system before being absorbed into the bloodstream. Hence, the level of effect relates quite closely to the length of time the material spends in the mouth, with the onset of effect generally taking 5-10 minutes. The effects build over the next hour and last for another hour before they begin to subside.<sup>21</sup>

Routes of administration that avoid the hepatic first-pass effect (i.e. inhalation, intravenous, intramuscular and sublingual use) are the quickest and most intense.<sup>22</sup> Salvinorin A can be isolated from the plant to make a powder which can be vaporized and inhaled. The onset of effects felt from vaporizing salvinorin A powder occurs in about 30 seconds and effects last for about 5-10 minutes and then subside over the next 30 minutes.<sup>23</sup>

Smoking is by far the most popular method of administration<sup>24</sup> and this is accomplished by smoking the dried leaves or a concentrated extract using a pipe or bong. Dried leaves may also be fortified with a concentrated extract of salvinorin A. A concentrated extract can also be used sublingually. Neither *S. divinorum* nor salvinorin A can be injected because the powder is insoluble in water.<sup>25</sup>

#### 4.2.3 Legitimate Use of the Substance, including Therapeutic, Scientific, Industrial or Commercial Uses

*Salvia divinorum* has traditionally been used for spiritual and medicinal purposes by the Mazatec

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<sup>19</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>20</sup> Arasteh K, Poudevida S, Farre M, Roset PN, Cami J. Response patterns of the Spanish version of the 49-item short form of the Addiction Research Center Inventory after the use of sedatives, stimulants, and opioids. *Drug Alcohol Depend.* 1999 Jun 1;55(1-2):117-25.

<sup>21</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>22</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.

<sup>23</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>24</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62 and Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>25</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs.* 1994 Jul-Sep;26(3):277-83.



Indians in Oaxaca, Mexico,<sup>26</sup> where an infusion of the leaves or the leaves themselves are ingested to treat gastrointestinal problems, headaches, rheumatism, anemia and swelling of the stomach.<sup>27</sup> Its main use today is, however, for its psychedelic properties in the aid of producing “mystical” or hallucinogenic experiences as part of spiritual rituals.<sup>28</sup>

Although selective kappa receptor agonists have been shown to produce analgesic effects, adverse effects such as psychotomimesis, dysphoria and diuresis have been observed in studies investigating their therapeutic use.<sup>29</sup> In addition, while it has been speculated that KOR agonists may be useful in the treatment of certain psychiatric disorders including Alzheimer’s disease, schizophrenia, dementia and bipolar disorder,<sup>30</sup> much more research is needed in order to substantiate these hypotheses. Similarly, another study has suggested that chemical analogues of salvinorin A may be a useful treatment for those suffering from addiction to other substances.<sup>31</sup> That said there are presently no recognized medical uses for *S. divinorum* in Canada.

Similarly, there are no known industrial or commercial uses for *S. divinorum* in Canada. Most websites offering *S. divinorum* cuttings and seeds for sale appear to do so in the context of growing the plant for “recreational” purposes, rather than out of horticultural interest or for its esthetic appeal. *S. divinorum* is also marketed as incense. However, there is no evidence that *S. divinorum* has any fragrant properties that would legitimize such a use. Therefore it is believed that the marketing of this plant as an incense is a recent invention to avoid compliance and enforcement actions by Health Canada.

#### 4.2.4 Potential for Abuse and/or Addiction Liability

Salvinorin A is a potent, selective agonist of the  $\kappa$ -opioid receptor (KOR), and in contrast to the euphoria produced by  $\mu$ -opioid receptor (MOR) agonists such as morphine, KOR agonists are negatively reinforcing and aversive. In addition, KOR agonists have analgesic properties but are not associated with respiratory depression like MOR agonists. Finally, while MOR agonists increase the release of dopamine, the activation of KOR decreases dopamine release in the

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<sup>26</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>27</sup> Munro, T. *The Chemistry of Salvia divinorum*. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

<sup>28</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage *Salvia divinorum*. *Life Sci.* 2005 Dec 22;78(5):527-31.

<sup>29</sup> Barker RL, Fawcett J, Barkin SJ. 2002. Chronic pain management with a focus on the role of newer antidepressants and centrally acting agents. In: *Pain Management: A Practical Guide for Clinicians*, 6th edition, Weiner RS ed. CRC Press, Boca Raton, FL. pp. 415-34 and Tidgewell et al., 2004. A facile method for the preparation of deuterium labelled salvinorin A: *Biorganic & Medicinal Chemistry Letters*, 14: 5099-5102.

<sup>30</sup> Sheffler DJ & Roth BL. Salvinorin A: the ‘magic mint’ hallucinogen finds a molecular target in the kappa opioid receptor. *Trends Pharmacol Sci.* 2003 Mar;24(3):107-109.

<sup>31</sup> Prisinzano TE. Natural products as tools for neuroscience: discovery and development of novel agents to treat drug abuse. *J Nat Prod.* 2009 Mar 27;72(3):581-7.

nucleus accumbens.<sup>32</sup> In the case of MOR agonists, the increase of dopamine acts as a positive reinforcer. This action motivates the user to use the drug again, which could lead to drug abuse and/or addiction. For KOR agonists, this is not the case.

The aversive effects of KOR agonists suggest that the risk of addiction to *S. divinorum* is negligible. However, very few controlled scientific studies of the physical and psychotropic effects of *S. divinorum* on humans have been carried out. Therefore, it is difficult to predict with certainty its potential for addiction and abuse. In studies that have been conducted, there is conflicting information around the addiction liability of *S. divinorum* in both animals and humans. Some users have noted that they require increasing doses of salvinorin A in order to achieve the desired effect and the stimulated cerebral KOR may act as a mechanism of tolerance.<sup>33</sup> Further studies in this area and on the KOR mediated decrease of dopamine are also required in order to fully understand the addiction potential of this substance.

While concerns for the potential of abuse were once minimal because 1 kg of dried leaves yields only 3 to 6 human doses of salvinorin A, it was discovered that vaporizing and inhaling 200-500 micrograms had profound hallucinogenic effects.<sup>34</sup> Given that only small doses of this substance are necessary to achieve the desired effects, there is a higher potential for abuse. The extraction of salvinorin A from the plant is simple, and with care, approximately 1.5 grams of pure salvinorin A per kilogram of dried leaves (8kg of fresh leaves) can be isolated. This is enough for 2000 human doses.<sup>35</sup>

#### **4.2.5 Evidence of Extent of Actual Abuse of the Substance in Canada and Internationally**

In Canada, the extent of actual abuse of *Salvia divinorum* and/or salvinorin A is relatively unknown. There is, however, some data regarding the prevalence of use of *Salvia divinorum* in Canada, despite the lack of legitimate uses for this plant. Questions about the use of *S. divinorum* were included in the 2009 Ontario Student Drug Use and Health Survey, the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey.

It is difficult to determine the extent of actual abuse of *S. divinorum* in Canada or elsewhere as there appear to be inconsistencies in the literature regarding risk aversion. For example, one author states: "Many who have used salvinorin A find the experience extremely unnerving, frightening and overly intense and most have no desire to repeat the experience."<sup>36</sup> However,

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<sup>32</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.

<sup>33</sup> Bucheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>34</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>35</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs*. 1994 Jul-Sep;26(3):277-83.

<sup>36</sup> Turner DM. *Salvinorin - The Psychedelic Essence of Salvia Divinorum*. Panther Press, San Francisco, CA 1996.

another study suggested that this is not the experience of all recreational users of *S. divinorum*.<sup>37</sup> Over eighty percent of users surveyed on a web-based questionnaire about their *S. divinorum* use said that they would probably or definitely use *S. divinorum* again.<sup>38</sup> Users have reported the negative effects of *S. divinorum* as: the short duration of action, lack of control over the experience, persisting negative effects (most often anxiety),<sup>39</sup> sweating, chills, increased diuresis, impaired vigilance,<sup>40</sup> and negative after-effects including tiredness, feeling head heavy, dizziness, physical exhaustion, and some degree of malaise or 'hangover' as they 'comedown' from the drug.<sup>41</sup>

The results from the 2009 Ontario Student Drug Use and Health Survey were published on November 18, 2009 and indicate that:

- Among all responding students in Ontario, 4.4% reported using *Salvia divinorum* at least once in the past year. In comparison, 58.2% indicated they had used alcohol, 25.6% indicated they had used cannabis and 5.0% indicated they had used hallucinogens other than LSD and PCP in the past year;
- Males (6.2%) were significantly more likely than females (2.3%) to report using *Salvia divinorum*;
- There is significant grade variation, with *Salvia divinorum* use most likely among 11<sup>th</sup>

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<sup>37</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62, Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry.* 2005 Jan;38(1):1-5, and Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs.* 1994 Jul-Sep;26(3):277-83.

<sup>38</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>39</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>40</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry.* 2005 Jan;38(1):1-5.

<sup>41</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

- graders (8.6%) and 12<sup>th</sup> graders (8.4%); and
- There are significant regional variations, with students in Northern Ontario (9.2%) most likely to use *Salvia divinorum*.

The results of the 2008-2009 Youth Smoking Survey were published on May 31, 2010 and indicate that:

- 4.9% of students stated that they had used *S. divinorum* in the last twelve months. In comparison, 53.0% indicated they had used alcohol, 27.3% indicated they had used cannabis and 6.9% indicated they had used other hallucinogens in the last twelve months;
- 2.6% of students in Grades 7-9 and 7.0% of students in Grades 10-12 had used *S. divinorum* in the last twelve months; and
- Males (6.6%) were more likely to have used *S. divinorum* in the past twelve months compared to females (3.2%).

The scope of the previously mentioned studies did not provide for any explanations regarding differences in usage between ages, genders and regions. In this regard, it is difficult to speculate on the causality of such differences.

The Canadian Alcohol and Drug Use Monitoring Survey specifically examined salvia for the first time in 2009. An estimated 1.6% of Canadians, aged 15 years and older, reported that they had used salvia in their lifetime, and 0.2% reported using it in the past-year. In comparison, the prevalence of past-year cannabis use among Canadians 15 years of age and older was 10.6%. 1.2% of respondents reported using cocaine or crack in the past 12 months, 0.9% had used ecstasy and 0.7% used illicit hallucinogens.

Health Canada's Drug Analysis Services (DAS) has identified salvinorin A in a number of samples seized by law enforcement, as shown in the following table. It is, however, difficult to determine how this data reflects the extent of actual abuse of salvinorin A in Canada.

**NUMBER OF SAMPLES FOUND TO CONTAIN SALVINORIN A**

Year	Count
2006	9
2007	8
2008	4
2009	20
2010 (as of May 7)	8

The National Forensic Laboratory Information System (NFLIS) and the System to Retrieve Information from Drug Evidence (STRIDE) in the United States are Drug Enforcement Agency (DEA) databases that collect scientifically verified data on analyzed samples in state and local forensic labs as well as samples from DEA labs. The following table shows the quantity of *S. divinorum* products that were seized from 2000 through to 2009.

**ANALYZED SALVIA DIVINORUM or SALVINORIN A SEIZURES**

(Number of Items/Exhibits)

Source	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009*
NFLIS-State/Local <sup>1</sup>	0	0	0	0	1	8	12	12	70	34
STRIDE <sup>2</sup>	0	0	1	1	1	0	0	0	N/A	N/A
<b>TOTAL</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>1</b>	<b>2</b>	<b>8</b>	<b>12</b>	<b>12</b>	<b>70</b>	<b>34</b>

Data Source: NFLIS & STRIDE, 2008 data queried 11/24/08, updated 06/10/2010

<sup>1</sup> NFLIS reported seizures of *Salvia divinorum* and/or salvinorin A

<sup>2</sup> STRIDE reported items of *Salvia divinorum*.

\* Includes only January – May data in 2009.

Once again, it is difficult to determine how this data can be used to reflect the actual extent of abuse of *S. divinorum* and salvinorin A in the United States.

#### 4.2.6 Risk to Personal and Public Health and Safety

The increase in both the number of enquiries from various municipalities and members of the public and the amount of media interest regarding the availability of *Salvia divinorum* in Canada may be an indication that the recreational use of *S. divinorum* as a hallucinogen is on the rise. However, there are no available statistics that indicate there has been a significant increase in *S. divinorum* use in the Canadian population.

The potential for harm to the user and/or other individuals is primarily related to the hallucinogenic properties of the substance. As this substance is typically smoked, there is no risk of infectious disease transmission as is the case when a drug is injected. Users may get up and walk around without apparent awareness of their movements, behaviour or surroundings, and distinction between self and surroundings is often lost. At doses greater than 1mg of salvinorin A, out of body experiences are frequent and loss of consciousness has been reported.<sup>42</sup> There is little information regarding the social behaviours of persons under the influence of *S. divinorum* products, and what risks their activities such as operating a motorized vehicle may pose to the general public. There is also very little data regarding the toxicity, teratogenicity or other long-term effects of *S. divinorum* use.<sup>43</sup>

As far as law enforcement is concerned, the Department has only received a limited number of communications indicating concern with respect to *S. divinorum*. The Royal Canadian Mounted Police (RCMP) has stated that while *S. divinorum* is readily available, it has not become a popular drug in Canada, probably due to its aversive effects such as anxiety and introversion.

A handful of case reports regarding the physiological and psychotropic effects of *S. divinorum* use have been published in the academic literature. An international case report described the perceptions of a 19 year-old man after inhaling *S. divinorum* smoke. The peak psychotropic effects, including prickling of the skin, fever-like hot flashes, muscular tremor, and depersonalization, were reached in less than five minutes after inhalation of an unknown amount

<sup>42</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>43</sup> Grundmann O, Phipps SM, Zadezensky I, Butterweck V. *Salvia divinorum* and Salvinorin A: An Update on Pharmacology and Analytical Methodology. Planta Med 2007 Jun;73:1039-1046.

s.21(1)(a)

s.21(1)(b)

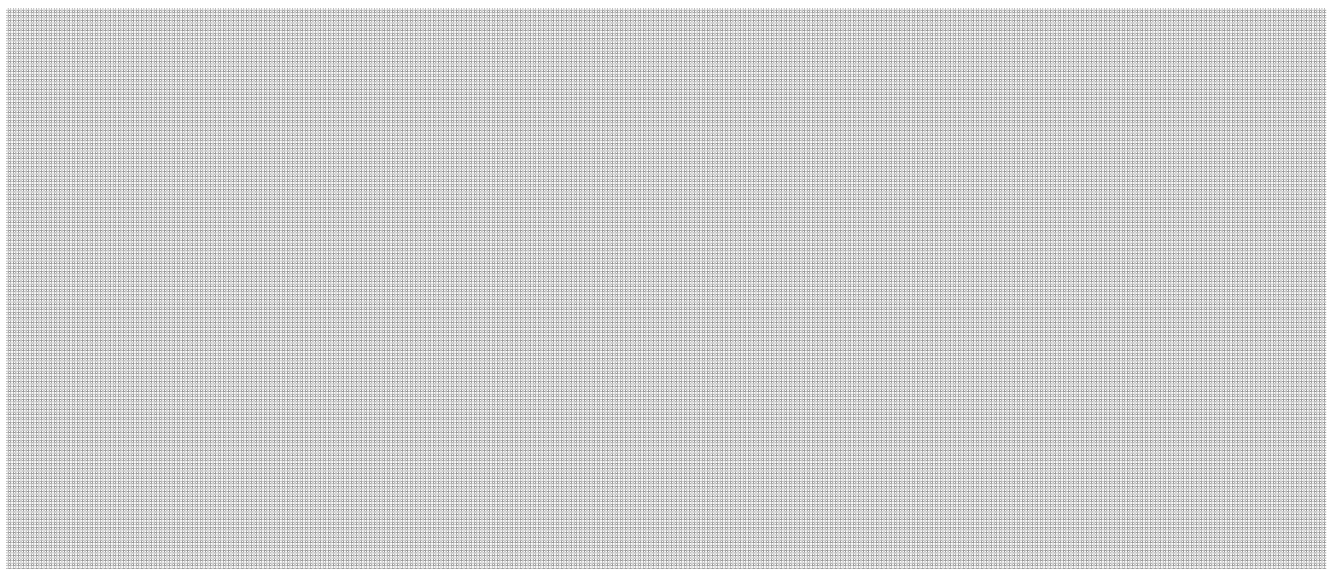
of smoke from burning dried leaves.<sup>44</sup> Another report involved a 15-year-old male who presented to psychiatric emergency services with acute onset of paranoia, déjà vu, blunted affect, difficulties in thought processing and slowed speech after smoking *Salvia divinorum* over an unknown period of time. During his hospitalization all symptoms improved significantly except the feeling of déjà vu. Based on this case presentation, the author suggested that the feelings of déjà vu may be a long-term effect of *S. divinorum* use.<sup>45</sup> However, given that this is the only case report in which déjà vu was associated with the use of *S. divinorum*, more reports are needed to substantiate this finding.

In addition to the above-mentioned reports, in 2006, a case was reported in the U.S. in which a 17-year-old boy committed suicide after smoking *S. divinorum* for an unknown period of time.<sup>46</sup> It should be noted that alcohol and general depression were the main confounders in this case. After this case was reported, the state of Delaware passed a law which classified *S. divinorum* as a Schedule I controlled substance along with other hallucinogenic substances.

Like many drugs of abuse, users are often unaware of the potency and adulterants in the product they purchase. A study by Wolowich *et al.* (2006), showed that the salvinorin A content in five out of five *S. divinorum* products was falsely indicated on the label and 4 out of 5 products contained unidentified adulterants (i.e. vitamin E, caffeine).<sup>47</sup>

Information found in scientific literature about the use and abuse of *S. divinorum* indicates that *S. divinorum* may pose a risk to the health and safety of Canadians. There are several reports of domestic adverse reactions related to the use of *S. divinorum* that have been received through the Canada Vigilance database. However, this does not reflect true incidence due to under-reporting.

## 5. ASSESSMENT OF RISKS AND BENEFITS



<sup>45</sup> Singh S. (2007) Adolescent salvia substance abuse. *Addiction*. 102, 823-824.

<sup>46</sup> <http://www.kvbc.com/Global/story.asp?S=4893692>

<sup>47</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

**Page(s) 001495 to\à 001496**

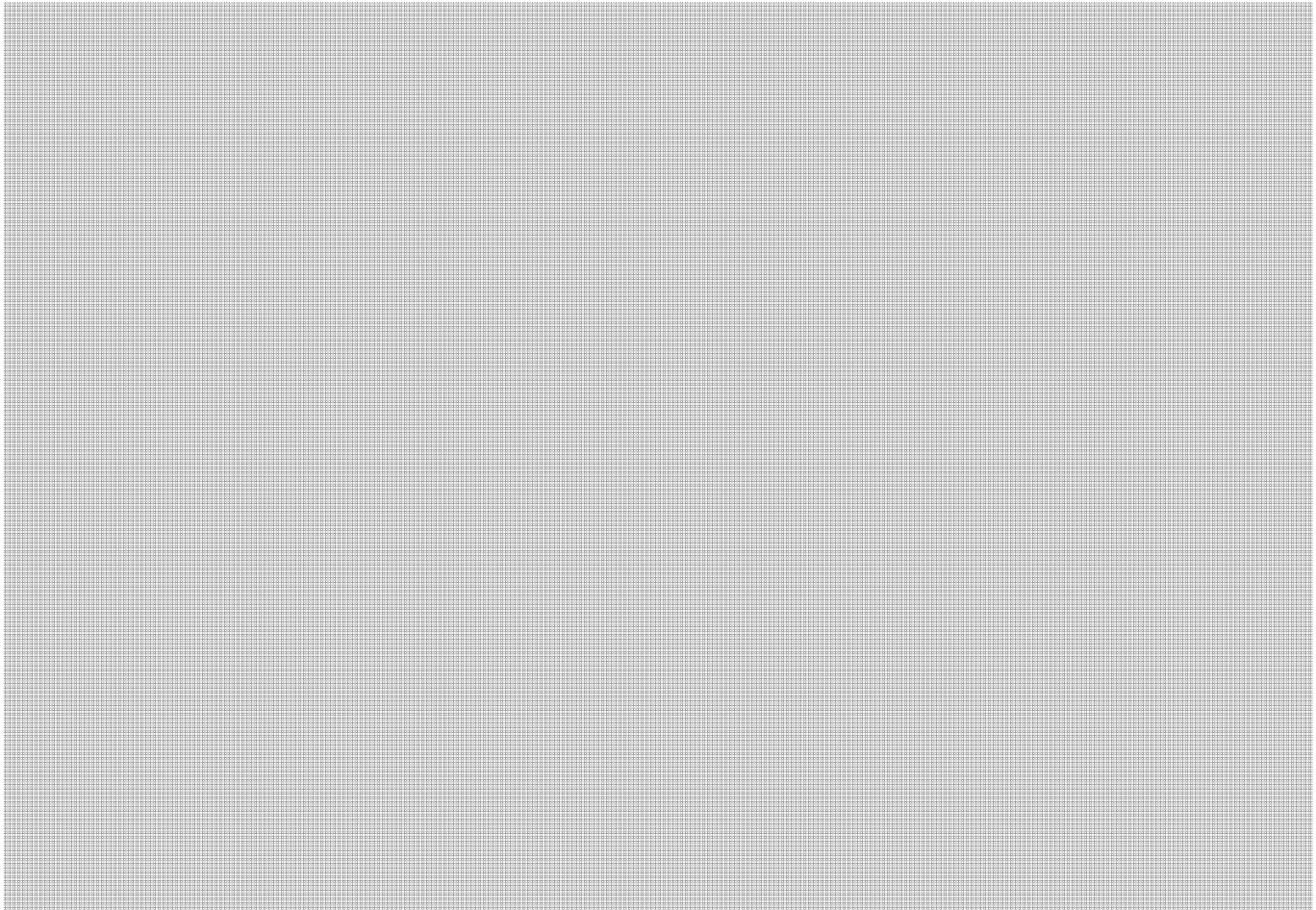
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**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**

s.21(1)(a)

s.21(1)(b)



## 7. CONSIDERATIONS

The KOR-mediated aversive and dysphoric effects of *Salvia divinorum* do not appear to be hampering its use as young adults have begun smoking the leaves and leaf extract recreationally.<sup>49</sup> It can be purchased through online botanical companies and other drug promotion sites and is often touted as a legal alternative to substances such as cannabis and mescaline.<sup>50</sup> Interestingly, after being widely available for over a decade, the drug does not appear to have had the same social impact as LSD or ecstasy.<sup>51</sup>

While there has been an increase over the past few years in the number of enquiries from various municipalities and members of the public regarding the availability of *Salvia divinorum* as a hallucinogen, there does not appear to be a significant increase in the reported use of this substance.

The NHPR are limited in their capacity to control the availability of *S. divinorum* in that *S. divinorum* products are often declared as incense and therefore cannot be considered unapproved natural health products. In addition, compliance and enforcement actions such as voluntary stop-

<sup>49</sup> Hazelden Foundation, 2004. Drug Abuse Trends. June 2004. URL: [www.research.hazelden.org](http://www.research.hazelden.org).

<sup>50</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

<sup>51</sup> Munro, T. The Chemistry of *Salvia divinorum*. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007  
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s.21(1)(a)

s.21(1)(b)

sales, forfeiture, destruction, and administrative seizure, cannot be implemented unless the marketing of the product indicates that it is to be used for human consumption and can modify an organic function.

*Salvia divinorum* and salvinorin A meet the criteria for scheduling a substance under the CDSA. While neither the plant nor salvinorin A are scheduled under any of the UN Drug Control Conventions, a number of countries and American states have taken steps to control the distribution and use of these substances. *S. divinorum* and salvinorin A are pharmacologically similar to other substances included in Schedule III to the CDSA, such as LSD and psilocybin. There are also currently no legitimate therapeutic, commercial or industrial uses for *S. divinorum*. While the potential for physical dependence of *S. divinorum* appears to be low, there is a significant potential for its abuse as a 'legal' hallucinogen. There is very little information with regards to the long-term effects of *S. divinorum* use. There is also evidence of abuse, particularly by Canadian youth and adolescents, and potential for risk to public health and safety.

## 8. RECOMMENDATIONS

## 9. CONSULTATIONS

The Drug Analysis Services (DAS) was contacted in order to provide any data available regarding the identification of salvinorin A in samples submitted by law enforcement.

The Royal Canadian Mounted Police (RCMP) was contacted in order to establish their views with respect to *S. divinorum* use in Canada. The RCMP advised that *S. divinorum* is readily available and law enforcement agencies have no legal means to prevent its sale.

OCS has received a number of correspondences from Canada Border Services Agency (CBSA) officers concerning a lack of information regarding the status of *S. divinorum* and how the plant should be treated at the border. CBSA officers have also expressed concern regarding the plant's hallucinogenic properties. At present, only shipments of *S. divinorum* that are represented as health products that modify organic functions can be refused for import under the NHPR.

OCS brought *S. divinorum* and salvinorin A to the Controlled Substances Scheduling Working Group (CSS-WG) in August 2010 to discuss the possibility of regulatory control of these substances. The CSS-WG recommended that both *S. divinorum* and salvinorin A be included under Schedule III to the CDSA.

## 10. IMPLEMENTATION AND EVALUATION

**Page(s) 001499 to\à 001499**

**Is(Are) exempted pursuant to section(s)  
est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**

# Issue Analysis Summary

DRAFT

*- add to recommend to schedule active ingredients*

## Scheduling *Salvia Divinorum* and Salvinorin A under the CDSA

Regulatory Policy Division  
Office of Controlled Substances

Controlled Substances and Tobacco and Directorate

October 25, 2010

**Comment [S1]:** There should be a discussion on why either on both; this was not discussed by the WG

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### CONTENTS

1. APPROVALS
2. ISSUE
3. PURPOSE
4. CONTEXT
5. ASSESSMENT OF RISKS AND BENEFITS
6. IDENTIFICATION AND ANALYSIS OF OPTIONS
7. CONSIDERATIONS
8. RECOMMENDATION(S)
9. CONSULTATIONS
10. IMPLEMENTATION AND EVALUATION

### 1. APPROVALS

This Issue Analysis Summary is approved.

Jocelyn Kula, A/Director  
Office of Controlled Substances  
Controlled Substances and Tobacco Directorate

[DD/MM/2010]

### 2. ISSUE

Health Canada has received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum* (*S. divinorum*), which is currently not regulated under the *Controlled Drugs and Substances Act* (CDSA). These requests are further to reports from scientific and media sources suggesting that *S. divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has also noted an ongoing media interest regarding the

*S. divinorum*

**Comment [S2]:** There is total inconsistency throughout the document regarding the name; the name should be the same throughout

**Comment [S3]:** I don't believe there has been many enquiries regarding and/or salvinorin A specifically

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availability of *S. divinorum* in Canada.

### 3. PURPOSE

To assess *Salvia divinorum* against the criteria for the addition of a substance to one of the Schedules to the CDSA, and determine whether these substances should be regulated as controlled substances in Canada.

**Comment [S4]:** While the effects of salvinorin A were considered, the assessment was not made on "and/or salvinorin A"

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### 4. CONTEXT

*Salvia divinorum* is a species of sage which belongs to the mint family, and which is found in the form of dried leaves, extract and plant cuttings. Also called "diviner's sage", the plant is known to induce illusions and hallucinations when chewed or smoked. Salvinorin A, the psychoactive ingredient in *S. divinorum* is a neoclerodane diterpene, which is found primarily in the leaves, and to a lesser extent in the stem of the plant.<sup>1</sup>

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*Salvia divinorum* is a substance not currently scheduled under the CDSA. It can be imported and sold legally in Canada to anyone of any age, anywhere in Canada provided it is not represented as a health product or hallucinogen. In addition, the *S. divinorum* sold in Canada is currently not subject to any specific quality or safety standards.

*S. divinorum* is widely touted as a "legal" hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs among adolescents and young adults.<sup>2</sup> While very little is known about how and where *S. divinorum* is sold in Canada, it is suspected that it is mainly purchased over the Internet and/or bought at head shops or alternative life style stores, etc. *S. divinorum* cuttings are also available from a number of garden supply companies.

The use of *S. divinorum* as a psychotropic agent first came to Health Canada's attention in 2002. In 2004, Health Canada received four adverse drug reaction (ADR) reports associated with the use of *S. divinorum* as a hallucinogen, with three being considered non-serious (requiring no medical attention) and the fourth being considered serious (medical intervention was required). The serious ADR report involved the concomitant use of alcohol in a person diagnosed with Attention Deficit Disorder.

Further to the receipt of the aforementioned ADRs, the Marketed Health Products Directorate (MHPD) and the Natural Health Products Directorate (NHPD) of the Health Products and Food Branch (HPFB) prepared an issue analysis summary (IAS) in November 2005, which recommended that *S. divinorum* and its active ingredient salvinorin A be regulated as controlled

<sup>1</sup> U.S. Department of Justice Drug Enforcement Administration. 2002. Drugs and Chemicals of Concern: Salvia Divinorum (salvinorin A, divinorin A) URL:

[http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm) Nov 2008

<sup>2</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.

substances. This recommendation was maintained when the IAS was updated in November 2006.

Later, in December 2005, MHPD and NHPD prepared a Signal Assessment (SA) (updated in June 2007) that eventually led to the preparation of a Health Risk Assessment (HRA), which concluded that *S. divinorum* or salvinorin A-containing health products would constitute a Type II Health Risk according to the Health Hazard Classification of the Recall Policy of the Health Products and Food Branch Inspectorate (HBFBI). Such a risk is defined as “a situation in which the use of, or exposure to, a product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote”.

Further to a discussion with the Assistant Deputy Minister (ADM) of HECS????, in April 2007, the (then) Drug Strategy and Controlled Substances Directorate (DSCSD) (now Controlled Substances and Tobacco Directorate, CSTD) organized a meeting with MHPD, NHPD and HPFBI to discuss *S. divinorum*. HPFBI was to determine appropriate compliance activities regarding *S. divinorum* and consult with the Canada Border Services Agency (CBSA) regarding the movement of products containing *S. divinorum* into and out of Canada.

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On September 13, 2007, a further meeting between (the then) DSCSD, MHPD, NHPD and HPFBI led to the conclusion that DSCSD would conduct a scheduling assessment of *S. divinorum* in order to explore the possibility of scheduling this substance under the CDSA.

In September 2008, the Director Generals of DSCSD, MHPD, TPD and the HPFBI agreed that media lines and an “It’s Your Health” article on *S. divinorum* would be prepared.

#### 4.1 Relevant Legislative Frameworks in Canada

##### 4.1.1 Food and Drug Regulations (under the Food and Drugs Act)

The *Food and Drug Regulations* (F&DR) serve to ensure the safety, efficacy, and quality of health products offered for sale in Canada, including drugs and medical devices. Prior to being given market authorization, a manufacturer must present substantive scientific evidence that their product is safe, efficacious and of high quality. For drugs, Health Canada reviews this information carefully and, if the review is satisfactory, a Notice of Compliance (NOC) is issued and appropriate Drug Identification Numbers (DINs) are assigned.

A “drug” is defined under the F&DR as any substance or mixture of substances manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
- (b) restoration, correction or modification of organic functions in human beings or animals, or

(c) disinfection in premises in which food is manufactured, prepared or kept;

As no products containing *S. divinorum* or its extracts have been reviewed and approved by Health Canada as of October 2010, it is illegal to market *S. divinorum* when it is represented as a drug.



#### 4.1.2 Natural Health Products Regulations (under the Food and Drugs Act)

The *Natural Health Products Regulations* (NHPR) aim to provide Canadians with ready access to natural health products (NHPs) that are safe, effective, and of high quality, while respecting freedom of choice and philosophical and cultural diversity. The NHPR require that all licensed products display a Natural Product Number (NPN), or, in the case of a homeopathic medicine, a Drug Identification Number - Homeopathic Medicine (DIN-HM), on their labels. These numbers are issued once a product is authorized for sale in Canada further to the submission of a product license application in which the applicant attests to all of the conditions set out in a natural health product monograph prepared and published by the Natural Health Products Directorate or submission of a product license application that provides sufficient evidence of quality, safety and efficacy that is assessed and approved by NHPD by the non-compendial route. The NHPR also require that all manufacturers, packagers, labelers, and importers be licensed which in turn requires the presence of procedures respecting distribution records, product recalls, product handling, storage and delivery, and all other aspects of Good Manufacturing Practices as set out in the NHPR.

Robin wrote

The definition of an NHP under the NHPR has both a function and substance component. The function component refers to those substances that are manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
- (b) restoring or correcting organic functions in humans; or
- (c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

The substance component refers to the requirement that all of the medicinal ingredients of an NHP must be substances set out in Schedule 1 to the NHPR, which is a list of included substances. Included substances are those substances that are traditional or homeopathic medicines, and of which none of the ingredients are substances set out in Schedule 2, which is a list of excluded substances. Excluded substances include any substance listed on Schedules I to V of the CDSA. Section 2(2) of the NHPR excludes those substances (except homeopathic medicines) whose sale is required to be pursuant to a prescription as per Section C.01.043 of the

F&DR. As per section 93(1)(b)(vi) of the NHPR, every natural health product must be labeled with its authorized recommended use or purpose. In the case of *S. divinorum*, it is generally marketed for its hallucinogenic properties which are considered a modification of an organic function. Therefore products that contain *S. divinorum* and are manufactured, sold or represented for use as a hallucinogen meet the definition of an NHP.

As of October 2010, no products containing *S. divinorum* have been reviewed and approved by Health Canada and no NPNs or DIN-HMs have been issued for such products. Therefore sales of *S. divinorum* are illegal under the NHPR if it is represented for use as a hallucinogen or if other health claims regarding the modification of organic functions are made.

#### **4.1.3 Controlled Drugs and Substances Act and its Regulations**

The CDSA provides a legislative framework for the control of substances that can alter mental processes and that may produce harm to the health of an individual or to society when diverted or misused. Except as authorized under its regulations, activities such as possession, possession for the purposes of trafficking, trafficking, importation, exportation, possession for the purposes of exportation and production of controlled substances are prohibited under the CDSA.

The substances regulated under the CDSA are grouped into eight Schedules, and each Schedule is associated with particular offences and penalties as described in Part I of the CDSA.

In determining whether a substance should be regulated as a controlled substance, and into which Schedule of the CDSA it should be placed, Health Canada considers a number of factors including:

- International requirements and trends in the control and/or scheduling;
- Chemical and/or pharmacological similarity to substances listed in the Schedules to the CDSA;
- Legitimate use of the substance, including therapeutic, scientific, industrial or commercial uses;
- Potential for abuse and/or addiction liability;
- Evidence of extent of actual abuse of the substance in Canada and internationally; and
- Risk to personal and public health and safety.

#### **4.2 Assessment of *Salvia Divinorum* for Scheduling Purposes**

##### **4.2.1 International Requirements and Trends in the Control and/or Scheduling**

At the present time, neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and therefore do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

##### ***Australia***

In June 2002, Australia became the first country to prohibit the sale, supply, possession and use of *S. divinorum* and salvinorin A. Both *S. divinorum* and salvinorin A are listed in Schedule 9 of Australia's *Standard for the Uniform Scheduling of Drugs and Poisons* on the basis of "high potential for abuse and risk to public health and safety."<sup>3</sup> Schedule 9 is Australia's most restrictive drug schedule, and includes "substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities."<sup>4</sup>

### **Belgium**

A decree was passed in Belgium on October 22, 2006 which added *S. divinorum* to the list of controlled substances. This list includes substances such as psilocybin mushrooms, khat and peyote cactus.<sup>5</sup>

### **Denmark**

In 2003, Denmark added *S. divinorum* and salvinorin A to their list of "category B" controlled substances, a category which also includes psilocybin mushrooms, cocaine, amphetamine, and several others substances that are only legal for medicinal and scientific purposes. Illegal possession carries a penalty of up to two years in prison.

### **Germany**

*S. divinorum* (plant and plant parts) was added to Appendix I of the *Narcotics Act* in Germany on March 1, 2008, making it illegal to produce, traffic, or possess. The law does not specifically mention salvinorin A.

### **Italy**

On June 25, 2004, the Italian Ministry of Health issued an ordinance prohibiting the sale of *S. divinorum* and its active constituent salvinorin A. On January 11, 2005, the Ministry of Health made possession of *S. divinorum* and salvinorin A illegal by placing them in "*Tabella I*" of the *Tabella Sostanze Stupefacenti o Psicotrope*.

### **Japan**

On November 9, 2006, the Japanese government added a group of thirty-three drugs to its list of

<sup>3</sup> <http://www.tga.gov.au/ndpsc/record/rr200111.pdf>

<sup>4</sup> [http://www.cognitiveliberty.org/news/salvia\\_australia.htm](http://www.cognitiveliberty.org/news/salvia_australia.htm)

<sup>5</sup>

<http://eldd.emcdda.europa.eu/html.cfm/index5176EN.html?pluginMethod=eldd.shownewsdetails&id=20/12/2006BELGIUM:%20New%20substances%20controlled%20include%20mCPP%20and%20khat>



controlled substances, including salvinorin A. The drugs are banned under a revised pharmaceutical law, under which persons involved in their illegal import, production, and sale, i.e. beyond medical treatment or research purposes, will be subject to up to five years imprisonment or a fine of up to five million yen.

### ***Spain***

On January 28, 2004, the Spanish Ministry of Health and Consumption issued an order prohibiting the sale of *S. divinorum*. The regulation went into effect on May 6, 2004 and only prohibits activities related to commerce. Possession and/or use are not considered to be criminal offences.

### ***Other Countries***

It is illegal to possess or sell *Salvia divinorum* in Croatia, Latvia, Lithuania, Poland, Romania, South Korea and Sweden. In Russia it is illegal to grow or sell *S. divinorum*, but it is legal to possess it. In Estonia, Finland, Iceland and Norway, *S. divinorum* is treated as a medicinal herb and it is illegal to import it without a relevant prescription from a doctor.

**Deleted:** is illegal to possess or sell

### ***United States of America***

*S. divinorum* and salvinorin A are not included in the Schedules to the United States *Controlled Substances Act* although both *S. divinorum* and salvinorin A have been added to a list of chemicals "of concern" but this has no legal implications. According to the National Institute for Drug Abuse, the Drug Enforcement Agency is considering classifying salvia as a Schedule I drug. This Schedule includes substances such as LSD and marijuana.

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In addition, some individual states have implemented laws restricting its use, sale and/or distribution. As of July 2010, a number of states have enacted legislation placing regulatory controls on *S. divinorum* and/or salvinorin A including Delaware, Georgia, Florida, Hawaii, Illinois, Kansas, Kentucky, Maryland, Mississippi, Missouri, Nebraska, North Dakota, Ohio, Oklahoma, South Dakota, Wisconsin, Virginia, California, Louisiana, Maine, North Carolina, and Tennessee. By way of example, additional details regarding the regulation of *S. divinorum* in these last five states are provided below.

#### ***California***

As of January 1, 2009, the sale or distribution of *S. divinorum* or salvinorin A, or any substance or material containing *S. divinorum* or salvinorin A, to any person under 18 years of age is a misdemeanor punishable by imprisonment in a county jail for not more than six months, a fine of no more than \$1,000, or both.

#### ***Louisiana***

In 2005, Louisiana passed a bill which prohibits the possession, production, manufacture and distribution of a material, compound, mixture, or preparation intended for human consumption and that contains a hallucinogenic plant. A "hallucinogenic plant" is defined as "any part or portion" of a plant on a list of forty plants, which includes *S. divinorum*.

### Maine

In Maine, *S. divinorum* and salvinorin A are regulated in the same way as tobacco products; adults eighteen years of age or over can legally purchase and use the material, but selling or providing *S. divinorum* or salvinorin A to anyone under the age of eighteen is a criminal offence. Possession by a minor is a civil violation, punishable by a fine, community service, or both.

### North Carolina

On December 1, 2009, the North Carolina State Legislature brought a new law into force which made *Salvia divinorum* and salvinorin A illegal. The only legal *S. divinorum* activities are the growing for aesthetic, landscaping, or decorative purposes or university-affiliated medical or pharmacological research.

**Comment [S5]:** Since these are considered legitimate uses, it should be reflected in section 4.2.3

### Tennessee

On July 1, 2006, Tennessee classified the deliberate production, manufacture, distribution, or possession of the active chemical ingredient in the hallucinogenic plant *S. divinorum* as a Class A misdemeanor. It is not, however, a criminal offence to possess, plant, cultivate, grow, or harvest *S. divinorum* for aesthetic, landscaping, or decorative purposes. The law also does not apply to any dosage that is legally obtainable from a retail establishment without a prescription when (and if) it is recognized by the Food and Drug Administration as a homeopathic drug.

**Comment [S6]:** Same comment as for North Carolina

#### 4.2.2 Chemical and/or Pharmacological Similarity to Substances Listed in the Schedules to the CDSA

The psychoactive ingredient in *Salvia divinorum* is the neoclerodane diterpene salvinorin A.<sup>6</sup>

Salvinorin A is an hallucinogen with a distinct structure, and it does not interact with the serotonin type-2A receptor or any other molecular target of classical hallucinogens.<sup>8</sup> Instead, the available

**Comment [HABR7]:** There is little evidence that the terpenoids in cannabis are psychotropic. They are hypothesized to "possibly" contribute to the "high" but there is very little in the way of conclusive evidence on that (vs. what is known about cannabinoids). Terpenoids are mainly thought to contribute to the smell of cannabis. I also don't think this part is really relevant and should be removed.

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<sup>6</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage *Salvia divinorum*. Life Sci. 2005 Dec 22;78(5):527-31.

<sup>8</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. Pharmacotherapy. 2006 Sep;26(9):1268-72.

research suggests the psychotropic effects of salvinorin A are mediated by its agonistic actions at the  $\kappa$ -opioid (KOR) receptor.<sup>9</sup> Its mechanism of action is therefore unique.<sup>10</sup>

The psychoactive effects of *S. divinorum* vary in onset and duration and include perceptual distortions such as the sensation of becoming an object, having visions of various two-dimensional surfaces, films and membranes, revisiting places of the past (particularly childhood), perceived loss of the body and/or identity, various sensations of motion (being pulled or twisted by a force of some kind), uncontrollable hysterical laughter, and overlapping realities (perceptions of being in more than one place).<sup>11</sup> Laughter, happiness, a sense of well-being and dissociative effects were deemed the most positive aspects of *S. divinorum* by users, second only to the "trip" that the drug elicits.<sup>12</sup> Depersonalization, speaking gibberish, widening of consciousness and subjective illusions of rapid movement, flying or hovering have also been reported.<sup>13</sup>

The psychotomimetic effects of *S. divinorum* closely resemble schizoid symptoms induced by lysergic acid diethylamide (LSD) or phencyclidine (PCP).<sup>14</sup> Yet, it is said to have only weak influence on the prevailing mood of the user which differentiates it from other hallucinogens such as LSD and psilocybin.<sup>15</sup> Its strong dissociative effects are often compared to those of ketamine.<sup>16</sup> Users have reported that the psychedelic effects of *S. divinorum* were most similar to those caused by psilocybin mushrooms.<sup>17</sup> However, users familiar with the effects of other hallucinogens agree that despite certain similarities to classical hallucinogens, the visions and overall experience are quite unique.<sup>18</sup>

<sup>9</sup> Roth BL, Baner K, Westkaemper R, Siebert D, Rice KC, Steinberg S, Ernsberger P, Rothman RB. Salvinorin A: a potent naturally occurring nonnitrogenous kappa opioid selective agonist. *Proc Natl Acad Sci U S A*. 2002 Sep 3;99(18):11934-9.

<sup>10</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>11</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>12</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>13</sup> Bücheler R, Gleiter CH, Schworer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5 and Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>14</sup> Bücheler R, Gleiter CH, Schworer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>15</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>16</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five Salvia divinorum herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

<sup>17</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>18</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6 and González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

*S. divinorum* causes an unusually high degree of sedation, weakness and fatigue, while the increased de-realization is not commonly reported for classical psychedelics.<sup>19</sup> The combination of these effects seems to correlate with that of other KOR agonists such as pentazocine.<sup>20</sup>

The onset and intensity of the effects of *Salvia divinorum* appear to be related to the route of administration. Traditional uses generally produce mild effects because the leaves are rolled and chewed or crushed and prepared as a foamy infusion whereby the salvinorin A is degraded in the gastrointestinal system before being absorbed into the bloodstream. Hence, the level of effect relates quite closely to the length of time the material spends in the mouth, with the onset of effect generally taking 5-10 minutes. The effects build over the next hour and last for another hour before they begin to subside.<sup>21</sup>

Routes of administration that avoid the hepatic first-pass effect (i.e. inhalation, intravenous, intramuscular and sublingual use) provide the quickest and most intense effect.<sup>22</sup> Salvinorin A can be isolated from the plant to make a powder which can be vaporized and inhaled. The effects felt from vaporizing salvinorin A are experienced in about 30 seconds, last for about 5-10 minutes, and then subside over the next 30 minutes.<sup>23</sup>

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Smoking the dried leaves or a concentrated extract using a pipe or bong is by far the most popular method of administration.<sup>24</sup> Dried leaves may also be fortified with a concentrated extract of salvinorin A. A concentrated extract can also be used sublingually. Neither *S. divinorum* nor salvinorin A can be injected because the powder is insoluble in water.<sup>25</sup>

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#### 4.2.3 Legitimate Use of the Substance, including Therapeutic, Scientific, Industrial or Commercial Uses

*Salvia divinorum* has traditionally been used for spiritual and medicinal purposes by the Mazatec

<sup>19</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>20</sup> Arasteh K, Poudevida S, Farre M, Roset PN, Cami J. Response patterns of the Spanish version of the 49-item short form of the Addiction Research Center Inventory after the use of sedatives, stimulants, and opioids. *Drug Alcohol Depend.* 1999 Jun 1;55(1-2):117-25.

<sup>21</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>22</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.

<sup>23</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>24</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62 and Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>25</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (*divinorin*) A. *J Psychoactive Drugs.* 1994 Jul-Sep;26(3):277-83.

Indians in Oaxaca, Mexico<sup>26</sup>. For medicinal purposes (gastrointestinal problems, headaches, rheumatism, anemia and swelling of the stomach<sup>27</sup>) an infusion of the leaves or the leaves themselves are ingested. Its main use today is, however, for its psychedelic properties in the aid of producing "mystical" or hallucinogenic experiences as part of spiritual rituals.<sup>29</sup>

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Comment [HABR8]: Where? In Western society?

Deleted: to treat gastrointestinal problems, headaches, rheumatism, anemia and swelling of the stomach.<sup>28</sup>

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Comment [S9]: We need to verify that

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Although selective KOR agonists have been shown to produce analgesic effects, adverse effects such as psychotomimesis, dysphoria and diuresis have been observed limiting further studies investigating their therapeutic use<sup>30</sup>. In addition, while it has been speculated that KOR agonists may be useful in the treatment of certain psychiatric disorders including Alzheimer's disease, schizophrenia, dementia and bipolar disorder,<sup>31</sup> but there has been no clinical research to support these hypotheses. That said there are presently no recognized medical uses for *S. divinorum* in Canada.

Similarly, there are no known industrial or commercial uses for *S. divinorum* in Canada. Most websites offering *S. divinorum* cuttings and seeds for sale appear to do so in the context of growing the plant for "recreational" purposes, rather than out of horticultural interest or for its esthetic appeal. *S. divinorum* is also marketed as incense. However, there is no evidence that *S. divinorum* has any fragrant properties that would legitimize such a use. Therefore it is believed that the marketing of this plant as an incense is a means to avoid compliance and enforcement actions by Health Canada.

\* decorative purpose

#### 4.2.4 Potential for Abuse and/or Addiction Liability

Salvinorin A is a potent, KOR selective agonist and in contrast to the euphoria produced by MOR agonists such as morphine, KOR agonists are negatively reinforcing and aversive. In addition, KOR agonists have analgesic properties but are not associated with respiratory depression like MOR agonists. Finally, while MOR agonists increase the release of dopamine, the activation of KOR decreases dopamine release in the nucleus accumbens.<sup>33</sup> In the case of

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Comment [HABR11]: Reference needed.

<sup>26</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>27</sup> Munro, T. The Chemistry of Salvia divinorum. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

<sup>29</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage Salvia divinorum. Life Sci. 2005 Dec 22;78(5):527-31.

<sup>30</sup> Barker RL, Fawcett J, Barkin SJ. 2002. Chronic pain management with a focus on the role of newer antidepressants and centrally acting agents. In: Pain Management: A Practical Guide for Clinicians, 6th edition, Weiner RS ed. CRC Press, Boca Raton, FL. pp. 415-34 and Tidgewell et al., 2004. A facile method for the preparation of deuterium labelled salvinorin A: Biorganic & Medicinal Chemistry Letters, 14: 5099-5102.

<sup>31</sup> Sheffler DJ & Roth BL. Salvinorin A: the 'magic mint' hallucinogen finds a molecular target in the kappa opioid receptor. Trends Pharmacol Sci. 2003 Mar;24(3):107-109.

<sup>33</sup> Gustein HB & Akil H. Opioid Analgesics. In: Goodman and Gilman's The Pharmacological Basis of Therapeutics 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.

MOR agonists, the increase of dopamine acts as a positive reinforcer. This action motivates the user to use the drug again, which could lead to drug abuse and/or addiction. For KOR agonists, this is not the case.

The aversive effects of KOR agonists suggest that the risk of addiction to *S. divinorum* is negligible. However, very few controlled scientific studies of the physical and psychotropic effects of *S. divinorum* on humans have been carried out and the results have been conflicting. For example, one author states: "Many who have used salvinorin A find the experience extremely unnerving, frightening and overly intense and most have no desire to repeat the experience."<sup>34</sup> However, another study suggested that this is not the experience of all recreational users of *S. divinorum*.<sup>35</sup> Over eighty percent of users surveyed on a web-based questionnaire about their *S. divinorum* use said that they would probably or definitely use *S. divinorum* again.<sup>36</sup> Users have reported the negative effects of *S. divinorum* as: the short duration of action, lack of control over the experience, persisting negative effects (most often anxiety),<sup>37</sup> sweating, chills, increased diuresis, impaired vigilance,<sup>38</sup> and negative after-effects including tiredness, feeling head heavy, dizziness, physical exhaustion, and some degree of malaise or 'hangover' as they 'comedown' from the drug.<sup>39</sup>

In addition, some users have noted that they require increasing doses of salvinorin A in order to achieve the desired effect and the stimulated cerebral KOR may act as a mechanism of tolerance.<sup>40</sup> Further studies in this area and on the KOR mediated decrease of dopamine are also required in order to fully understand the addiction potential of this substance.

While concerns for the potential of abuse were initially considered minimal given that 1 kg of dried leaves only yield 3 to 6 human doses of salvinorin A for oral consumption, it was then discovered that vaporizing and inhaling 200-500 micrograms had profound hallucinogenic

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**Comment [HABR12]:** Oral? What kind of doses are we talking about?

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<sup>34</sup> Turner DM. Salvinorin - The Psychedelic Essence of Salvia Divinorum. Panther Press, San Francisco, CA 1996.

<sup>35</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62, Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5, and Valdés LJ 3rd. Salvia divinorum and the unique diterpene hallucinogen, Salvinorin (divinorin) A. J Psychoactive Drugs. 1994 Jul-Sep;26(3):277-83.

<sup>36</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>37</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>38</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5.

<sup>39</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>40</sup> Bucheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5.

effects.<sup>41</sup> Given that only small doses of this substance are now necessary to achieve the desired effects through inhalation, the potential for abuse is much higher. Also, the extraction of salvinorin A from the plant is simple, and with care, approximately 1.5 grams of pure salvinorin A per kilogram of dried leaves (8kg of fresh leaves) can be isolated. This is enough for 2000 human doses.<sup>42</sup>

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#### 4.2.5 Evidence of Extent of Actual Abuse of the Substance in Canada and Internationally

In Canada, the prevalence of the use *Salvia divinorum* has recently been documented. Questions about the use of *S. divinorum* were included in the 2009 Ontario Student Drug Use and Health Survey, the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey.

The results from the 2009 Ontario Student Drug Use and Health Survey were published on November 18, 2009 and indicate that:

- Among all responding students in Ontario, 4.4% reported using *Salvia divinorum* at least once in the past year. In comparison, 58.2% indicated they had used alcohol, 25.6%

<sup>41</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>42</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs.* 1994 Jul-Sep;26(3):277-83.

<sup>49</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

indicated they had used cannabis and 5.0% indicated they had used hallucinogens other than LSD and PCP in the past year;

- Males (6.2%) were significantly more likely than females (2.3%) to report using *Salvia divinorum*;
- There is significant grade variation, with *Salvia divinorum* use most likely among 11<sup>th</sup> graders (8.6%) and 12<sup>th</sup> graders (8.4%); and

The results of the 2008-2009 Youth Smoking Survey were published on May 31, 2010 and indicate that:

- 4.9% of students stated that they had used *S. divinorum* in the last twelve months. In comparison, 53.0% indicated they had used alcohol, 27.3% indicated they had used cannabis and 6.9% indicated they had used other hallucinogens in the last twelve months;
- 2.6% of students in Grades 7-9 and 7.0% of students in Grades 10-12 had used *S. divinorum* in the last twelve months; and
- Males (6.6%) were more likely to have used *S. divinorum* in the past twelve months compared to females (3.2%).

**Deleted:** <#>There are significant regional variations, with students in Northern Ontario (9.2%) most likely to use *Salvia divinorum*.¶

The Canadian Alcohol and Drug Use Monitoring Survey specifically examined salvia for the first time in 2009. An estimated 1.6% of Canadians, aged 15 years and older, reported that they had used salvia in their lifetime, and 0.2% reported using it in the past-year. In comparison, the prevalence of past-year cannabis use among Canadians 15 years of age and older was 10.6%, while 1.2% of respondents reported using cocaine or crack in the past 12 months, 0.9% ecstasy and 0.7% illicit hallucinogens. *Salvia* appears however to be a substances that is tried largely by youth with a 7.3% prevalence of lifetime use.

**Deleted:** The scope of the previously mentioned studies did not provide for any explanations regarding differences in usage between ages, genders and regions. In this regard, it is difficult to speculate on the causality of such differences.¶

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Health Canada's Drug Analysis Services (DAS) has identified salvinorin A in a number of samples seized by law enforcement, as shown in the following table. It is, however, difficult to determine how this data reflects the extent of actual abuse of salvinorin A in Canada.

**NUMBER OF SAMPLES FOUND TO CONTAIN SALVINORIN A**

Year	Count
2006	9
2007	8
2008	4
2009	20
2010 (as of May 7)	8

text

The National Forensic Laboratory Information System (NFLIS) and the System to Retrieve Information from Drug Evidence (STRIDE) in the United States are Drug Enforcement Agency (DEA) databases that collect scientifically verified data on analyzed samples in state and local forensic labs as well as samples from DEA labs. The following table shows the quantity of *S. divinorum* products that were seized from 2000 through to 2009.

**ANALYZED SALVIA DIVINORUM or SALVINORIN A SEIZURES**



(Number of Items/Exhibits)

Source	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009*
NFLIS-State/Local <sup>1</sup>	0	0	0	0	1	8	12	12	70	34
STRIDE <sup>2</sup>	0	0	1	1	1	0	0	0	N/A	N/A
<b>TOTAL</b>	0	0	1	1	2	8	12	12	70	34

Data Source: NFLIS & STRIDE, 2008 data queried 11/24/08, updated 06/10/2010

<sup>1</sup> NFLIS reported seizures of *Salvia divinorum* and/or salvinorin A

<sup>2</sup> STRIDE reported items of *Salvia divinorum*.

\* Includes only January – May data in 2009.

*text*

Once again, it is difficult to determine how this data can be used to reflect the actual extent of abuse of *S. divinorum* and salvinorin A in the United States.

*only seizures  
etc legal  
seized by accident  
think it something  
else.*

The increase in both the number of enquiries to Health Canada from various municipalities and members of the public and the amount of media interest regarding the availability of *Salvia divinorum* in Canada may be an indication that the recreational use of *S. divinorum* as a hallucinogen is on the rise, but it may also only reflect an increased awareness of the phenomenon.

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#### 4.2.6 Risk to Personal and Public Health and Safety

The potential for harm to the user and/or other individuals is primarily related to the hallucinogenic properties of the substance. As this substance is typically smoked, there is no risk of infectious disease transmission as is the case when a drug is injected. Users may get up and walk around without apparent awareness of their movements, behaviour or surroundings, and distinction between self and surroundings is often lost. At doses greater than 1mg of salvinorin A, out of body experiences are frequent and loss of consciousness has been reported.<sup>49</sup> There is little information regarding the social behaviours of persons under the influence of *S. divinorum* products, and what risks their activities such as operating a motorized vehicle may pose to the general public. There is also very little data regarding the toxicity, teratogenicity or other long-term effects of *S. divinorum* use.<sup>50</sup>

Deleted: The increase in both the number of enquiries from various municipalities and members of the public and the amount of media interest regarding the availability of *Salvia divinorum* in Canada may be an indication that the recreational use of *S. divinorum* as a hallucinogen is on the rise. However, there are no available statistics that indicate there has been a significant increase in *S. divinorum* use in the Canadian population. ¶

As far as law enforcement is concerned, the Department has only received a limited number of communications indicating concern with respect to *S. divinorum*. The Royal Canadian Mounted Police (RCMP) has stated that while *S. divinorum* is readily available, it has not become a popular drug in Canada, probably due to its aversive effects such as anxiety and introversion.

A handful of case reports regarding physiological and psychotropic effects of *S. divinorum* use have been published in the scientific/medical literature. For example, an international case report described the perceptions of a 19 year-old man after inhaling *S. divinorum* smoke. The peak psychotropic effects, including prickling of the skin, fever-like hot flashes, muscular tremor, and depersonalization, were reached in less than five minutes after inhalation of an unknown amount

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Deleted: A

<sup>50</sup> Grundmann O, Phipps SM, Zadezensky I, Butterweck V. *Salvia divinorum* and Salvinorin A: An Update on Pharmacology and Analytical Methodology. *Planta Med* 2007 Jun;73:1039-1046.

*CBSA stop w/ health claim  
at border? → where.*

s.21(1)(a)

s.21(1)(b)

of smoke from burning dried leaves.<sup>51</sup> Another report involved a 15-year-old male who presented to psychiatric emergency services with acute onset of paranoia, déjà vu, blunted affect, difficulties in thought processing and slowed speech after smoking *Salvia divinorum* over an unknown period of time. During his hospitalization all symptoms improved significantly except the feeling of déjà vu. Based on this case presentation, the author suggested that the feelings of déjà vu may be a long-term effect of *S. divinorum* use.<sup>52</sup> However, given that this is the only case report in which déjà vu was associated with the use of *S. divinorum*, more reports are needed to substantiate this finding.

In addition to the above-mentioned reports, in 2006, a case was reported in the U.S. in which a 17-year-old boy committed suicide after smoking *S. divinorum* for an unknown period of time.<sup>53</sup> It should be noted that alcohol and general depression were the main confounders in this case. After this case was reported, the state of Delaware passed a law which classified *S. divinorum* as a Schedule I controlled substance along with other hallucinogenic substances.

Like many drugs of abuse, users are often unaware of the potency and adulterants in the product they purchase. A study by Wolowich *et al.* (2006), showed that the salvinorin A content in five out of five *S. divinorum* products was falsely indicated on the label and 4 out of 5 products contained unidentified adulterants (i.e. vitamin E, caffeine).<sup>54</sup>

There are also several reports of domestic adverse reactions related to the use of *S. divinorum* that have been received through the Canada Vigilance database. However, this does not reflect true incidence due to under-reporting.

5. ASSESSMENT OF RISKS AND BENEFITS

*of substance?*

6. IDENTIFICATION AND ANALYSIS OF OPTIONS

**Deleted:** Information found in scientific literature about the use and abuse of *S. divinorum* indicates that *S. divinorum* may pose a risk to the health and safety of Canadians. T

**Page(s) 001516 to\à 001517**

**Is(Are) exempted pursuant to section(s)  
est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**

## 7. CONSIDERATIONS

The KOR-mediated aversive and dysphoric effects of *Salvia divinorum* do not appear to be hampering its use as young adults are smoking the leaves and leaf extract recreationally.<sup>56</sup> It can be purchased through online botanical companies and other drug promotion sites and is often touted as a legal alternative to substances such as cannabis and mescaline.<sup>57</sup> Interestingly, after being widely available for over a decade, the drug does not appear to have had the same social impact as LSD or ecstasy.<sup>58</sup>

**Comment [S19]:** Should also reference CADUMS

**Deleted:** have begun

**Comment [S20]:** We don't know about increase/decrease use

The NHPR are limited in their capacity to control the availability of *S. divinorum* in that *S. divinorum* products are often declared as incense and therefore cannot be considered unapproved natural health products. In addition, compliance and enforcement actions such as voluntary stop-sales, forfeiture, destruction, and administrative seizure, cannot be implemented unless the marketing of the product indicates that it is to be used for human consumption and can modify an organic function.

**Deleted:** While there has been an increase over the past few years in the number of enquiries from various municipalities and members of the public regarding the availability of *Salvia divinorum* as a hallucinogen, there does not appear to be a significant increase in the reported use of this substance. ¶

regulation  
vs  
non-regulatory.

*Salvia divinorum* and salvinin A meet the criteria for scheduling a substance under the CDSA. While neither the plant nor salvinin A are scheduled under any of the UN Drug Control Conventions, a number of countries and American states have taken steps to control the distribution and use of these substances. *S. divinorum* and salvinin A are pharmacologically similar to other substances included in Schedule III to the CDSA, such as LSD and psilocybin. There are also currently no legitimate therapeutic, commercial or industrial uses for *S. divinorum*.

While the addiction potential of *S. divinorum* appears to be low, there is a significant potential for its abuse as a 'legal' hallucinogen. There is very little information with regards to the long-term effects of *S. divinorum* use. There is also evidence of abuse, particularly by Canadian youth and potential for health risks as well as risks to public health and safety.

**Deleted:** for physical dependence

**Deleted:** and adolescents;

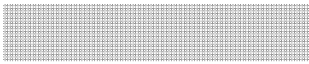
**Deleted:** for

**Deleted:** ¶

## 8. RECOMMENDATIONS

<sup>57</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

<sup>58</sup> Munro, T. The Chemistry of *Salvia divinorum*. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.



**9. CONSULTATIONS**

The Drug Analysis Services (DAS) was contacted in order to provide any data available regarding the identification of salvinorin A in samples submitted by law enforcement.

**s.21(1)(a)**  
**s.21(1)(b)**

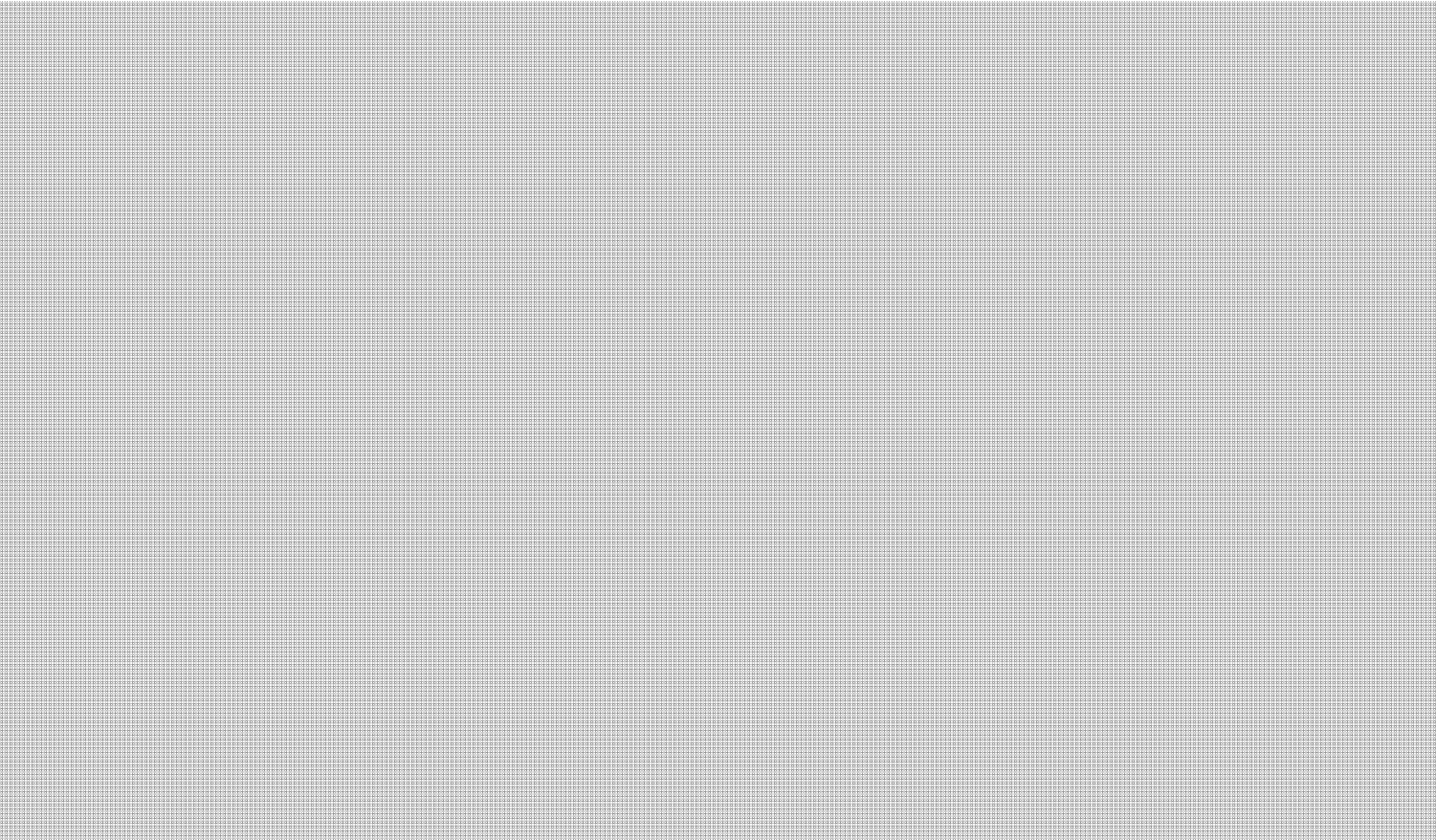
The Royal Canadian Mounted Police (RCMP) was contacted in order to establish their views with respect to *S. divinorum* use in Canada. The RCMP advised that *S. divinorum* is readily available and law enforcement agencies have no legal means to prevent its sale.

OCS has received a number of correspondences from Canada Border Services Agency (CBSA) officers concerning a lack of information regarding the status of *S. divinorum* and how the plant should be treated at the border. CBSA officers have also expressed concern regarding the plant's hallucinogenic properties. At present, only shipments of *S. divinorum* that are represented as health products that modify organic functions can be refused for import under the NHPR.

OCS brought *S. divinorum* and salvinorin A to the Controlled Substances Scheduling Working Group (CSS-WG) in August 2010 to discuss the possibility of regulatory control of these substances. After assessing the available information against the 6 criteria, the CSS-WG recommended that both *S. divinorum* and salvinorin A be included under Schedule III to the CDSA.

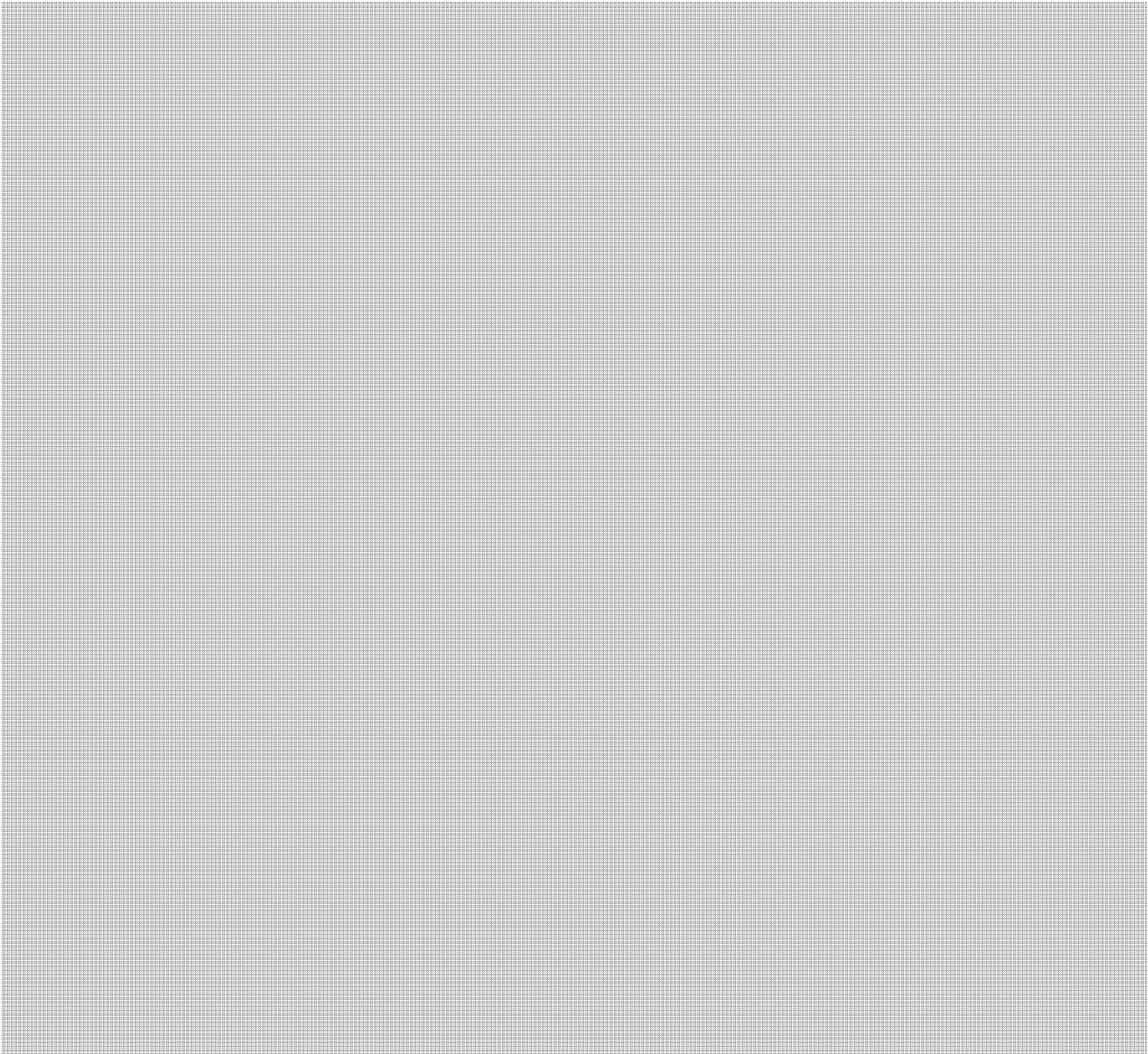
**Comment [S21]:** Need a para regarding whether to schedule salvia and/ salvinorin a; that was not discussed by the WG  
**Deleted:** Th

**10. IMPLEMENTATION AND EVALUATION**



s.21(1)(a)  
s.21(1)(b)

It is difficult to determine the extent of actual abuse of *S. divinorum* in Canada or elsewhere as there appear to be inconsistencies in the literature regarding risk aversion. For example, one author states: "Many who have used salvinorin A find the experience extremely unnerving, frightening and overly intense and most have no desire to repeat the experience."<sup>1</sup> However, another study suggested that this is not the experience of all recreational users of *S. divinorum*.<sup>2</sup> Over eighty percent of users surveyed on a web-based questionnaire about their *S. divinorum* use said that they would probably or definitely use *S. divinorum* again.<sup>3</sup> Users have reported the negative effects of *S. divinorum* as: the short duration of action, lack of control over the experience, persisting negative effects (most often anxiety),<sup>4</sup> sweating, chills, increased diuresis, impaired vigilance,<sup>5</sup> and negative after-effects including tiredness, feeling head heavy, dizziness, physical exhaustion, and some degree of malaise or 'hangover' as they 'comedown' from the drug.<sup>6</sup>



**Page(s) 001521 to\à 001521**

**Is(Are) exempted pursuant to section(s)  
est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**

s.19(1)



**Fw: Legal status of Salvia**  
Isabel Shanahan to: Stephanie Chandler

2010-10-26 10:50 AM

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Isabel Shanahan  
Assistant to the Manager  
Policy & Regulatory Affairs Division  
Office of Controlled Substances  
Healthy Environments and Consumer Safety Branch  
Tel: (613) 946-0123 Fax: (613) 946-4224

----- Forwarded by Isabel Shanahan/HC-SC/GC/CA on 2010-10-26 10:50 AM -----

From: OCS-BSC/HC-SC/GC/CA  
To: [REDACTED]  
Date: 2010-10-26 10:44 AM  
Subject: Legal status of Salvia

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Dear [REDACTED]

I am writing in response to your email enquiry dated October 6, 2010, in which you have requested information concerning the legal status of Salvia.

In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA). However, when *S. divinorum* is marketed with a claim to modify brain function (such as for use as a hallucinogen), it meets the definition of a natural health product under the *Natural Health Products Regulations* (NHPR). It is illegal to manufacture, sell or provide natural health products without their being authorized by Health Canada prior to sale. As of October 2010, no such products containing *S. divinorum* or salvinorin A have been authorized for sale by Health Canada.

*Salvia divinorum* products that are not in compliance with the NHPR may be subject to compliance and enforcement action by Health Canada. Complaints about the illegal sale of drugs containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

Health Canada recommends that you avoid using this plant because very little is known about the effects it may have on your body and/or brain functions. There is also no way to predict how it will affect you with each use. Health Canada is currently reviewing all the available information regarding *Salvia divinorum* to determine whether it should be regulated under the CDSA.

Please do not hesitate to contact me should you have any further questions.

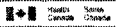
001522



Sincerely,


Jocelyn Kula  
A/Director  
Office of Controlled Substances  
Controlled Substances and Tobacco Directorate  
Healthy Environments and Consumer Safety Directorate  
(613) 952-2177

Notice of Intent  
-after JK approves.

 Health Canada / Santé Canada

## Scheduling Substances under the *Controlled Drugs and Substances Act*

CSS-WG Discussion  
October 27, 2010



Canada

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### OUTLINE

- Purposes
- Background
- Proposed EAC
- Draft CDSA Scheduling Policy Document
- CDSA Scheduling Process
- Proposed Next Steps



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### PURPOSES

1. To present a draft policy setting out the process by which substances are scheduled under the *Controlled Drugs and Substances Act* (CDSA)
2. To seek approval to consult stakeholders on a draft policy that proposes the establishment of an Expert Advisory Committee (EAC) to support CDSA scheduling



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### BACKGROUND (1)

- In 2007, stakeholders criticized the transparency and rigour of the CDSA scheduling process
  - Former ADM launched the Scheduling Transparency Project
- In response to recommendations presented in a 2008 external contractor review of CDSA scheduling process:
  1. The Controlled Substances Scheduling Working Group, a HECSB-HPFB committee, has been established to coordinate CDSA scheduling assessments and improve the timing of info-sharing between Branches
  2. HC will continue to publish Notices to Interested Parties in *Canada Gazette* (CG) Part I to provide public with (a) an opportunity to comment on proposals and (b) a point of contact for those seeking more info



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### BACKGROUND (2)

3. CSTD has developed a draft public policy document describing the CDSA scheduling process, including the key scheduling factors
  4. CSTD has decided to publish decision documents, similar to HPFB Summary Basis of Decisions, which will enhance transparency of CDSA scheduling process
- In addition, the 2008 External Review highlighted that many jurisdictions, e.g., US, UK, EU, Australia, New Zealand, etc. have an expert/external advisory committee to support their scheduling process



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### PROPOSED EAC (1)

- **Rationale** – Stakeholders demanding for more openness and transparency in regulatory decision-making has led to a call for greater defensibility
- **Mandate** - To provide CSTD with expert medical/scientific advice on:
  - Addiction liability, potential for abuse, health risks, etc. of a substance
  - How a substance under review compares, based on the factors identified above, to substances currently scheduled under the CDSA
  - Any other issues/questions presented by the DG, CSTD



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### PROPOSED EAC (2)

- **Membership** - experts on abuse, addiction, pharmacology of substances of abuse, epidemiology
  - Ad hoc representation of law enforcement, criminology, social work
- **Examples of EAC Role/Function:**
  - Determine how to Salvia and other plants with psychoactive properties that are currently unscheduled, e.g., Jimson Weed, morning glory, compare with substances scheduled under CDSA
  - Independently review abuse and addiction data in controversial cases, e.g., tramadol, in order to further support the defensibility of scheduling assessments



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### CDSA SCHEDULING PROCESS (1)

- 1. Substance Identification**
  - United Nations decision to schedule substances under international drug control conventions
  - Info on abuse/addiction/liability/other risk of substance
- 2. Info Collection and Preliminary Review**
  - Info collected from a variety of sources
  - CSS-WG establishes substance profile and determines whether sufficient info for CDSA scheduling assessment, could request advice from proposed EAC
- 3. Notice to Interested Parties in CG, Part I (optional)**
  - Notices not be published for new pharmaceuticals



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### CDSA SCHEDULING PROCESS (2)

- 4. CDSA Scheduling Assessment**
  - Development of an Issue Analysis Summary (IAS) reflective of available info, assessing substance against 6 CDSA scheduling factors
  - CSS-WG reviews IAS and makes a scheduling recommendation
  - CSS-WG could recommend that advice be sought from proposed EAC before finalising its recommendation
- 5. Scheduling Decision**
  - CSS-WG makes scheduling recommendation to CSTD senior management for approval



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### CDSA SCHEDULING PROCESS (3)

#### 6. Federal Regulatory Process

- Pre-publication of proposed regulation in CG Part I with comment period (minimum of 30 days)
- CSS-WG could request advice from the EAC on issues/questions raised during this process
- Development of final regulation and publication in CG Part II

#### 7. Public Notification of Scheduling Decision

- CDSA Scheduling Decision document published on HC website to provide a summary of scientific info considered during CDSA scheduling assessment
- Confidential business information and other sensitive info will not be disclosed, in accordance with the *Privacy Act*



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### PROPOSED NEXT STEPS

- **Fall 2010:** ADM decision on including the proposed EAC in the draft CDSA scheduling policy for external consultation
- **Winter 2010:** release of draft *Policy on the Scheduling of Substances under the CDSA* for external consultation
- **Spring 2011:** Consultation of key stakeholders, e.g., relevant industries, trade associations, national associations, P/T licensing authorities for pharmacy, medicine, etc.
- **Fall 2011:** Release of final CDSA Scheduling Policy for Controlled Substances



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Shouldn't Salmia<sup>IAS</sup> have:  
1 - gone to Jk for approval  
2 - NOI  
3 - CSS-WG reviews IAS  
?

- DG sign off before  
Notice of Intent?



**Fw: NHP Importation (for Salvia IAS)**

Courtney Smith to: Tiana Branch, Stephanie Chandler

2010-10-27 05:53 PM

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History: This message has been replied to.

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Hi both - I received an out of office from Denis and Tiffany, and am passing along to you.

---- Forwarded by Courtney Smith/HC-SC/GC/CA on 2010-10-27 05:52 PM ----

**NHP Importation (for Salvia IAS)**

Courtney Smith to: Denis Arsenault

2010-10-27 05:51 PM

Cc: Tiffany Thornton

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As discussed. Something to this effect may clarify statements relating to import under the NHPR in the 'context' and the 'options'.

*S. divinorum* can be legally imported and sold in Canada. However, if an *s.divinorum* product is marketed with a health claim, it would meet the definition of an NHP. This means that while the domestic sale, and the importation for sale, of these products would be prohibited in the absence of a market authorization, importation of limited quantities for personal use would be permitted. Therefore this substance is easily accessible.

I will have to follow up regarding the availability of border stats (I'm unsure if we have this information available).

# Issue Analysis Summary

DRAFT

## Scheduling *Salvia Divinorum* under the CDSA

Regulatory Policy Division  
Office of Controlled Substances  
Controlled Substances and Tobacco and Directorate

October 27, 2010

### CONTENTS

1. APPROVALS
2. ISSUE
3. PURPOSE
4. CONTEXT
5. ASSESSMENT OF RISKS AND BENEFITS
6. IDENTIFICATION AND ANALYSIS OF OPTIONS
7. CONSIDERATIONS
8. RECOMMENDATION(S)
9. CONSULTATIONS
10. IMPLEMENTATION AND EVALUATION

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### 1. APPROVALS

This Issue Analysis Summary is approved.

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Jocelyn Kula, A/Director  
Office of Controlled Substances  
Controlled Substances and Tobacco Directorate

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[DD/MM/2010]

### 2. ISSUE

Health Canada has received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum* (*S. divinorum*,) which is not currently regulated under the *Controlled Drugs and Substances Act* (CDSA). These requests are further to reports from scientific and media sources suggesting that *S. divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has also noted an ongoing media interest regarding the

availability of *S. divinorum* in Canada.

### 3. PURPOSE

To assess *S. divinorum* against the criteria for the addition of a substance to one of the Schedules to the CDSA, and determine whether these substances should be regulated as controlled substances in Canada.

### 4. CONTEXT

*S. divinorum* is a species of sage which belongs to the mint family, and which is found in the form of dried leaves, extract and plant cuttings. Also called "diviner's sage", the plant is known to induce illusions and hallucinations when chewed or smoked. Salvinorin A, the psychoactive ingredient in *S. divinorum* is a neoclerodane diterpene which is found primarily in the leaves, and to a lesser extent in the stem of the plant.<sup>1</sup>

*S. divinorum* is widely touted as a "legal" hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs among adolescents and young adults.<sup>2</sup> While very little is known about how and where *S. divinorum* is sold in Canada, it is suspected that it is mainly purchased over the Internet and/or bought at head shops or alternative life style stores, etc. *S. divinorum* cuttings are also available from a number of garden supply companies.

*S. divinorum* is a substance not currently scheduled under the CDSA. It can be imported and sold legally in Canada to anyone of any age, anywhere in Canada provided it is not sold as a health product or hallucinogen. In addition, the *S. divinorum* sold in Canada is currently not subject to any specific quality or safety standards.

The use of *S. divinorum* as a psychotropic agent first came to Health Canada's attention in 2002. In 2004, Health Canada received four adverse drug reaction (ADR) reports associated with the use of *S. divinorum* as a hallucinogen, with three being considered non-serious (requiring no medical attention) and the fourth being considered serious (medical intervention was required). The serious ADR report involved the concomitant use of alcohol in a person diagnosed with Attention Deficit Disorder.

Further to the receipt of the aforementioned ADRs, the Marketed Health Products Directorate (MHPD) and the Natural Health Products Directorate (NHPD) of the Health Products and Food Branch (HPFB) prepared an issue analysis summary (IAS) in November 2005, which recommended that *S. divinorum* and its active ingredient salvinorin A be regulated as controlled

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<sup>1</sup> U.S. Department of Justice Drug Enforcement Administration. 2002. Drugs and Chemicals of Concern: Salvia Divinorum (salvinorin A, divinorin A) URL:

[http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm) Nov 2008

<sup>2</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.



substances. This recommendation was maintained when the IAS was updated in November 2006.

Later, in December 2005, MHPD and NHPD prepared a Signal Assessment (SA) (updated in June 2007) that eventually led to the preparation of a Health Risk Assessment (HRA), which concluded that *S. divinorum* or salvinorin A-containing health products would constitute a Type II Health Risk according to the Health Hazard Classification of the Recall Policy of the Health Products and Food Branch Inspectorate (HBFBI). Such a risk is defined as “a situation in which the use of, or exposure to, a product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote”.

Further to a discussion with the Assistant Deputy Minister (ADM) of the Healthy Environments and Consumer Safety Branch (HECSB) in April 2007, the (then) Drug Strategy and Controlled Substances Directorate (DSCSD) (now Controlled Substances and Tobacco Directorate, CSTD) organized a meeting with MHPD, NHPD and HPFBI to discuss *S. divinorum*. HPFBI was to determine appropriate compliance activities regarding *S. divinorum* and consult with the Canada Border Services Agency (CBSA) regarding the movement of products containing *S. divinorum* into and out of Canada.

On September 13, 2007, a further meeting between DSCSD, MHPD, NHPD and HPFBI led to the conclusion that DSCSD would conduct a scheduling assessment of *S. divinorum* in order to explore the possibility of scheduling this substance under the CDSA.

In September 2008, the Director Generals of DSCSD, MHPD, TPD and the HPFBI agreed that media lines and an “It’s Your Health” article on *S. divinorum* would be prepared.

#### **4.1 Relevant Legislative Frameworks in Canada**

##### **4.1.1 Food and Drug Regulations (under the Food and Drugs Act)**

The *Food and Drug Regulations* (F&DR) serve to ensure the safety, efficacy, and quality of health products offered for sale in Canada, including drugs and medical devices. Prior to being given market authorization, a manufacturer must present substantive scientific evidence that their product is safe, efficacious and of high quality. For drugs, Health Canada reviews this information carefully and, if the review is satisfactory, a Notice of Compliance (NOC) is issued and appropriate Drug Identification Numbers (DINs) are assigned.

A “drug” is defined under the F&DR as any substance or mixture of substances manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
- (b) restoration, correction or modification of organic functions in human beings or animals, or

- (c) disinfection in premises in which food is manufactured, prepared or kept;

As no products containing *S. divinorum* or its extracts have been reviewed and approved by Health Canada as of October 2010, it is illegal to market *S. divinorum* when it is represented as a drug.

#### **4.1.2 Natural Health Products Regulations (under the Food and Drugs Act)**

The *Natural Health Products Regulations* (NHPR) aim to provide Canadians with ready access to natural health products (NHPs) that are safe, effective, and of high quality, while respecting freedom of choice and philosophical and cultural diversity. The NHPR require that all licensed products display a Natural Product Number (NPN), or, in the case of a homeopathic medicine, a Drug Identification Number - Homeopathic Medicine (DIN-HM), on their labels. These numbers are issued once a product is authorized for sale in Canada further to the submission of a product license application. In this application, the applicant attests to all of the conditions set out in a natural health product monograph prepared and published by the Natural Health Products Directorate. The applicant may also submit a product license application that provides sufficient evidence of quality, safety and efficacy that is assessed and approved by NHPD by the non-compendial route. The NHPR also require that all manufacturers, packagers, labelers, and importers be licensed which in turn requires the presence of procedures respecting distribution records, product recalls, product handling, storage and delivery, and all other aspects of Good Manufacturing Practices as set out in the NHPR.

The definition of an NHP under the NHPR has both a function and substance component. The function component refers to those substances that are manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
- (b) restoring or correcting organic functions in humans; or
- (c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

The substance component refers to the requirement that all of the medicinal ingredients of an NHP must be substances set out in Schedule 1 to the NHPR, which is a list of included substances. Included substances are those substances that are traditional or homeopathic medicines, and of which none of the ingredients are substances set out in Schedule 2, which is a list of excluded substances. Excluded substances include any substance listed on Schedules I to V of the CDSA. Section 2(2) of the NHPR excludes those substances (except homeopathic medicines) whose sale is required to be pursuant to a prescription as per Section C.01.043 of the F&DR. As per section 93(1)(b)(vi) of the NHPR, every natural health product must be labeled with its authorized recommended use or purpose. In the case of *S. divinorum*, it is generally

marketed for its hallucinogenic properties which are considered a modification of an organic function. Therefore products that contain *S. divinorum* and are manufactured, sold or represented for use as a hallucinogen meet the definition of an NHP.

As of October 2010, no products containing *S. divinorum* have been reviewed and approved by Health Canada and no NPNs or DIN-HMs have been issued for such products. Therefore sales of *S. divinorum* are illegal under the NHPR if it is represented for use as a hallucinogen or if other health claims regarding the modification of organic functions are made.

#### **4.1.3 Controlled Drugs and Substances Act and its Regulations**

The CDSA provides a legislative framework for the control of substances that can alter mental processes and that may produce harm to the health of an individual or to society when diverted or misused. Except as authorized under its regulations, activities such as possession, possession for the purposes of trafficking, trafficking, importation, exportation, possession for the purposes of exportation and production of controlled substances are prohibited under the CDSA.

The substances regulated under the CDSA are grouped into eight Schedules, and each Schedule is associated with particular offences and penalties as described in Part I of the CDSA.

In determining whether a substance should be regulated as a controlled substance, and into which Schedule of the CDSA it should be placed, Health Canada considers a number of factors including:

- International requirements and trends in the control and/or scheduling;
- Chemical and/or pharmacological similarity to substances listed in the Schedules to the CDSA;
- Legitimate use of the substance, including therapeutic, scientific, industrial or commercial uses;
- Potential for abuse and/or addiction liability;
- Evidence of extent of actual abuse of the substance in Canada and internationally; and
- Risk to personal and public health and safety.

#### **4.2 Assessment of *S. Divinorum* for Scheduling Purposes**

##### **4.2.1 International Requirements and Trends in the Control and/or Scheduling**

At the present time, neither *S. divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and therefore do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

##### ***Australia***

In June 2002, Australia became the first country to prohibit the sale, supply, possession and use of *S. divinorum* and salvinorin A. Both *S. divinorum* and salvinorin A are listed in Schedule 9 of Australia's *Standard for the Uniform Scheduling of Drugs and Poisons* on the basis of "high potential for abuse and risk to public health and safety."<sup>3</sup> Schedule 9 is Australia's most restrictive drug schedule, and includes "substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities."<sup>4</sup>

### ***Belgium***

A decree was passed in Belgium on October 22, 2006 which added *S. divinorum* to the list of controlled substances. This list includes substances such as psilocybin mushrooms, khat and peyote cactus.<sup>5</sup>

### ***Denmark***

In 2003, Denmark added *S. divinorum* and salvinorin A to their list of "category B" controlled substances, a category which also includes psilocybin mushrooms, cocaine, amphetamine, and several others substances that are only legal for medicinal and scientific purposes. Illegal possession carries a penalty of up to two years in prison.

### ***Germany***

*S. divinorum* (plant and plant parts) was added to Appendix I of the *Narcotics Act* in Germany on March 1, 2008, making it illegal to produce, traffic, or possess. The law does not specifically mention salvinorin A.

### ***Italy***

On June 25, 2004, the Italian Ministry of Health issued an ordinance prohibiting the sale of *S. divinorum* and its active constituent salvinorin A. On January 11, 2005, the Ministry of Health made possession of *S. divinorum* and salvinorin A illegal by placing them in "*Tabella I*" of the *Tabella Sostanze Stupefacenti o Psicotrope*.

### ***Japan***

On November 9, 2006, the Japanese government added a group of thirty-three drugs to its list of controlled substances, including salvinorin A. The drugs are banned under a revised

<sup>3</sup> <http://www.tga.gov.au/ndpsc/record/tr200111.pdf>

<sup>4</sup> [http://www.cognitiveliberty.org/news/salvia\\_australia.htm](http://www.cognitiveliberty.org/news/salvia_australia.htm)

<sup>5</sup>

<http://eldd.emcdda.europa.eu/html.cfm/index5176EN.html?pluginMethod=eldd.shownewsdetails&id=20/12/2006BELGIUM:%20New%20substances%20controlled%20include%20mCPP%20and%20khat>

pharmaceutical law, under which persons involved in their illegal import, production, and sale, i.e. beyond medical treatment or research purposes, will be subject to up to five years imprisonment or a fine of up to five million yen.

### ***Spain***

On January 28, 2004, the Spanish Ministry of Health and Consumption issued an order prohibiting the sale of *S. divinorum*. The regulation went into effect on May 6, 2004 and only prohibits activities related to commerce. Possession and/or use are not considered to be criminal offences.

### ***Other Countries***

It is illegal to possess or sell *S. divinorum* in Croatia, Latvia, Lithuania, Poland, Romania, South Korea and Sweden. In Russia it is illegal to grow or sell *S. divinorum*, but it is legal to possess it. In Estonia, Finland, Iceland and Norway, *S. divinorum* is treated as a medicinal herb and it is illegal to import it without a relevant prescription from a doctor.

### ***United States of America***

*S. divinorum* and salvinorin A are not included in the Schedules to the United States *Controlled Substances Act* although both *S. divinorum* and salvinorin A have been added to a list of chemicals "of concern", but this has no legal implications. According to the National Institute for Drug Abuse, the Drug Enforcement Agency is considering *classifying S. divinorum* and/or salvinorin A as Schedule I drugs. This Schedule includes substances such as LSD and marijuana.

In addition, some individual states have implemented laws restricting its use, sale and/or distribution. As of July 2010, a number of states have enacted legislation placing regulatory controls on *S. divinorum* and/or salvinorin A including Delaware, Georgia, Florida, Hawaii, Illinois, Kansas, Kentucky, Maryland, Mississippi, Missouri, Nebraska, North Dakota, Ohio, Oklahoma, South Dakota, Wisconsin, Virginia, California, Louisiana, Maine, North Carolina, and Tennessee. By way of example, additional details regarding the regulation of *S. divinorum* in these last five states are provided below.

#### ***California***

As of January 1, 2009, the sale or distribution of *S. divinorum* or salvinorin A, or any substance or material containing *S. divinorum* or salvinorin A, to any person under 18 years of age is a misdemeanor punishable by imprisonment in a county jail for not more than six months, a fine of no more than \$1,000, or both.

#### ***Louisiana***

In 2005, Louisiana passed a bill which prohibits the possession, production, manufacture

and distribution of a material, compound, mixture, or preparation intended for human consumption and that contains a hallucinogenic plant. A "hallucinogenic plant" is defined as "any part or portion" of a plant on a list of forty plants, which includes *S. divinorum*.

### ***Maine***

In Maine, *S. divinorum* and salvinorin A are regulated in the same way as tobacco products; adults eighteen years of age or over can legally purchase and use the material, but selling or providing *S. divinorum* or salvinorin A to anyone under the age of eighteen is a criminal offence. Possession by a minor is a civil violation, punishable by a fine, community service, or both.

### ***North Carolina***

On December 1, 2009, the North Carolina State Legislature brought a new law into force which made *S. divinorum* and salvinorin A illegal. The only legal *S. divinorum* activities are the growing for aesthetic, landscaping, or decorative purposes or university-affiliated medical or pharmacological research.

### ***Tennessee***

On July 1, 2006, Tennessee classified the deliberate production, manufacture, distribution, or possession of the active chemical ingredient in the hallucinogenic plant *S. divinorum* as a Class A misdemeanor. It is not, however, a criminal offence to possess, plant, cultivate, grow, or harvest *S. divinorum* for aesthetic, landscaping, or decorative purposes. The law also does not apply to any dosage that is legally obtainable from a retail establishment without a prescription when (and if) it is recognized by the Food and Drug Administration as a homeopathic drug.

#### **4.2.2 Chemical and/or Pharmacological Similarity to Substances Listed in the Schedules to the CDSA**

The psychoactive ingredient in *S. divinorum* is the neoclerodane diterpene salvinorin A.<sup>6</sup> Another plant which contains psychotropic terpenoids is *Artemisia absinthium* (wormwood).<sup>7</sup>

Salvinorin A is a hallucinogen with a distinct structure and it does not interact with the serotonin type-2A receptor or any other molecular target of classical hallucinogens.<sup>8</sup> Instead, the available

<sup>6</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage *Salvia divinorum*. *Life Sci.* 2005 Dec 22;78(5):527-31.

<sup>8</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.

research suggests<sup>9</sup> the psychotropic effects of salvinorin A are mediated by its agonistic actions at the  $\kappa$ -opioid (KOR) receptor.<sup>9</sup> Its mechanism of action is therefore unique.<sup>10</sup>

The psychoactive effects of *S. divinorum* vary in onset and duration and include perceptual distortions such as the sensation of becoming an object, having visions of various two-dimensional surfaces, films and membranes, revisiting places of the past (particularly childhood), perceived loss of the body and/or identity, various sensations of motion (being pulled or twisted by a force of some kind), uncontrollable hysterical laughter, and overlapping realities (perceptions of being in more than one place).<sup>11</sup> Laughter, happiness, a sense of well-being and dissociative effects were deemed the most positive aspects of *S. divinorum* by users, second only to the "trip" that the drug elicits.<sup>12</sup> Depersonalization, speaking gibberish, widening of consciousness and subjective illusions of rapid movement, flying or hovering have also been reported.<sup>13</sup>

The psychotomimetic effects of *S. divinorum* closely resemble schizoid symptoms induced by lysergic acid diethylamide (LSD) or phencyclidine (PCP).<sup>14</sup> Yet, it is said to have only weak influence on the prevailing mood of the user which differentiates it from other hallucinogens such as LSD and psilocybin.<sup>15</sup> Its strong dissociative effects are often compared to those of ketamine.<sup>16</sup> Users have reported that the psychedelic effects of *S. divinorum* were most similar to those caused by psilocybin mushrooms.<sup>17</sup> However, users familiar with the effects of other hallucinogens agree that despite certain similarities to classical hallucinogens, the visions and overall experience are quite unique.<sup>18</sup>

<sup>9</sup> Roth BL, Baner K, Westkaemper R, Siebert D, Rice KC, Steinberg S, Ernsberger P, Rothman RB. Salvinorin A: a potent naturally occurring nonnitrogenous kappa opioid selective agonist. Proc Natl Acad Sci U S A. 2002 Sep 3;99(18):11934-9.

<sup>10</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>11</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>12</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>13</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5 and Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>14</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5.

<sup>15</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>16</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five Salvia divinorum herbal products. Pharmacotherapy. 2006 Sep;26(9):1268-72.

<sup>17</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>18</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6 and González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

*S. divinorum* causes an unusually high degree of sedation, weakness and fatigue, <sup>and</sup> while the increased de-realization is not commonly reported for classical psychedelics.<sup>19</sup> The combination of these effects seems to correlate with that of other KOR agonists such as pentazocine.<sup>20</sup>

The onset and intensity of the effects of *S. divinorum* appear to be related to the route of administration. Traditional uses generally produce mild effects because the leaves are rolled and chewed or crushed and prepared as a foamy infusion whereby the salvinorin A is degraded in the gastrointestinal system before being absorbed into the bloodstream. Hence, the level of effect relates quite closely to the length of time the material spends in the mouth, with the onset of effect generally taking 5-10 minutes. The effects build over the next hour and last for another hour before they begin to subside.<sup>21</sup>

Routes of administration that avoid the hepatic first-pass effect (i.e. inhalation, intravenous, intramuscular and sublingual use) provide the quickest and most intense effect.<sup>22</sup> Salvinorin A can be isolated from the plant to make a powder which can be vaporized and inhaled. The effects felt from vaporizing salvinorin A are experienced in about 30 seconds, last for about 5-10 minutes, and then subside over the next 30 minutes.<sup>23</sup>

Smoking the dried leaves or a concentrated extract using a pipe or bong is by far the most popular method of administration.<sup>24</sup> Dried leaves may also be fortified with a concentrated extract of salvinorin A. A concentrated extract can also be used sublingually. Neither *S. divinorum* nor salvinorin A can be injected because the powder is insoluble in water.<sup>25</sup>

#### 4.2.3 Legitimate Use of the Substance, including Therapeutic, Scientific, Industrial or Commercial Uses

*S. divinorum* has traditionally been used for spiritual and medicinal purposes by the Mazatec

<sup>19</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>20</sup> Arasteh K, Poudevida S, Farre M, Roset PN, Cami J. Response patterns of the Spanish version of the 49-item short form of the Addiction Research Center Inventory after the use of sedatives, stimulants, and opioids. *Drug Alcohol Depend.* 1999 Jun 1;55(1-2):117-25.

<sup>21</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>22</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.

<sup>23</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>24</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62 and Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>25</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs.* 1994 Jul-Sep;26(3):277-83.



Indians in Oaxaca, Mexico<sup>(26)</sup> For medicinal purposes (gastrointestinal problems, headaches, rheumatism, anemia and swelling of the stomach)<sup>(27)</sup> an infusion of the leaves or the leaves themselves are ingested. (However, its main use in Mexico today is believed to be for its psychedelic properties in the aid of producing “mystical” or hallucinogenic experiences as part of spiritual rituals.<sup>29</sup>

Although selective KOR agonists have been shown to produce analgesic effects, adverse effects such as psychotomimesis, dysphoria and diuresis have been observed in studies investigating their therapeutic use.<sup>30</sup> In addition, while it has been speculated that KOR agonists may be useful in the treatment of certain psychiatric disorders including Alzheimer’s disease, schizophrenia, dementia and bipolar disorder,<sup>31</sup> but there has been no clinical research to support these hypotheses. That said there are presently no recognized medical uses for *S. divinorum* in Canada.

Similarly, there are no known industrial or commercial uses for *S. divinorum* in Canada. Most websites offering *S. divinorum* cuttings and seeds for sale appear to do so in the context of growing the plant for “recreational” purposes, rather than out of horticultural interest or for its esthetic appeal. However, it should be acknowledged that this does not preclude the possibility of a person growing this plant for purely decorative purposes. *S. divinorum* is also marketed as incense. However, there is no evidence that *S. divinorum* has any fragrant properties that would legitimize such a use. Therefore it is believed that the marketing of this plant as an incense is a means to avoid compliance and enforcement actions by Health Canada.

#### 4.2.4 Potential for Abuse and/or Addiction Liability

Salvinorin A is a potent, KOR<sup>(32)</sup> selective agonist and in contrast to the euphoria produced by MOR agonists such as morphine, KOR agonists are negatively reinforcing and aversive.<sup>33</sup> In addition, KOR agonists have analgesic properties<sup>(34)</sup> but are not associated with respiratory

<sup>26</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>27</sup> Munro, T. The Chemistry of Salvia divinorum. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

<sup>29</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage Salvia divinorum. Life Sci. 2005 Dec 22;78(5):527-31.

<sup>30</sup> Barker RL, Fawcett J, Barkin SJ. 2002. Chronic pain management with a focus on the role of newer antidepressants and centrally acting agents. In: Pain Management: A Practical Guide for Clinicians, 6th edition, Weiner RS ed. CRC Press, Boca Raton, FL. pp. 415-34 and Tidgewell et al., 2004. A facile method for the preparation of deuterium labelled salvinorin A: Biorganic & Medicinal Chemistry Letters, 14: 5099-5102.

<sup>31</sup> Sheffler DJ & Roth BL. Salvinorin A: the ‘magic mint’ hallucinogen finds a molecular target in the kappa opioid receptor. Trends Pharmacol Sci. 2003 Mar;24(3):107-109.

<sup>33</sup> Killinger BA, Peet MM, Baker LE. Salvinorin A fails to substitute for the discriminative stimulus effects of LSD or ketamine in Sprague-Dawley rats. Pharmacology, Biochemistry & Behaviour. 2010 May 96; 260-265.

depression like MOR agonists.<sup>34</sup> Finally, while MOR agonists increase the release of dopamine, the activation of KOR decreases dopamine release in the nucleus accumbens.<sup>35</sup> In the case of MOR agonists, the increase of dopamine acts as a positive reinforcer. This action motivates the user to use the drug again, which could lead to drug abuse and/or addiction. For KOR agonists, this is not the case.

The aversive effects of KOR agonists suggest that the risk of addiction to *S. divinorum* is negligible. However, very few controlled scientific studies of the physical and psychotropic effects of *S. divinorum* on humans have been carried out and the results have been conflicting. For example, one author states: "Many who have used salvinorin A find the experience extremely unnerving, frightening and overly intense and most have no desire to repeat the experience."<sup>36</sup> However, another study suggested that this is not the experience of all recreational users of *S. divinorum*.<sup>37</sup> Over eighty percent of users surveyed on a web-based questionnaire about their *S. divinorum* use said that they would probably or definitely use *S. divinorum* again.<sup>38</sup> Users have reported the negative effects of *S. divinorum* as: the short duration of action, lack of control over the experience, persisting negative effects (most often anxiety),<sup>39</sup> sweating, chills, increased diuresis, impaired vigilance,<sup>40</sup> and negative after-effects including tiredness, feeling head heavy, dizziness, physical exhaustion, and some degree of malaise or 'hangover' as they 'comedown' from the drug.<sup>41</sup>

In addition, some users have noted that they require increasing doses of salvinorin A in order to achieve the desired effect and the stimulated cerebral KOR may act as a mechanism of tolerance.<sup>42</sup> Therefore, it is difficult to predict with certainty its potential for addiction and abuse.

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<sup>34</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.

<sup>35</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.

<sup>36</sup> Turner DM. Salvinorin - The Psychedelic Essence of Salvia Divinorum. Panther Press, San Francisco, CA 1996.

<sup>37</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62, Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). *Pharmacopsychiatry.* 2005 Jan;38(1):1-5, and Valdès LJ 3rd. Salvia divinorum and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs.* 1994 Jul-Sep;26(3):277-83.

<sup>38</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>39</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>40</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). *Pharmacopsychiatry.* 2005 Jan;38(1):1-5.

<sup>41</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>42</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's

In studies that have been conducted, there is conflicting information around the addiction liability of *S. divinorum* in both animals and humans. Further studies in this area and on the KOR mediated decrease of dopamine are also required in order to fully understand the addiction potential of this substance.

While concerns for the potential of abuse were initially considered minimal given that 1 kg of dried leaves only yield 3 to 6 human doses of salvinorin A for oral consumption, it was then discovered that vaporizing and inhaling 200-500 micrograms had profound hallucinogenic effects.<sup>43</sup> Given that only small doses of this substance are now necessary to achieve the desired effects through inhalation, the potential for abuse is much higher. Also, the extraction of salvinorin A from the plant is simple, and with care, approximately 1.5 grams of pure salvinorin A per kilogram of dried leaves (8kg of fresh leaves) can be isolated. This is enough for 2000 oral doses.<sup>44</sup>

#### 4.2.5 Evidence of Extent of Actual Abuse of the Substance in Canada and Internationally

In Canada, the prevalence of <sup>of</sup> the use of *S. divinorum* has recently been documented. Questions about the use of salvia were included in the 2009 Ontario Student Drug Use and Health Survey, the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey. In some cases it is not clear if responses indicate the use of *S. divinorum* or salvinorin A given the use of the term "salvia".

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Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5.

<sup>43</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>44</sup> Valdès LJ 3rd. Salvia divinorum and the unique diterpene hallucinogen, Salvinorin (divinorin) A. J Psychoactive Drugs. 1994 Jul-Sep;26(3):277-83.

The results from the 2009 Ontario Student Drug Use and Health Survey were published on November 18, 2009 and indicate that:

- Among all responding students in Ontario, 4.4% reported using *S. divinorum* at least once in the past year. In comparison, 58.2% indicated they had used alcohol, 25.6% indicated they had used cannabis and 5.0% indicated they had used hallucinogens other than LSD and PCP in the past year;
- Males (6.2%) were significantly more likely than females (2.3%) to report using *S. divinorum*;
- There is significant grade variation, with *S. divinorum* use most likely among 11<sup>th</sup> graders (8.6%) and 12<sup>th</sup> graders (8.4%); and

The results of the 2008-2009 Youth Smoking Survey were published on May 31, 2010 and indicate that:

- 4.9% of students stated that they had used salvia in the last twelve months. In comparison, 53.0% indicated they had used alcohol, 27.3% indicated they had used cannabis and 6.9% indicated they had used other hallucinogens in the last twelve months;
- 2.6% of students in Grades 7-9 and 7.0% of students in Grades 10-12 had used salvia in the last twelve months; and
- Males (6.6%) were more likely to have used salvia in the past twelve months compared to females (3.2%).

The Canadian Alcohol and Drug Use Monitoring Survey specifically examined salvia for the first time in 2009. An estimated 1.6% of Canadians, aged 15 years and older, reported that they had

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<sup>51</sup> Siebert DJ. Salvia divinorum and salvinin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

used salvia in their lifetime, and 0.2% reported using it in the past-year. In comparison, the prevalence of past-year cannabis use among Canadians 15 years of age and older was 10.6%, while 1.2% of respondents reported using cocaine or crack in the past 12 months, 0.9% ecstasy and 0.7% illicit hallucinogens. Salvia appears, however, to be a substance that is tried largely by youth with a 7.3% prevalence of lifetime use.

According to the 2009 Monitoring the Future survey, annual prevalence of use of *S. divinorum* among 12th graders in the United States is 5.7%. The American Substance Abuse and Mental Health Services Administration's 2006 National Survey on Drug Use and Health found that, of respondents aged 12 or older, 1.8 million had used *S. divinorum* at least once in their lifetime and 756,000 had used the substance in the past year. Among youth aged 12 to 17, males were more likely than females to have used *S. divinorum* in the past year (0.9% vs. 0.3%).

Health Canada's Drug Analysis Services (DAS) has identified salvinorin A in a number of samples seized by law enforcement, ranging from 9 samples in 2006 to 20 samples in 2009. It is, however, difficult to determine how this data reflects the extent of actual abuse of salvinorin A in Canada, given that *S. divinorum* is not an illegal substance and would likely only be seized accidentally or during the seizure of other illicit substances.

The National Forensic Laboratory Information System (NFLIS) and the System to Retrieve Information from Drug Evidence (STRIDE) in the United States are Drug Enforcement Agency (DEA) databases that collect scientifically verified data on analyzed samples in state and local forensic labs as well as samples from DEA labs. While in 2000 no seized samples were found to contain *S. divinorum* or salvinorin A, 70 samples tested positive in 2008. Once again, it is difficult to determine how this data can be used to reflect the actual extent of abuse of *S. divinorum* and salvinorin A in the United States as both these substances are not listed in the *Controlled Substances Act*.

The increase in both the number of enquiries to Health Canada from various municipalities and members of the public and the amount of media interest regarding the availability of *Salvia divinorum* in Canada may be an indication that the recreational use of *S. divinorum* as a hallucinogen is on the rise, <sup>no users</sup> but it may also only reflect an increased awareness of the phenomenon.

#### 4.2.6 Risk to Personal and Public Health and Safety

The potential for harm to the user and/or other individuals is primarily related to the hallucinogenic properties of the substance. As this substance is typically smoked, there is no risk of infectious disease transmission as is the case when a drug is injected. Users may get up and walk around without apparent awareness of their movements, behaviour or surroundings, and distinction between self and surroundings is often lost. At doses greater than 1mg of salvinorin A, out of body experiences are frequent and loss of consciousness has been reported.<sup>51</sup> There is little information regarding the social behaviours of persons under the influence of *S. divinorum* products, and what risks their activities such as operating a motorized vehicle may pose to the general public. There is also very little data regarding the toxicity, teratogenicity or other long-

term effects of *S. divinorum* use.<sup>52</sup>

As far as law enforcement is concerned, the Department has only received a limited number of communications indicating concern with respect to *S. divinorum*. The Royal Canadian Mounted Police (RCMP) has stated that while *S. divinorum* is readily available, it has not become a popular drug in Canada, probably due to its aversive effects such as anxiety and introversion.

A handful of case reports regarding physiological and psychotropic effects of *S. divinorum* use have been published in the scientific/medical literature. For example, an international case report described the perceptions of a 19 year-old man after inhaling *S. divinorum* smoke. The peak psychotropic effects, including prickling of the skin, fever-like hot flashes, muscular tremor, and depersonalization, were reached in less than five minutes after inhalation of an unknown amount of smoke from burning dried leaves.<sup>53</sup> Another report involved a 15-year-old male who presented to psychiatric emergency services with acute onset of paranoia, déjà vu, blunted affect, difficulties in thought processing and slowed speech after smoking *S. divinorum* over an unknown period of time. During his hospitalization all symptoms improved significantly except the feeling of déjà vu. Based on this case presentation, the author suggested that the feelings of déjà vu may be a long-term effect of *S. divinorum* use.<sup>54</sup> However, given that this is the only case report in which déjà vu was associated with the use of *S. divinorum*, more reports are needed to substantiate this finding.

In addition to the above-mentioned reports, in 2006, a case was reported in the U.S. in which a 17-year-old boy committed suicide after smoking *S. divinorum* for an unknown period of time.<sup>55</sup> It should be noted that alcohol and general depression were the main confounders in this case. After this case was reported, the state of Delaware passed a law which classified *S. divinorum* as a Schedule I controlled substance along with other hallucinogenic substances.

Like many drugs of abuse, users are often unaware of the potency and adulterants in the product they purchase. A study by Wolowich *et al.* (2006), showed that the salvinorin A content in five out of five *S. divinorum* products was falsely indicated on the label and 4 out of 5 products contained unidentified adulterants (i.e. vitamin E, caffeine).<sup>56</sup>

There are also several reports of domestic adverse reactions related to the use of *S. divinorum* that have been received through the Canada Vigilance database. However, this does not reflect true incidence due to under-reporting.

## 5. ASSESSMENT OF RISKS AND BENEFITS

---

<sup>52</sup> Grundmann O, Phipps SM, Zadezensky I, Butterweck V. *Salvia divinorum* and Salvinorin A: An Update on Pharmacology and Analytical Methodology. *Planta Med* 2007 Jun;73:1039-1046.

<sup>54</sup> Singh S. (2007) Adolescent salvia substance abuse. *Addiction*. 102, 823-824.

<sup>55</sup> <http://www.kvbc.com/Global/story.asp?S=4893692>

<sup>56</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

**Page(s) 001545 to\à 001545**

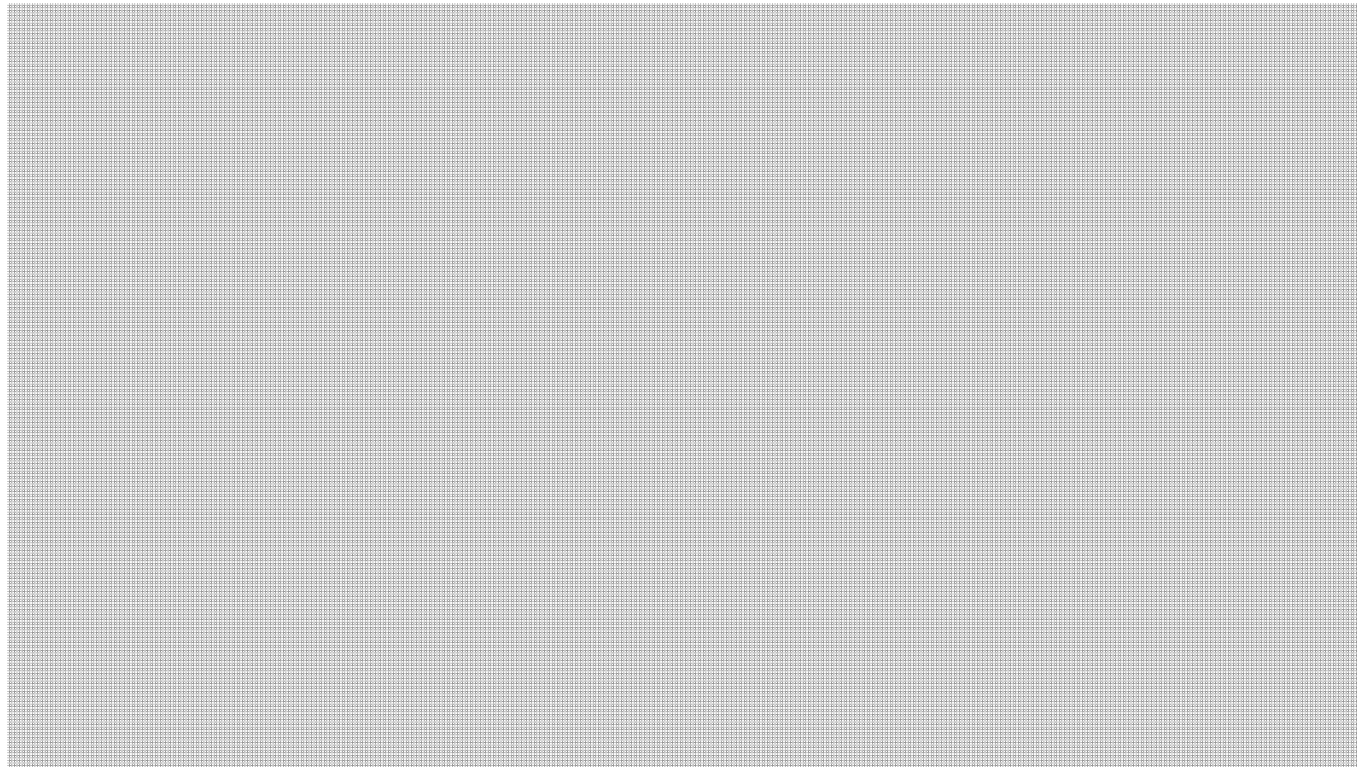
**Is(Are) exempted pursuant to section(s)  
est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**

s.21(1)(a)

s.21(1)(b)



## 7. CONSIDERATIONS

The NHPR are limited in their capacity to control the availability of *S. divinorum* in that *S. divinorum* products are often declared as incense and therefore cannot be considered unapproved natural health products. In addition, compliance and enforcement actions such as voluntary stop-sales, forfeiture, destruction, and administrative seizure, cannot be implemented unless the marketing of the product indicates that it is to be sold for human consumption in order to modify an organic function. Unlicensed natural health products are also permitted to be imported provided they are for personal use only.

Non-regulatory options for the control of *S. divinorum* were also considered, such as the development of an educational campaign to highlight the risks associated with using this plant. However, ~~given~~ the risks associated with this substance, as well as the confusion concerning its enforcement as a natural health product only when it is sold for use with a health claim, do not make this option viable.

*S. divinorum* meets the criteria for scheduling a substance under the CDSA. While neither the plant nor its main active component salvinorin A are scheduled under any of the UN Drug Control Conventions, a number of countries and American states have taken steps to control the distribution and use of these substances. *S. divinorum* and salvinorin A are pharmacologically similar to other substances included in Schedule III to the CDSA, such as LSD and psilocybin. There are also currently no legitimate therapeutic, commercial or industrial uses for *S. divinorum*. While the addiction potential of *S. divinorum* appears to be low, there is a significant potential for its abuse as a 'legal' hallucinogen. There is very little information with regards to the long-term effects of *S. divinorum* use. There is also evidence of abuse, particularly by Canadian youth and potential for health risks as well as risks to public health and safety.

individual



s.21(1)(a)  
s.21(1)(b)

In light of a recommendation to include *S. divinorum* under Schedule III to the CDSA, it is also recommended that the main psychoactive ingredient of this plant, salvinorin A, ~~also~~ be scheduled. <sup>gives</sup> Salvinorin A can easily be extracted from *S. divinorum* and this substance ~~results in~~ the plant's <sup>is</sup> hallucinogenic properties. Therefore salvinorin A results in the same risks as *S. divinorum* and ~~its scheduling will mitigate such threats to the personal and public health and safety of Canadians.~~ <sup>AND should also be controlled under the CDSA.</sup>

## 8. RECOMMENDATIONS

## 9. CONSULTATIONS

The Drug Analysis Services (DAS) was contacted in order to provide any data available regarding the identification of salvinorin A in samples submitted by law enforcement.

The Royal Canadian Mounted Police (RCMP) was contacted in order to establish their views with respect to *S. divinorum* use in Canada. The RCMP advised that *S. divinorum* is readily available and law enforcement agencies have no legal means to prevent its sale.

OCS has received a number of correspondences from Canada Border Services Agency (CBSA) officers concerning a lack of information regarding the status of *S. divinorum* and how the plant should be treated at the border. CBSA officers have also expressed concern regarding the plant's <sup>for sale</sup> hallucinogenic properties. At present, only shipments of *S. divinorum* that are represented as health products that modify organic functions can be refused for import under the NHPR.

OCS brought *S. divinorum* to the Controlled Substances Scheduling Working Group (CSS-WG) in August 2010 to discuss the possibility of regulatory control of this substance. After assessing the available information against the six criteria listed in the Context section of this Issue Analysis Summary, the CSS-WG recommended that *S. divinorum* be included under Schedule III to the CDSA.

## 10. IMPLEMENTATION AND EVALUATION

**Page(s) 001548 to\à 001548**

**Is(Are) exempted pursuant to section(s)  
est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**



**Re: Fw: NHP Importation (for Salvia IAS)** 

Courtney Smith to: Stephanie Chandler

2010-10-28 09:10 AM

Cc: Denis Arsenault, Tiana Branch

---

Hi Stephanie

No, they wouldn't; like the information on US seizures included in the IAS, this info would only demonstrate that the products are present. It would not give any indication of prevalence.

Re: Fw: NHP Importation (for Salvia IAS)

**Re: Fw: NHP Importation (for Salvia IAS)** 

Stephanie Chandler to: Courtney Smith

2010-10-28 09:02 AM

Cc: Denis Arsenault, Tiana Branch

---

Hi Courtney,

Thanks for your input below.

Also FYI, we have contacted the Border Integrity unit in the past, and we were told that given the lack of regulatory control of salvia, if such stats were available, they wouldn't adequately describe the actual quantities of salvia being imported.

Regards,

Stephanie

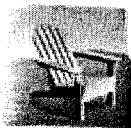
Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

---

Courtney Smith

Hi both - I received an out of office from Denis a...

2010-10-27 05:53:25 PM



**Fw: IAS Salvia - American stats for CSS-WG**

Allison Vadneau to: Tanja Kalajdzic, Denis Arsenault, Robin Marles, Stephanie Chandler, Hanan Abramovici, Colette Strnad, Bruna Brands, Courtney Smith, Tiana Branch, Irshad Mulla  
Cc: Suzanne Desjardins, Isabel Shanahan, Laura Cooney, Collin Pinto, Evelyn Soo, Jocelyn Kula  
This message is digitally signed.

2010-10-28 12:52 PM

Please find below some statistics from US surveys on salvia use.

Allison Vadneau  
Research Analyst / Analyste en recherche  
Office of Drugs and Alcohol Research and Surveillance /  
Bureau de la recherche et de la surveillance des drogues et de l'alcool  
Controlled Substances and Tobacco Directorate /  
Direction des substances contrôlées et de la lutte au tabagisme  
Health Canada / Santé Canada  
123 Slater St., Ottawa, ON  
K1A 0K9  
Ph: 613-946-3738  
Fax: 613-952-5188  
----- Forwarded by Allison Vadneau/HC-SC/GC/CA on 2010-10-28 12:49 PM -----

From: Suzanne Desjardins/HC-SC/GC/CA  
To: Allison Vadneau/HC-SC/GC/CA@HWC  
Date: 2010-10-28 12:43 PM  
Subject: Re: Salvia - American stats for CSS-WG draft doc

merci beaucoup

svp envoie au CSS\_WG

Suzanne

Allison Vadneau Suzanne, I did online searches for data on salvi... 2010-10-28 10:57:50 AM

From: Allison Vadneau/HC-SC/GC/CA  
To: Suzanne Desjardins/HC-SC/GC/CA@HWC  
Date: 2010-10-28 10:57 AM  
Subject: Salvia - American stats for CSS-WG draft doc

Suzanne,

I did online searches for data on salvia use from USA surveys. (For input to CSS-WG meeting document)

Below is the only information I was able to find.

- 1 - data from 2009 Monitoring the Future for 12th grade students, past year use.
- 2- stats from 2006 National Survey on Drug Use and Health on salvia use, lifetime, past year by age groups.

**1- 2009 Monitoring the Future**

- Annual prevalence among 12th graders: 5.7%(Question was only asked to 12th graders)

## 2- SAMHSA's 2006 National Survey on Drug Use and Health

- According to the 2006 National Survey on Drug Use and Health of persons aged 12 or older, 1.8 million used *Salvia divinorum* at least once in their lifetime;

756,000 used the drug in the past year.

source:

[http://www.justice.gov/dea/concern/Salvia%20divinorum%20and%20salvinorin%20A\\_Feb%202010%20wo%20image.pdf](http://www.justice.gov/dea/concern/Salvia%20divinorum%20and%20salvinorin%20A_Feb%202010%20wo%20image.pdf)

- Among youth aged 12 to 17, males were more likely than females to have used *Salvia divinorum* in the past year (0.9% vs. 0.3%)

- In 2006, young adults aged 18 to 25 were more likely than youths aged 12 to 17 or adults aged 26 or older to be past year users of LSD, Ecstasy, and *Salvia divinorum*.

Table 1. Percentages and Standard Errors (SE)* of Past Year Hallucinogen Use** among Persons Aged 12 or Older, by Age Group: 2006								
Hallucinogen	12 or Older		12 to 17		18 to 25		26 or Older	
	%	SE	%	SE	%	SE	%	SE
LSD	0.3	0.02	0.4	0.05	1.2	0.10	0.1	0.02
PCP	0.1	0.02	0.2	0.04	0.2	0.04	0.0 <sup>+</sup>	0.02
Ecstasy	0.9	0.04	1.2	0.09	3.8	0.19	0.3	0.04
Ketamine	0.1	0.02	0.1	0.03	0.2	0.04	0.1	0.02
DMT/AMT/Foxy***	0.0 <sup>+</sup>	0.01	0.1	0.02	0.2	0.05	0.0 <sup>+</sup>	0.01
<i>Salvia divinorum</i>	0.3	0.02	0.6	0.06	1.7	0.12	0.0 <sup>+</sup>	0.01

Source: SAMHSA, 2006 NSDUH.

**Table 2. Percentages and Standard Errors (SE)\* of Past Year Hallucinogen Use\*\* among Persons Aged 12 to 25, by Age Group and Gender: 2006**

Hallucinogen	12 to 17				18 to 25			
	Male		Female		Male		Female	
	%	SE	%	SE	%	SE	%	SE
LSD	0.4	0.07	0.4	0.08	1.5	0.15	0.8	0.12
PCP	0.2	0.06	0.3	0.06	0.3	0.06	0.2	0.06
Ecstasy	1.0	0.11	1.4	0.14	4.3	0.28	3.2	0.24
Ketamine	0.1	0.03	0.2	0.05	0.3	0.07	0.2	0.04
DMT/AMT/Foxy***	0.1	0.03	0.0*	0.01	0.3	0.09	0.1	0.03
<i>Salvia divinorum</i>	0.9	0.10	0.3	0.06	2.7	0.20	0.7	0.10

Source: SAMHSA, 2006 NSDUH.

<http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf>

Allison Vadneau  
 Research Analyst / Analyste en recherche  
 Office of Drugs and Alcohol Research and Surveillance /  
 Bureau de la recherche et de la surveillance des drogues et de l'alcool  
 Controlled Substances and Tobacco Directorate /  
 Direction des substances contrôlées et de la lutte au tabagisme  
 Health Canada / Santé Canada  
 123 Slater St., Ottawa, ON  
 K1A 0K9  
 Ph: 613-946-3738  
 Fax: 613-952-5188



**Re: NHP Importation (for Salvia IAS)**

Denis Arsenault to: Courtney Smith

Cc: Tiffany Thornton, Stephanie Chandler

2010-10-29 08:43 AM

Hi Courtney,

Thanks for this. If you do find border stats, please also send them to Stephanie Chandler as she is holding the pen on revising the IAS.

Denis

---

Denis Arsenault, A/Manager / Gestionnaire p.i.  
Regulatory Policy Division /  
Division des politiques réglementaires,  
Office of Controlled Substances /  
Bureau des substances contrôlées,  
Health Canada / Santé Canada  
Tel/Tél: (613) 957-6828  
Fax / Télécopieur : (613) 946-4224  
E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca

---

Courtney Smith

As discussed. Something to this effect may clari...

2010-10-27 05:51:23 PM

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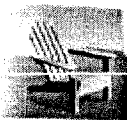
From: Courtney Smith/HC-SC/GC/CA  
To: Denis Arsenault/HC-SC/GC/CA@HWC  
Cc: Tiffany Thornton/HC-SC/GC/CA@HWC  
Date: 2010-10-27 05:51 PM  
Subject: NHP Importation (for Salvia IAS)

---

As discussed. Something to this effect may clarify statements relating to import under the NHPR in the 'context' and the 'options'.

*S. divinorum* can be legally imported and sold in Canada. However, if an *s. divinorum* product is marketed with a health claim, it would meet the definition of an NHP. This means that while the domestic sale, and the importation for sale, of these products would be prohibited in the absence of a market authorization, importation of limited quantities for personal use would be permitted. Therefore this substance is easily accessible.

I will have to follow up regarding the availability of border stats (I'm unsure if we have this information available).



**Re: CSS-WG comments re: Salvia IAS?** 

Allison Vadneau to: Stephanie Chandler

This message is digitally signed.

2010-10-29 12:28 PM

History: This message has been replied to.

Hi Stephanie,

I will send out an e-mail now for a last request for comments on the IAS.

I'm worried that people may have been forwarding their responses to Tiffany rather than to myself, and Tiffany is still out of the office.

I will get back to you asap with comments if anything is sent to me.

Allison Vadneau

Research Analyst / Analyste en recherche

Office of Drugs and Alcohol Research and Surveillance /

Bureau de la recherche et de la surveillance des drogues et de l'alcool

Controlled Substances and Tobacco Directorate /

Direction des substances contrôlées et de la lutte au tabagisme

Health Canada / Santé Canada

123 Slater St., Ottawa, ON

K1A 0K9

Ph: 613-946-3738

Fax: 613-952-5188

Stephanie Chandler Hi Allison, Just wanted to check if you had rec... 2010-10-29 12:12:48 PM

From: Stephanie Chandler/HC-SC/GC/CA  
To: Allison Vadneau/HC-SC/GC/CA@HWC  
Date: 2010-10-29 12:12 PM  
Subject: CSS-WG comments re: Salvia IAS?

Hi Allison,

Just wanted to check if you had received any other comments from the CSS-WG regarding the Salvia IAS. I received your comments with regard to US stats and comments from Courtney Smith, but I haven't received any from NHPD. I believe Robin was going to forward you them by noon today?

We'd like to send the draft IAS to the Director, OCS by COB today, so if you could forward any other comments ASAP it would be greatly appreciated.

Thanks!

Stephanie

Stephanie Chandler

Junior Regulatory Project Officer

Regulatory Policy Division/ Division de la politique réglementaire

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs

Health Canada/ Santé Canada

Tel: (613) 946-0124, Fax: (613) 946-4224

E-Mail: stephanie.chandler@hc-sc.gc.ca





**Re: CSS-WG Comments on IAS :Salvia** 

Suzanne Desjardins to: Allison Vadneau

2010-10-29 01:08 PM

Cc: Tanja Kalajdzic, Denis Arsenault, Robin Marles, Hanan Abramovici, Irshad Mulla, Collin Pinto, Colette Strnad, Bruna Brands, Evelyn Soo, Courtney Smith, Jocelyn Kula, Tiana Branch, Stephanie Chandler, Tiffany Thornton

We will have additional comments on the IAS at a later stage, but for the purpose of submitting the draft to Jocelyn today, we have provided them earlier this week.

Thanks

Suzanne

Allison Vadneau

Good afternoon, Please advise if you have any...

2010-10-29 12:32:23 PM

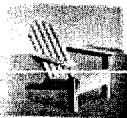
From: Allison Vadneau/HC-SC/GC/CA  
To: Suzanne Desjardins/HC-SC/GC/CA@HWC, Tanja Kalajdzic/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, Robin Marles/HC-SC/GC/CA@HWC, Hanan Abramovici/HC-SC/GC/CA@HWC, Irshad Mulla/HC-SC/GC/CA@HWC, Collin Pinto/HC-SC/GC/CA@HWC, Colette Strnad/HC-SC/GC/CA@HWC, Bruna Brands/HC-SC/GC/CA@HWC, Evelyn Soo/HC-SC/GC/CA@HWC, Courtney Smith/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Tiana Branch/HC-SC/GC/CA@HWC  
Cc: Stephanie Chandler/HC-SC/GC/CA@HWC, Tiffany Thornton/HC-SC/GC/CA@HWC  
Date: 2010-10-29 12:32 PM  
Subject: CSS-WG Comments on IAS :Salvia

Good afternoon,

Please advise if you have any further comments for the Salvia IAS. Input needs to be provided as soon as possible as the IAS will be sent to the Director of OCS by COB today.

Thank you,

Allison Vadneau  
Research Analyst / Analyste en recherche  
Office of Drugs and Alcohol Research and Surveillance /  
Bureau de la recherche et de la surveillance des drogues et de l'alcool  
Controlled Substances and Tobacco Directorate /  
Direction des substances contrôlées et de la lutte au tabagisme  
Health Canada / Santé Canada  
123 Slater St., Ottawa, ON  
K1A 0K9  
Ph: 613-946-3738  
Fax: 613-952-5188



**Fw: CSS-WG Comments on IAS :Salvia**

Allison Vadneau to: Stephanie Chandler

This message is digitally signed.

2010-10-29 01:26 PM

Hi Stephanie,

I am forwarding comments from Evelyn on to you.

Other than Suzanne, which you were copied on, I have not received any further comments.

Thanks!

Allison Vadneau

Research Analyst / Analyste en recherche

Office of Drugs and Alcohol Research and Surveillance /

Bureau de la recherche et de la surveillance des drogues et de l'alcool

Controlled Substances and Tobacco Directorate /

Direction des substances contrôlées et de la lutte au tabagisme

Health Canada / Santé Canada

123 Slater St., Ottawa, ON

K1A 0K9

Ph: 613-946-3738

Fax: 613-952-5188

----- Forwarded by Allison Vadneau/HC-SC/GC/CA on 2010-10-29 01:26 PM -----

From: Evelyn Soo/HC-SC/GC/CA  
To: Allison Vadneau/HC-SC/GC/CA@HWC  
Date: 2010-10-29 01:08 PM  
Subject: Re: CSS-WG Comments on IAS :Salvia

Hi Allison

Sorry I haven't had much time to review this as I have been out of the office most of this week but I added one comment on p.2 to change substances to substance.

Cheers

Evelyn



Draft Salvia Divinorum IAS\_Oct 25 2010 SD HA cmts Oct 27 10.doc

Evelyn C Soo, PhD

National Compliance and Exemption Division | Division de la conformité et des exemptions nationales

Office of Controlled Substances | Bureau des substances contrôlées

Healthy Environments and Consumer Branch (HECS) | Direction de la santé environnementale et de la sécurité des consommateurs (DSESC)

Health Canada | Santé Canada

123 Slater St. Ottawa ON K1A 0K9 | 123 rue Slater Ottawa ON K1A 0K9

evelyn.soo@hc-sc.gc.ca

Telephone | Téléphone 613-948-8964

Facsimile | Télécopieur 613-952-8576

Government of Canada | Gouvernement du Canada

Allison Vadneau

Good afternoon, Please advise if you have any...

2010-10-29 12:32:23 PM

From: Allison Vadneau/HC-SC/GC/CA  
To: Suzanne Desjardins/HC-SC/GC/CA@HWC, Tanja Kalajdzic/HC-SC/GC/CA@HWC, Denis  
Arsenault/HC-SC/GC/CA@HWC, Robin Marles/HC-SC/GC/CA@HWC, Hanan  
Abramovici/HC-SC/GC/CA@HWC, Irshad Mulla/HC-SC/GC/CA@HWC, Collin  
Pinto/HC-SC/GC/CA@HWC, Colette Strnad/HC-SC/GC/CA@HWC, Bruna  
Brands/HC-SC/GC/CA@HWC, Evelyn Soo/HC-SC/GC/CA@HWC, Courtney  
Smith/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Tiana  
Branch/HC-SC/GC/CA@HWC  
Cc: Stephanie Chandler/HC-SC/GC/CA@HWC, Tiffany Thornton/HC-SC/GC/CA@HWC  
Date: 2010-10-29 12:32 PM  
Subject: CSS-WG Comments on IAS :Salvia

---

Good afternoon,

Please advise if you have any further comments for the Salvia IAS.  
Input needs to be provided as soon as possible as the IAS will be sent to the Director of OCS by COB  
today.

Thank you,

Allison Vadneau  
Research Analyst / Analyste en recherche  
Office of Drugs and Alcohol Research and Surveillance /  
Bureau de la recherche et de la surveillance des drogues et de l'alcool  
Controlled Substances and Tobacco Directorate /  
Direction des substances contrôlées et de la lutte au tabagisme  
Health Canada / Santé Canada  
123 Slater St., Ottawa, ON  
K1A 0K9  
Ph: 613-946-3738  
Fax: 613-952-5188



Re: NHP Importation (for Salvia IAS)

Courtney Smith to: Denis Arsenault

Cc: Tiffany Thornton, Stephanie Chandler, Collin Pinto

2010-10-29 01:43 PM

Hi Denis

I will be sure to do so. However, as I have nothing readily available, this is to confirm that I have no further comments for the time being.

Courtney

Re: NHP Importation (for Salvia IAS)

Re: NHP Importation (for Salvia IAS)

Denis Arsenault to: Courtney Smith

2010-10-29 08:43 AM

Cc: Tiffany Thornton, Stephanie Chandler

Hi Courtney,

Thanks for this. If you do find border stats, please also send them to Stephanie Chandler as she is holding the pen on revising the IAS.

Denis

Denis Arsenault, A/Manager / Gestionnaire p.i.  
Regulatory Policy Division /  
Division des politiques réglementaires,  
Office of Controlled Substances /  
Bureau des substances contrôlées,  
Health Canada / Santé Canada  
Tel/Tél: (613) 957-6828  
Fax / Télécopieur : (613) 946-4224  
E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca

Courtney Smith As discussed. Something to this effect may clari...

2010-10-27 05:51:23 PM

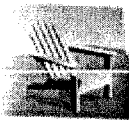
From: Courtney Smith/HC-SC/GC/CA  
To: Denis Arsenault/HC-SC/GC/CA@HWC  
Cc: Tiffany Thornton/HC-SC/GC/CA@HWC  
Date: 2010-10-27 05:51 PM  
Subject: NHP Importation (for Salvia IAS)

As discussed. Something to this effect may clarify statements relating to import under the NHPR in the 'context' and the 'options'.

*S. divinorum* can be legally imported and sold in Canada. However, if an *s. divinorum* product is marketed with a health claim, it would meet the definition of an NHP. This means that while the domestic sale, and the importation for sale, of these products would be prohibited in the absence of a market authorization,

importation of limited quantities for personal use would be permitted. Therefore this substance is easily accessible.

I will have to follow up regarding the availability of border stats (I'm unsure if we have this information available).



**Fw: CSS-WG Comments on IAS :Salvia**  
Allison Vadneau to: Stephanie Chandler  
This message is digitally signed.

2010-10-29 02:37 PM

History: This message has been replied to.

Hi Stephanie,  
I don't know if these are too late but I just saw them now.  
Comments from Robin re IAS Salvia.

Thanks!

Allison Vadneau  
Research Analyst / Analyste en recherche  
Office of Drugs and Alcohol Research and Surveillance /  
Bureau de la recherche et de la surveillance des drogues et de l'alcool  
Controlled Substances and Tobacco Directorate /  
Direction des substances contrôlées et de la lutte au tabagisme  
Health Canada / Santé Canada  
123 Slater St., Ottawa, ON  
K1A 0K9  
Ph: 613-946-3738  
Fax: 613-952-5188

----- Forwarded by Allison Vadneau/HC-SC/GC/CA on 2010-10-29 02:36 PM -----

From: Robin Marles/HC-SC/GC/CA  
To: Allison Vadneau/HC-SC/GC/CA@HWC  
Date: 2010-10-29 02:01 PM  
Subject: Re: CSS-WG Comments on IAS :Salvia

Here are my comments on the NHP Regulations section, as promised. I have not bothered to reproduce all the other corrections submitted by Hanan, Suzanne etc. that we discussed and agreed to at the meeting. You already have that from others.



Draft Salvia Divinorum IAS\_Oct 25 2010 ed by NHPD.doc

Robin

Robin J. Marles, Ph.D.  
Director, Bureau of Clinical Trials and Health Sciences / Directeur, Bureau des essais cliniques et des sciences de la santé  
Natural Health Products Directorate / Direction des produits de santé naturels  
Health Products and Food Branch / Direction générale des produits de santé et des aliments  
Health Canada / Santé Canada  
2936 Baseline Road, A.L. 3302C / 2936 chemin Baseline, Indice de l'adresse 3302C  
Ottawa, ON CANADA K1A 0K9  
(Courier / Livraison: K2H 1B3)  
Tel / Tél.: 613-948-6142; Fax / Téléc.: 613-946-1615  
E-mail / Courriel: robin.marles@hc-sc.gc.ca

Allison Vadneau/HC-SC/GC/CA



Allison



Vadneau/HC-SC/GC/CA

2010-10-29 12:32 PM

To Suzanne Desjardins/HC-SC/GC/CA@HWC, Tanja  
Kalajdzic/HC-SC/GC/CA@HWC, Denis  
Arsenault/HC-SC/GC/CA@HWC, Robin  
Marles/HC-SC/GC/CA@HWC, Hanan  
Abramovici/HC-SC/GC/CA@HWC, Irshad  
Mulla/HC-SC/GC/CA@HWC, Collin  
Pinto/HC-SC/GC/CA@HWC, Colette  
Strnad/HC-SC/GC/CA@HWC, Bruna  
Brands/HC-SC/GC/CA@HWC, Evelyn  
Soo/HC-SC/GC/CA@HWC, Courtney  
Smith/HC-SC/GC/CA@HWC, Jocelyn  
Kula/HC-SC/GC/CA@HWC, Tiana  
Branch/HC-SC/GC/CA@HWC  
cc Stephanie Chandler/HC-SC/GC/CA@HWC, Tiffany  
Thornton/HC-SC/GC/CA@HWC  
Subject CSS-WG Comments on IAS :Salvia

Good afternoon,

Please advise if you have any further comments for the Salvia IAS.  
Input needs to be provided as soon as possible as the IAS will be sent to the Director of OCS by COB  
today.

Thank you,

Allison Vadneau  
Research Analyst / Analyste en recherche  
Office of Drugs and Alcohol Research and Surveillance /  
Bureau de la recherche et de la surveillance des drogues et de l'alcool  
Controlled Substances and Tobacco Directorate /  
Direction des substances contrôlées et de la lutte au tabagisme  
Health Canada / Santé Canada  
123 Slater St., Ottawa, ON  
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Fax: 613-952-5188

# Issue Analysis Summary

DRAFT

## Scheduling *Salvia Divinorum* under the CDSA

Regulatory Policy Division  
Office of Controlled Substances  
Controlled Substances and Tobacco and Directorate

October 29, 2010

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1. APPROVALS
2. ISSUE
3. PURPOSE
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6. IDENTIFICATION AND ANALYSIS OF OPTIONS
7. CONSIDERATIONS
8. RECOMMENDATION(S)
9. CONSULTATIONS
10. IMPLEMENTATION AND EVALUATION

### 1. APPROVALS

This Issue Analysis Summary is approved.

Jocelyn Kula, A/Director  
Office of Controlled Substances  
Controlled Substances and Tobacco Directorate

[DD/MM/2010]

### 2. ISSUE

Health Canada has received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum* (*S. divinorum*), which is not currently regulated under the *Controlled Drugs and Substances Act* (CDSA). These requests are further to reports from scientific and media sources suggesting that *S. divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has also noted an ongoing media interest regarding the

**Comment [S1]:** There should be a discussion on why either on both; this was not discussed by the WG

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**Comment [S2]:** There is total inconsistency throughout the document regarding the name; the name should be the same throughout

**Comment [S3]:** I don't believe there has been many enquiries regarding and/or salvinorin A specifically

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availability of *S. divinorum* in Canada.

### 3. PURPOSE

To assess *S. divinorum* against the criteria for the addition of a substance to one of the Schedules to the CDSA, and determine whether this substance should be regulated as a controlled substance in Canada.

### 4. CONTEXT

*S. divinorum* is a species of sage which belongs to the mint family, and which is found in the form of dried leaves, extract and plant cuttings. Also called "diviner's sage", the plant is known to induce illusions and hallucinations when chewed or smoked. Salvinorin A, the psychoactive ingredient in *S. divinorum* is a neoclerodane diterpene, which is found primarily in the leaves, and to a lesser extent in the stem of the plant.<sup>1</sup>

*S. divinorum* is widely touted as a "legal" hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs among adolescents and young adults.<sup>2</sup> While very little is known about how and where *S. divinorum* is sold in Canada, it is suspected that it is mainly purchased over the Internet and/or bought at head shops or alternative life style stores, etc. *S. divinorum* cuttings are also available from a number of garden supply companies.

*S. divinorum* is a substance not currently scheduled under the CDSA. It can be imported and sold legally in Canada to anyone of any age, anywhere in Canada provided it is not sold as a health product or hallucinogen. In addition, the *S. divinorum* sold in Canada is currently not subject to any specific quality or safety standards.

The use of *S. divinorum* as a psychotropic agent first came to Health Canada's attention in 2002. In 2004, Health Canada received four adverse drug reaction (ADR) reports associated with the use of *S. divinorum* as a hallucinogen, with three being considered non-serious (requiring no medical attention) and the fourth being considered serious (medical intervention was required). The serious ADR report involved the concomitant use of alcohol in a person diagnosed with Attention Deficit Disorder.

Further to the receipt of the aforementioned ADRs, the Marketed Health Products Directorate (MHPD) and the Natural Health Products Directorate (NHPD) of the Health Products and Food Branch (HPFB) prepared an issue analysis summary (IAS) in November 2005, which recommended that *S. divinorum* and its active ingredient salvinorin A be regulated as controlled

**Comment [S4]:** While the effects of salvinorin A were considered, the assessment was not made on "and/or salvinorin A"

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*Salvia divinorum* is a substance not currently scheduled under the CDSA. It can be imported and sold legally in Canada to anyone of any age, anywhere in Canada provided it is not represented as a health product or hallucinogen. In addition, the *S. divinorum* sold in Canada is currently not subject to any specific quality or safety standards. ¶

<sup>1</sup> U.S. Department of Justice Drug Enforcement Administration. 2002. Drugs and Chemicals of Concern: Salvia Divinorum (salvinorin A, divinorin A) URL: [http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm) Nov 2008

<sup>2</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.

substances. This recommendation was maintained when the IAS was updated in November 2006.

Later, in December 2005, MHPD and NHPD prepared a Signal Assessment (SA) (updated in June 2007) that eventually led to the preparation of a Health Risk Assessment (HRA), which concluded that *S. divinorum* or salvinorin A-containing health products would constitute a Type II Health Risk according to the Health Hazard Classification of the Recall Policy of the Health Products and Food Branch Inspectorate (HBFBI). Such a risk is defined as “a situation in which the use of, or exposure to, a product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote”.

Further to a discussion with the Assistant Deputy Minister (ADM) of the Healthy Environments and Consumer Safety Branch (HECSB) in April 2007, the (then) Drug Strategy and Controlled Substances Directorate (DSCSD) (now Controlled Substances and Tobacco Directorate, CSTD) organized a meeting with MHPD, NHPD and HPFBI to discuss *S. divinorum*. HPFBI was to determine appropriate compliance activities regarding *S. divinorum* and consult with the Canada Border Services Agency (CBSA) regarding the movement of products containing *S. divinorum* into and out of Canada.

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On September 13, 2007, a further meeting between DSCSD, MHPD, NHPD and HPFBI led to the conclusion that DSCSD would conduct a scheduling assessment of *S. divinorum* in order to explore the possibility of scheduling this substance under the CDSA.

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In September 2008, the Director Generals of DSCSD, MHPD, TPD and the HPFBI agreed that media lines and an “It’s Your Health” article on *S. divinorum* would be prepared.

#### 4.1 Relevant Legislative Frameworks in Canada

##### 4.1.1 Food and Drug Regulations (under the Food and Drugs Act)

The *Food and Drug Regulations* (F&DR) serve to ensure the safety, efficacy, and quality of health products offered for sale in Canada, including drugs and medical devices. Prior to being given market authorization, a manufacturer must present substantive scientific evidence that their product is safe, efficacious and of high quality. For drugs, Health Canada reviews this information carefully and, if the review is satisfactory, a Notice of Compliance (NOC) is issued and appropriate Drug Identification Numbers (DINs) are assigned.

A “drug” is defined under the F&DR as any substance or mixture of substances manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
- (b) restoration, correction or modification of organic functions in human beings or animals, or

- (c) disinfection in premises in which food is manufactured, prepared or kept;

As no products containing *S. divinorum* or its extracts have been reviewed and approved by Health Canada as of October 2010, it is illegal to market *S. divinorum* when it is represented as a drug.

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#### 4.1.2 Natural Health Products Regulations (under the Food and Drugs Act)

The Natural Health Products Regulations (NHPR) aim to provide Canadians with ready access to natural health products (NHPs) that are safe, effective, and of high quality, while respecting freedom of choice and philosophical and cultural diversity. The NHPR require that all licensed products display a Natural Product Number (NPN), or, in the case of a homeopathic medicine, a Drug Identification Number - Homeopathic Medicine (DIN-HM), on their labels. These numbers are issued once a product is authorized for sale in Canada. A product licence may be obtained pursuant to an application in which the applicant attests to all of the conditions set out in a natural health product monograph prepared and published by the Natural Health Products Directorate. Alternatively, an applicant may submit a product license application that provides evidence of quality, safety and efficacy that is assessed as being sufficient and approved by NHPD by the full submission route. The NHPR also require that all manufacturers, packagers, labelers, and importers have a site license issued on the basis of sufficient evidence of procedures respecting distribution records, product recalls, product handling, storage and delivery, and all other aspects of Good Manufacturing Practices as set out in the NHPR.

Deleted: The Natural Health Products Regulations (NHPR) aim to provide Canadians with ready access to natural health products (NHPs) that are safe, effective, and of high quality, while respecting freedom of choice and philosophical and cultural diversity. The NHPR require that all licensed products display a Natural Product Number (NPN), or, in the case of a homeopathic medicine, a Drug Identification Number - Homeopathic Medicine (DIN-HM), on their labels. These numbers are issued once a product is authorized for sale in Canada further to the submission of a product license application in which the applicant attests to all of the conditions set out in a natural health product monograph prepared and published by the Natural Health Products Directorate or submission of a product license application that provides sufficient evidence of quality, safety and efficacy that is assessed and approved by NHPD by the non-compendial route. The NHPR also require that all manufacturers, packagers, labelers, and importers be licensed which in turn requires the presence of procedures respecting distribution records, product recalls, product handling, storage and delivery, and all other aspects of Good Manufacturing Practices as set out in the NHPR. ¶

The definition of an NHP under the NHPR has both a function and substance component. The function component refers to those substances that are manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
- (b) restoring or correcting organic functions in humans; or
- (c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

The substance component refers to the requirement that all of the medicinal ingredients of an NHP must be substances set out in Schedule 1 (a list of included substances) to the NHPR, a traditional medicine or a homeopathic medicine, and none of the ingredients can be substances set out in Schedule 2, a list of excluded substances which includes any substance listed on Schedules I to V of the CDSA. Section 2(2) of the NHPR excludes those substances (except homeopathic medicines) whose sale is required to be pursuant to a prescription as per Section C.01.043 of the F&DR.

As per section 93(1)(b)(vi) of the NHPR, every natural health product must be labeled with its

authorized recommended use or purpose. In the case of *S. divinorum*, it is generally marketed for its hallucinogenic properties which are considered a modification of an organic function. Therefore products that contain *S. divinorum* and are manufactured, sold or represented for use as a hallucinogen meet the definition of an NHP.

As of October 2010, no products containing *S. divinorum* have been authorized by Health Canada so no NPNs or DIN-HMs have been issued for such products. Therefore sales of *S. divinorum* are illegal under the NHPR if the product is represented for use as a hallucinogen or if other health claims are made.

#### 4.1.3 Controlled Drugs and Substances Act and its Regulations

The CDSA provides a legislative framework for the control of substances that can alter mental processes and that may produce harm to the health of an individual or to society when diverted or misused. Except as authorized under its regulations, activities such as possession, possession for the purposes of trafficking, trafficking, importation, exportation, possession for the purposes of exportation and production of controlled substances are prohibited under the CDSA.

The substances regulated under the CDSA are grouped into eight Schedules, and each Schedule is associated with particular offences and penalties as described in Part I of the CDSA.

In determining whether a substance should be regulated as a controlled substance, and into which Schedule of the CDSA it should be placed, Health Canada considers a number of factors including:

- International requirements and trends in the control and/or scheduling;
- Chemical and/or pharmacological similarity to substances listed in the Schedules to the CDSA;
- Legitimate use of the substance, including therapeutic, scientific, industrial or commercial uses;
- Potential for abuse and/or addiction liability;
- Evidence of extent of actual abuse of the substance in Canada and internationally; and
- Risk to personal and public health and safety.

#### 4.2 Assessment of *S. Divinorum* for Scheduling Purposes

##### 4.2.1 International Requirements and Trends in the Control and/or Scheduling

At the present time, neither *S. divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and therefore do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

*Australia*

**Deleted:** The substance component refers to the requirement that all of the medicinal ingredients of an NHP must be substances set out in Schedule 1 to the NHPR, which is a list of included substances. Included substances are those substances that are traditional or homeopathic medicines, and of which none of the ingredients are substances set out in Schedule 2, which is a list of excluded substances. Excluded substances include any substance listed on Schedules 1 to V of the CDSA. Section 2(2) of the NHPR excludes those substances (except homeopathic medicines) whose sale is required to be pursuant to a prescription as per Section C.01.043 of the F&DR. As per section 93(1)(b)(vi) of the NHPR, every natural health product must be labeled with its authorized recommended use or purpose. In the case of *S. divinorum*, it is generally marketed for its hallucinogenic properties which are considered a modification of an organic function. Therefore products that contain *S. divinorum* and are manufactured, sold or represented for use as a hallucinogen meet the definition of an NHP.¶

¶ As of October 2010, no products containing *S. divinorum* have been reviewed and approved by Health Canada and no NPNs or DIN-HMs have been issued for such products. Therefore sales of *S. divinorum* are illegal under the NHPR if it is represented for use as a hallucinogen or if other health claims regarding the modification of organic functions are made.¶

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In June 2002, Australia became the first country to prohibit the sale, supply, possession and use of *S. divinorum* and salvinorin A. Both *S. divinorum* and salvinorin A are listed in Schedule 9 of Australia's *Standard for the Uniform Scheduling of Drugs and Poisons* on the basis of "high potential for abuse and risk to public health and safety."<sup>3</sup> Schedule 9 is Australia's most restrictive drug schedule, and includes "substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities."<sup>4</sup>

### **Belgium**

A decree was passed in Belgium on October 22, 2006 which added *S. divinorum* to the list of controlled substances. This list includes substances such as psilocybin mushrooms, khat and peyote cactus.<sup>5</sup>

### **Denmark**

In 2003, Denmark added *S. divinorum* and salvinorin A to their list of "category B" controlled substances, a category which also includes psilocybin mushrooms, cocaine, amphetamine, and several others substances that are only legal for medicinal and scientific purposes. Illegal possession carries a penalty of up to two years in prison.

### **Germany**

*S. divinorum* (plant and plant parts) was added to Appendix I of the *Narcotics Act* in Germany on March 1, 2008, making it illegal to produce, traffic, or possess. The law does not specifically mention salvinorin A.

### **Italy**

On June 25, 2004, the Italian Ministry of Health issued an ordinance prohibiting the sale of *S. divinorum* and its active constituent salvinorin A. On January 11, 2005, the Ministry of Health made possession of *S. divinorum* and salvinorin A illegal by placing them in "*Tabella I*" of the *Tabella Sostanze Stupefacenti o Psicotrope*.

### **Japan**

On November 9, 2006, the Japanese government added a group of thirty-three drugs to its list of controlled substances, including salvinorin A. The drugs are banned under a revised

<sup>3</sup> <http://www.tga.gov.au/ndpsc/record/tr200111.pdf>

<sup>4</sup> [http://www.cognitiveliberty.org/news/salvia\\_australia.htm](http://www.cognitiveliberty.org/news/salvia_australia.htm)

<sup>5</sup>

<http://eldd.emcdda.europa.eu/html.cfm/index5176EN.html?pluginMethod=eldd.shownewsdetails&id=20/12/2006BELGIUM:%20New%20substances%20controlled%20include%20mCPP%20and%20khat>

pharmaceutical law, under which persons involved in their illegal import, production, and sale, i.e. beyond medical treatment or research purposes, will be subject to up to five years imprisonment or a fine of up to five million yen.

### **Spain**

On January 28, 2004, the Spanish Ministry of Health and Consumption issued an order prohibiting the sale of *S. divinorum*. The regulation went into effect on May 6, 2004 and only prohibits activities related to commerce. Possession and/or use are not considered to be criminal offences.

### **Other Countries**

It is illegal to possess or sell *S. divinorum* in Croatia, Latvia, Lithuania, Poland, Romania, South Korea and Sweden. In Russia it is illegal to grow or sell *S. divinorum*, but it is legal to possess it. In Estonia, Finland, Iceland and Norway, *S. divinorum* is treated as a medicinal herb and it is illegal to import it without a relevant prescription from a doctor.

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### **United States of America**

*S. divinorum* and salvinorin A are not included in the Schedules to the United States *Controlled Substances Act* although both *S. divinorum* and salvinorin A have been added to a list of chemicals "of concern", but this has no legal implications. According to the National Institute for Drug Abuse, the Drug Enforcement Agency is considering classifying *S. divinorum* and/or salvinorin A as Schedule I drugs. This Schedule includes substances such as LSD and marijuana.

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In addition, some individual states have implemented laws restricting its use, sale and/or distribution. As of July 2010, a number of states have enacted legislation placing regulatory controls on *S. divinorum* and/or salvinorin A including Delaware, Georgia, Florida, Hawaii, Illinois, Kansas, Kentucky, Maryland, Mississippi, Missouri, Nebraska, North Dakota, Ohio, Oklahoma, South Dakota, Wisconsin, Virginia, California, Louisiana, Maine, North Carolina, and Tennessee. By way of example, additional details regarding the regulation of *S. divinorum* in these last five states are provided below.

#### **California**

As of January 1, 2009, the sale or distribution of *S. divinorum* or salvinorin A, or any substance or material containing *S. divinorum* or salvinorin A, to any person under 18 years of age is a misdemeanor punishable by imprisonment in a county jail for not more than six months, a fine of no more than \$1,000, or both.

#### **Louisiana**

In 2005, Louisiana passed a bill which prohibits the possession, production, manufacture

and distribution of a material, compound, mixture, or preparation intended for human consumption and that contains a hallucinogenic plant. A "hallucinogenic plant" is defined as "any part or portion" of a plant on a list of forty plants, which includes *S. divinorum*.

### Maine

In Maine, *S. divinorum* and salvinorin A are regulated in the same way as tobacco products; adults eighteen years of age or over can legally purchase and use the material, but selling or providing *S. divinorum* or salvinorin A to anyone under the age of eighteen is a criminal offence. Possession by a minor is a civil violation, punishable by a fine, community service, or both.

### North Carolina

On December 1, 2009, the North Carolina State Legislature brought a new law into force which made *S. divinorum* and salvinorin A illegal. The only legal *S. divinorum* activities are the growing for aesthetic, landscaping, or decorative purposes or university-affiliated medical or pharmacological research.

### Tennessee

On July 1, 2006, Tennessee classified the deliberate production, manufacture, distribution, or possession of the active chemical ingredient in the hallucinogenic plant *S. divinorum* as a Class A misdemeanor. It is not, however, a criminal offence to possess, plant, cultivate, grow, or harvest *S. divinorum* for aesthetic, landscaping, or decorative purposes. The law also does not apply to any dosage that is legally obtainable from a retail establishment without a prescription when (and if) it is recognized by the Food and Drug Administration as a homeopathic drug.

#### 4.2.2 Chemical and/or Pharmacological Similarity to Substances Listed in the Schedules to the CDSA

The psychoactive ingredient in *S. divinorum* is the neoclerodane diterpene salvinorin A.<sup>6</sup> Another plant which contains psychotropic terpenoids is *Artemisia absinthium* (wormwood).<sup>7</sup> Salvinorin A is a hallucinogen with a distinct structure, and it does not interact with the serotonin type-2A receptor or any other molecular target of classical hallucinogens.<sup>8</sup> Instead, the available research suggests that the psychotropic effects of salvinorin A are mediated by its agonistic actions at the

<sup>6</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage *Salvia divinorum*. Life Sci. 2005 Dec 22;78(5):527-31.

<sup>7</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. Pharmacotherapy. 2006 Sep;26(9):1268-72.

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Comment [S5]: Since these are considered legitimate uses, it should be reflected in section 4.2.3

Comment [S6]: Same comment as for North Carolina

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$\kappa$ -opioid (KOR) receptor.<sup>9</sup> Its mechanism of action is therefore unique.<sup>10</sup>

The psychoactive effects of *S. divinorum* vary in onset and duration and include perceptual distortions such as the sensation of becoming an object, having visions of various two-dimensional surfaces, films and membranes, revisiting places of the past (particularly childhood), perceived loss of the body and/or identity, various sensations of motion (being pulled or twisted by a force of some kind), uncontrollable hysterical laughter, and overlapping realities (perceptions of being in more than one place).<sup>11</sup> Laughter, happiness, a sense of well-being and dissociative effects were deemed the most positive aspects of *S. divinorum* by users, second only to the "trip" that the drug elicits.<sup>12</sup> Depersonalization, speaking gibberish, widening of consciousness and subjective illusions of rapid movement, flying or hovering have also been reported.<sup>13</sup>

The psychotomimetic effects of *S. divinorum* closely resemble the schizoid symptoms induced by lysergic acid diethylamide (LSD) or phencyclidine (PCP).<sup>14</sup> Yet, it is said to have only a weak influence on the prevailing mood of the user which differentiates it from other hallucinogens such as LSD and psilocybin.<sup>15</sup> Its strong dissociative effects are often compared to those of ketamine.<sup>16</sup> Users have reported that the psychedelic effects of *S. divinorum* were most similar to those caused by psilocybin mushrooms.<sup>17</sup> However, users familiar with the effects of other hallucinogens agree that despite certain similarities to classical hallucinogens, the visions and overall experience are quite unique.<sup>18</sup>

<sup>9</sup> Roth BL, Baner K, Westkaemper R, Siebert D, Rice KC, Steinberg S, Ernsberger P, Rothman RB. Salvinorin A: a potent naturally occurring nonnitrogenous kappa opioid selective agonist. Proc Natl Acad Sci U S A. 2002 Sep 3;99(18):11934-9.

<sup>10</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>11</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>12</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>13</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5 and Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>14</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5.

<sup>15</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>16</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five Salvia divinorum herbal products. Pharmacotherapy. 2006 Sep;26(9):1268-72.

<sup>17</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>18</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6 and González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.



*S. divinorum* causes an unusually high degree of sedation, weakness and fatigue, and the increased de-realization is not commonly reported for classical psychedelics.<sup>19</sup> The combination of these effects seems to correlate with that of other KOR agonists such as pentazocine.<sup>20</sup>

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The onset and intensity of the effects of *S. divinorum* appear to be related to the route of administration. Traditional uses generally produce mild effects because the leaves are rolled and chewed or crushed and prepared as a foamy infusion whereby the salvinorin A is degraded in the gastrointestinal system before being absorbed into the bloodstream. Hence, the level of effect relates quite closely to the length of time the material spends in the mouth, with the onset of effect generally taking 5-10 minutes. The effects build over the next hour and last for another hour before they begin to subside.<sup>21</sup>

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Routes of administration that avoid the hepatic first-pass effect (i.e. inhalation, intravenous, intramuscular and sublingual use) provide the quickest and most intense effect.<sup>22</sup> Salvinorin A can be isolated from the plant to make a powder which can be vaporized and inhaled. The effects felt from vaporizing salvinorin A are experienced in about 30 seconds, last for about 5-10 minutes, and then subside over the next 30 minutes.<sup>23</sup>

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Smoking the dried leaves or a concentrated extract using a pipe or bong is by far the most popular method of administration.<sup>24</sup> Dried leaves may also be fortified with a concentrated extract of salvinorin A. A concentrated extract can also be used sublingually. Neither *S. divinorum* nor salvinorin A can be injected because the powder is insoluble in water.<sup>25</sup>

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#### 4.2.3 Legitimate Use of the Substance, including Therapeutic, Scientific, Industrial or Commercial Uses

*S. divinorum* has traditionally been used for spiritual and medicinal purposes by the Mazatec

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<sup>19</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>20</sup> Arasteh K, Poudevida S, Farre M, Roset PN, Cami J. Response patterns of the Spanish version of the 49-item short form of the Addiction Research Center Inventory after the use of sedatives, stimulants, and opioids. *Drug Alcohol Depend.* 1999 Jun 1;55(1-2):117-25.

<sup>21</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>22</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.

<sup>23</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>24</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62 and Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>25</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (*divinorin*) A. *J Psychoactive Drugs.* 1994 Jul-Sep;26(3):277-83.

Indians in Oaxaca, Mexico,<sup>26</sup> For medicinal purposes (gastrointestinal problems, headaches, rheumatism, anemia and swelling of the stomach) an infusion of the leaves or the leaves themselves are ingested.<sup>28</sup> However, its main use in Mexico today is believed to be for its psychedelic properties in the aid of producing "mystical" or hallucinogenic experiences as part of spiritual rituals.<sup>30</sup>

Although selective KOR agonists have been shown to produce analgesic effects, adverse effects such as psychotomimesis, dysphoria and diuresis have been observed in studies investigating their therapeutic use.<sup>31</sup> In addition, while it has been speculated that KOR agonists may be useful in the treatment of certain psychiatric disorders including Alzheimer's disease, schizophrenia, dementia and bipolar disorder, but there has been no clinical research to support these hypotheses.<sup>33</sup> That said there are presently no recognized medical uses for *S. divinorum* in Canada.

Similarly, there are no known industrial or commercial uses for *S. divinorum* in Canada. Most websites offering *S. divinorum* cuttings and seeds for sale appear to do so in the context of growing the plant for "recreational" purposes, rather than out of horticultural interest or for its esthetic appeal. However, it should be acknowledged that this does not preclude the possibility of a person growing this plant for purely decorative purposes. *S. divinorum* is also marketed as incense. However, there is no evidence that *S. divinorum* has any fragrant properties that would legitimize such a use. Therefore it is believed that the marketing of this plant as an incense is a means to avoid compliance and enforcement actions by Health Canada.

#### 4.2.4 Potential for Abuse and/or Addiction Liability

Salvinorin A is a potent, KOR-selective agonist and in contrast to the euphoria produced by

<sup>26</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>28</sup> Munro, T. The Chemistry of Salvia divinorum. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

<sup>30</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage Salvia divinorum. Life Sci. 2005 Dec 22;78(5):527-31.

<sup>31</sup> Barker RL, Fawcett J, Barkin SJ. 2002. Chronic pain management with a focus on the role of newer antidepressants and centrally acting agents. In: Pain Management: A Practical Guide for Clinicians, 6th edition, Weiner RS ed. CRC Press, Boca Raton, FL. pp. 415-34 and Tidgewell et al., 2004. A facile method for the preparation of deuterium labelled salvinorin A: Biorganic & Medicinal Chemistry Letters, 14: 5099-5102.

<sup>33</sup> Sheffler DJ & Roth BL. Salvinorin A: the 'magic mint' hallucinogen finds a molecular target in the kappa opioid receptor. Trends Pharmacol Sci. 2003 Mar;24(3):107-109.

<sup>35</sup> Killinger BA, Peet MM, Baker LE. Salvinorin A fails to substitute for the discriminative stimulus effects of LSD or ketamine in Sprague-Dawley rats. Pharmacology, Biochemistry & Behaviour. 2010 May 96; 260-265.

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MOR agonists such as morphine, KOR agonists are negatively reinforcing and aversive.<sup>35</sup> In addition, KOR agonists have analgesic properties, but are not associated with respiratory depression like MOR agonists.<sup>36</sup> Finally, while MOR agonists increase the release of dopamine, the activation of KOR decreases dopamine release in the nucleus accumbens.<sup>37</sup> In the case of MOR agonists, the increase of dopamine acts as a positive reinforcer. This action motivates the user to use the drug again, which could lead to drug abuse and/or addiction. For KOR agonists, this is not the case.

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The aversive effects of KOR agonists suggest that the risk of addiction to *S. divinorum* is negligible. However, very few controlled scientific studies of the physical and psychotropic effects of *S. divinorum* on humans have been carried out and the results have been conflicting. For example, one author states: "Many who have used salvinorin A find the experience extremely unnerving, frightening and overly intense and most have no desire to repeat the experience."<sup>38</sup> However, another study suggested that this is not the experience of all recreational users of *S. divinorum*.<sup>39</sup> Over eighty percent of users surveyed on a web-based questionnaire about their *S. divinorum* use said that they would probably or definitely use *S. divinorum* again.<sup>40</sup> Users have reported the negative effects of *S. divinorum* as: the short duration of action, lack of control over the experience, persisting negative effects (most often anxiety),<sup>41</sup> sweating, chills, increased diuresis, impaired vigilance,<sup>42</sup> and negative after-effects including tiredness, feeling head heavy, dizziness, physical exhaustion, and some degree of malaise or 'hangover' as they 'comedown' from the drug.<sup>43</sup>

In addition, some users have noted that they require increasing doses of salvinorin A in order to achieve the desired effect and the stimulated cerebral KOR may act as a mechanism of

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<sup>36</sup> Gusein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006. pp. 547-590.

<sup>37</sup> Gusein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006. pp. 547-590.

<sup>38</sup> Turner DM. Salvinorin - The Psychedelic Essence of Salvia Divinorum. Panther Press, San Francisco, CA 1996.

<sup>39</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62, Buecheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). *Pharmacopsychiatry.* 2005 Jan;38(1):1-5, and Valdés LJ 3rd. Salvia divinorum and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs.* 1994 Jul-Sep;26(3):277-83.

<sup>40</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>41</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>42</sup> Buecheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). *Pharmacopsychiatry.* 2005 Jan;38(1):1-5.

<sup>43</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

tolerance.<sup>44</sup> Therefore, it is difficult to predict with certainty its potential for addiction and abuse. In studies that have been conducted, there is conflicting information around the addiction liability of *S. divinorum* in both animals and humans. Further studies in this area and on the KOR mediated decrease of dopamine are also required in order to fully understand the addiction potential of this substance.

While concerns for the potential of abuse were initially considered minimal given that 1 kg of dried leaves only yield 3 to 6 human doses of salvinorin A for oral consumption, it was then discovered that vaporizing and inhaling 200-500 micrograms had profound hallucinogenic effects.<sup>45</sup> Given that only small doses of this substance are now necessary to achieve the desired effects through inhalation, the potential for abuse is much higher. Also, the extraction of salvinorin A from the plant is simple, and with care, approximately 1.5 grams of pure salvinorin A per kilogram of dried leaves (8kg of fresh leaves) can be isolated. This is enough for 2000 oral doses.<sup>46</sup>

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#### 4.2.5 Evidence of Extent of Actual Abuse of the Substance in Canada and Internationally

In Canada, the prevalence of use of *S. divinorum* has recently been documented. Questions about the use of salvia were included in the 2009 Ontario Student Drug Use and Health Survey, the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey. In some cases it is not clear if responses indicate the use of *S. divinorum* or salvinorin A given the use of the term "salvia".

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<sup>44</sup> Bucheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>45</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>46</sup> Valdés LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs*. 1994 Jul-Sep;26(3):277-83.

The results from the 2009 Ontario Student Drug Use and Health Survey were published on November 18, 2009 and indicate that:

- Among all responding students in Ontario, 4.4% reported using *S. divinorum* at least once in the past year. In comparison, 58.2% indicated they had used alcohol, 25.6% indicated they had used cannabis and 5.0% indicated they had used hallucinogens other than LSD and PCP in the past year;
- Males (6.2%) were significantly more likely than females (2.3%) to report using *S. divinorum*;
- There is significant grade variation, with *S. divinorum* use most likely among 11<sup>th</sup> graders (8.6%) and 12<sup>th</sup> graders (8.4%); and

The results of the 2008-2009 Youth Smoking Survey were published on May 31, 2010 and indicate that:

- 4.9% of students stated that they had used *salvia* in the last twelve months. In comparison, 53.0% indicated they had used alcohol, 27.3% indicated they had used cannabis and 6.9% indicated they had used other hallucinogens in the last twelve months;
- 2.6% of students in Grades 7-9 and 7.0% of students in Grades 10-12 had used *salvia* in the last twelve months; and
- Males (6.6%) were more likely to have used *salvia* in the past twelve months compared to females (3.2%).

The Canadian Alcohol and Drug Use Monitoring Survey specifically examined *salvia* for the first

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<sup>53</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

time in 2009. An estimated 1.6% of Canadians, aged 15 years and older, reported that they had used salvia in their lifetime, and 0.2% reported using it in the past-year. In comparison, the prevalence of past-year cannabis use among Canadians 15 years of age and older was 10.6%, while 1.2% of respondents reported using cocaine or crack in the past 12 months, 0.9% ecstasy and 0.7% illicit hallucinogens. Salvia appears however to be a substance that is tried largely by youth with a 7.3% prevalence of lifetime use.

According to the 2009 Monitoring the Future survey, annual prevalence of use of *S. divinorum* among 12th graders in the United States is 5.7%. The American Substance Abuse and Mental Health Services Administration's 2006 National Survey on Drug Use and Health found that, of respondents aged 12 or older, 1.8 million had used *S. divinorum* at least once in their lifetime and 756,000 had used the substance in the past year. Among youth aged 12 to 17, males were more likely than females to have used *S. divinorum* in the past year (0.9% vs. 0.3%).

Health Canada's Drug Analysis Services (DAS) has identified salvinorin A in a number of samples seized by law enforcement, ranging from 9 samples in 2006 to 20 samples in 2009. It is, however, difficult to determine how this data reflects the extent of actual abuse of salvinorin A in Canada, given that *S. divinorum* is not an illegal substance and would likely only be seized accidentally or during the seizure of other illicit substances.

The National Forensic Laboratory Information System (NFLIS) and the System to Retrieve Information from Drug Evidence (STRIDE) in the United States are Drug Enforcement Agency (DEA) databases that collect scientifically verified data on analyzed samples in state and local forensic labs as well as samples from DEA labs. While in 2000 no seized samples were found to contain *S. divinorum* or salvinorin A, 70 samples tested positive in 2008. Once again, it is difficult to determine how this data can be used to reflect the actual extent of abuse of *S. divinorum* and salvinorin A in the United States as both these substances are not listed in the *Controlled Substances Act*.

The increase in both the number of enquiries to Health Canada from various municipalities and members of the public and the amount of media interest regarding the availability of *S. divinorum* in Canada may be an indication that the recreational use of *S. divinorum* as a hallucinogen is on the rise. However, it may only reflect an increased awareness of the phenomenon.

#### 4.2.6 Risk to Personal and Public Health and Safety

The potential for harm to the user and/or other individuals is primarily related to the hallucinogenic properties of the substance. As this substance is typically smoked, there is no risk of infectious disease transmission as is the case when a drug is injected. Users may get up and walk around without apparent awareness of their movements, behaviour or surroundings, and distinction between self and surroundings is often lost. At doses greater than 1mg of salvinorin A, out of body experiences are frequent and loss of consciousness has been reported.<sup>53</sup> There is little information regarding the social behaviours of persons under the influence of *S. divinorum* products, and what risks their activities such as operating a motorized vehicle may pose to the general public. There is also very little data regarding the toxicity, teratogenicity or other long-

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term effects of *S. divinorum* use.<sup>54</sup>

As far as law enforcement is concerned, the Department has only received a limited number of communications indicating concern with respect to *S. divinorum*. The Royal Canadian Mounted Police (RCMP) has stated that while *S. divinorum* is readily available, it has not become a popular drug in Canada, probably due to its aversive effects such as anxiety and introversion.

A handful of case reports regarding physiological and psychotropic effects of *S. divinorum* use have been published in the scientific/medical literature. For example, an international case report described the perceptions of a 19 year-old man after inhaling *S. divinorum* smoke. The peak psychotropic effects, including prickling of the skin, fever-like hot flashes, muscular tremor, and depersonalization, were reached in less than five minutes after inhalation of an unknown amount of smoke from burning dried leaves.<sup>55</sup> Another report involved a 15-year-old male who presented to psychiatric emergency services with acute onset of paranoia, déjà vu, blunted affect, difficulties in thought processing and slowed speech after smoking *S. divinorum* over an unknown period of time. During his hospitalization all symptoms improved significantly except the feeling of déjà vu. Based on this case presentation, the author suggested that the feelings of déjà vu may be a long-term effect of *S. divinorum* use.<sup>56</sup> However, given that this is the only case report in which déjà vu was associated with the use of *S. divinorum*, more reports are needed to substantiate this finding.

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In addition to the above-mentioned reports, in 2006, a case was reported in the U.S. in which a 17-year-old boy committed suicide after smoking *S. divinorum* for an unknown period of time.<sup>57</sup> It should be noted that alcohol and general depression were the main confounders in this case. After this case was reported, the state of Delaware passed a law which classified *S. divinorum* as a Schedule I controlled substance along with other hallucinogenic substances.

Like many drugs of abuse, users are often unaware of the potency and adulterants in the product they purchase. A study by Wolowich *et al.* (2006), showed that the salvinorin A content in five out of five *S. divinorum* products was falsely indicated on the label and 4 out of 5 products contained unidentified adulterants (i.e. vitamin E, caffeine).<sup>58</sup>

There are also several reports of domestic adverse reactions related to the use of *S. divinorum* that have been received through the Canada Vigilance database. However, this does not reflect true incidence due to under-reporting.

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## 5. ASSESSMENT OF RISKS AND BENEFITS

<sup>54</sup> Grundmann O, Phipps SM, Zadezensky I, Butterweck V. *Salvia divinorum* and Salvinorin A: An Update on Pharmacology and Analytical Methodology. *Planta Med* 2007 Jun;73:1039-1046.

<sup>56</sup> Singh S. (2007) Adolescent salvia substance abuse. *Addiction*. 102, 823-824.

<sup>57</sup> <http://www.kvbc.com/Global/story.asp?S=4893692>

<sup>58</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

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**Is(Are) exempted pursuant to section(s)  
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**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**



s.21(1)(a)

s.21(1)(b)

### 7. CONSIDERATIONS

The NHPR are limited in their capacity to control the availability of *S. divinorum* in that *S. divinorum* products are often declared as incense and therefore cannot be considered unapproved natural health products. In addition, compliance and enforcement actions such as voluntary stop-sales, forfeiture, destruction, and administrative seizure, cannot be implemented unless the marketing of the product indicates that it is to be sold for human consumption in order to modify an organic function. Unlicensed natural health products are also permitted to be imported provided they are for personal use only.

Non-regulatory options for the control of *S. divinorum* were also considered, such as the development of an educational campaign to highlight the risks associated with using this plant. However, the risks associated with this substance, as well as the confusion concerning its enforcement as a natural health product only when it is sold for use with a health claim, do not make this option viable.

*S. divinorum* meets the criteria for scheduling a substance under the CDSA. While neither the plant nor its main active component salvinorin A are scheduled under any of the UN Drug Control Conventions, a number of countries and American states have taken steps to control the distribution and use of these substances. *S. divinorum* and salvinorin A are pharmacologically similar to other substances included in Schedule III to the CDSA, such as LSD and psilocybin. There are also currently no legitimate therapeutic, commercial or industrial uses for *S. divinorum*.

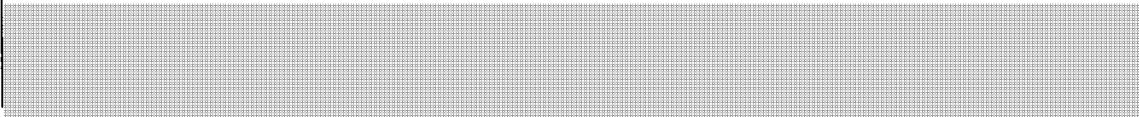
While the addiction potential of *S. divinorum* appears to be low, there is a significant potential for its abuse as a 'legal' hallucinogen. There is very little information with regards to the long-term effects of *S. divinorum* use. There is also evidence of abuse, particularly by Canadian youth and potential for individual health risks as well as risks to public health and safety.

- Deleted: <#>hallucinoge ... [29]
- Comment [S14]: Shou ... [30]
- Deleted: ¶ ... [31]
- Formatted: Highlight
- Deleted: have begun
- Deleted: smoking the lea ... [32]
- Deleted: While there has ... [33]
- Deleted: used for
- Deleted: and can
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- Deleted: alvia
- Formatted: Not Highlight
- Deleted: and
- Deleted: salvinorin A
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- Formatted: Not Highlight
- Deleted: for physical dependence
- Deleted: and adolescents.
- Formatted: Not Highlight
- Deleted: for

s.21(1)(a)  
s.21(1)(b)

In light of a recommendation to include *S. divinorum* under Schedule III to the CDSA, it is also recommended that the main psychoactive ingredient of this plant, salvinorin A, be scheduled. Salvinorin A can easily be extracted from *S. divinorum* and this substance gives the plant its hallucinogenic properties. Therefore salvinorin A results in the same risks as *S. divinorum* and should also be controlled under the CDSA in the same manner as *S. divinorum*.

8. RECOMMENDATIONS



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9. CONSULTATIONS

The Drug Analysis Services (DAS) was contacted in order to provide any data available regarding the identification of salvinorin A in samples submitted by law enforcement.

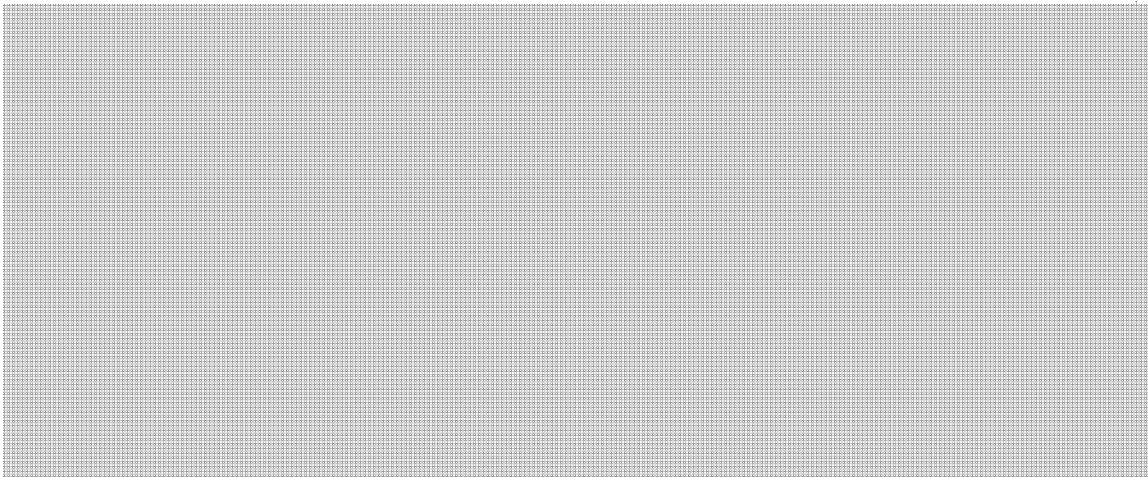
The Royal Canadian Mounted Police (RCMP) was contacted in order to establish their views with respect to *S. divinorum* use in Canada. The RCMP advised that *S. divinorum* is readily available and law enforcement agencies have no legal means to prevent its sale.

OCS has received a number of correspondences from Canada Border Services Agency (CBSA) officers concerning a lack of information regarding the status of *S. divinorum* and how the plant should be treated at the border. CBSA officers have also expressed concern regarding the plant's hallucinogenic properties. At present, only shipments of *S. divinorum* that are represented for sale as health products that modify organic functions can be refused for import under the NHPR.

OCS brought *S. divinorum* to the Controlled Substances Scheduling Working Group (CSS-WG) in August 2010 to discuss the possibility of regulatory control of this substance. After assessing the available information against the six criteria listed in the Context section of this Issue Analysis Summary, the CSS-WG recommended that *S. divinorum* be included under Schedule III to the CDSA.

- Comment [S15]: Need a para. regarding whether to schedule salvia and/ salvinorin a; that was not discussed by the WG
- Deleted: and salvinorin A
- Deleted: ese
- Deleted: s
- Deleted: 6
- Deleted: Th
- Deleted: both
- Deleted: divinor

10. IMPLEMENTATION AND EVALUATION



**Page(s) 001581 to\à 001581**

**Is(Are) exempted pursuant to section(s)  
est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**

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Page 14: [1] Deleted SDESJARD 2010-10-26 3:43:00 PM

It is difficult to determine the extent of actual abuse of *S. divinorum* in Canada or elsewhere as there appear to be inconsistencies in the literature regarding risk aversion. For example, one author states: "Many who have used salvinorin A find the experience extremely unnerving, frightening and overly intense and most have no desire to repeat the experience."<sup>1</sup> However, another study suggested that this is not the experience of all recreational users of *S. divinorum*.<sup>2</sup> Over eighty percent of users surveyed on a web-based questionnaire about their *S. divinorum* use said that they would probably or definitely use *S. divinorum* again.<sup>3</sup> Users have reported the negative effects of *S. divinorum* as: the short duration of action, lack of control over the experience, persisting negative effects (most often anxiety),<sup>4</sup> sweating, chills, increased diuresis, impaired vigilance,<sup>5</sup> and negative after-effects including tiredness, feeling head heavy, dizziness, physical exhaustion, and some degree of malaise or 'hangover' as they 'comedown' from the drug.<sup>6</sup>

---

Page 14: [2] Deleted SDESJARD 2010-10-26 3:43:00 PM

There are significant regional variations, with students in Northern Ontario (9.2%) most likely to use *Salvia divinorum*.

---

Page 14: [3] Comment [S10] STCHANDL 2010-10-27 4:20:00 PM

Survey specifically asked about "salvia" rather than *S. divinorum* or salvinorin A

---

Page 14: [4] Deleted SDESJARD 2010-10-26 3:44:00 PM

The scope of the previously mentioned studies did not provide for any explanations regarding differences in usage between ages, genders and regions. In this regard, it is difficult to speculate on the causality of such differences.

---

Page 15: [5] Deleted STCHANDL 2010-10-27 3:29:00 PM

### NUMBER OF SAMPLES FOUND TO CONTAIN SALVINORIN A

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<sup>1</sup> Turner DM. Salvinorin - The Psychedelic Essence of Salvia Divinorum. Panther Press, San Francisco, CA 1996.

<sup>2</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62, Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5, and Valdès LJ 3rd. Salvia divinorum and the unique diterpene hallucinogen, Salvinorin (divinorin) A. J Psychoactive Drugs. 1994 Jul-Sep;26(3):277-83.

<sup>3</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>4</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>5</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5.

<sup>6</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

s.21(1)(a)  
s.21(1)(b)

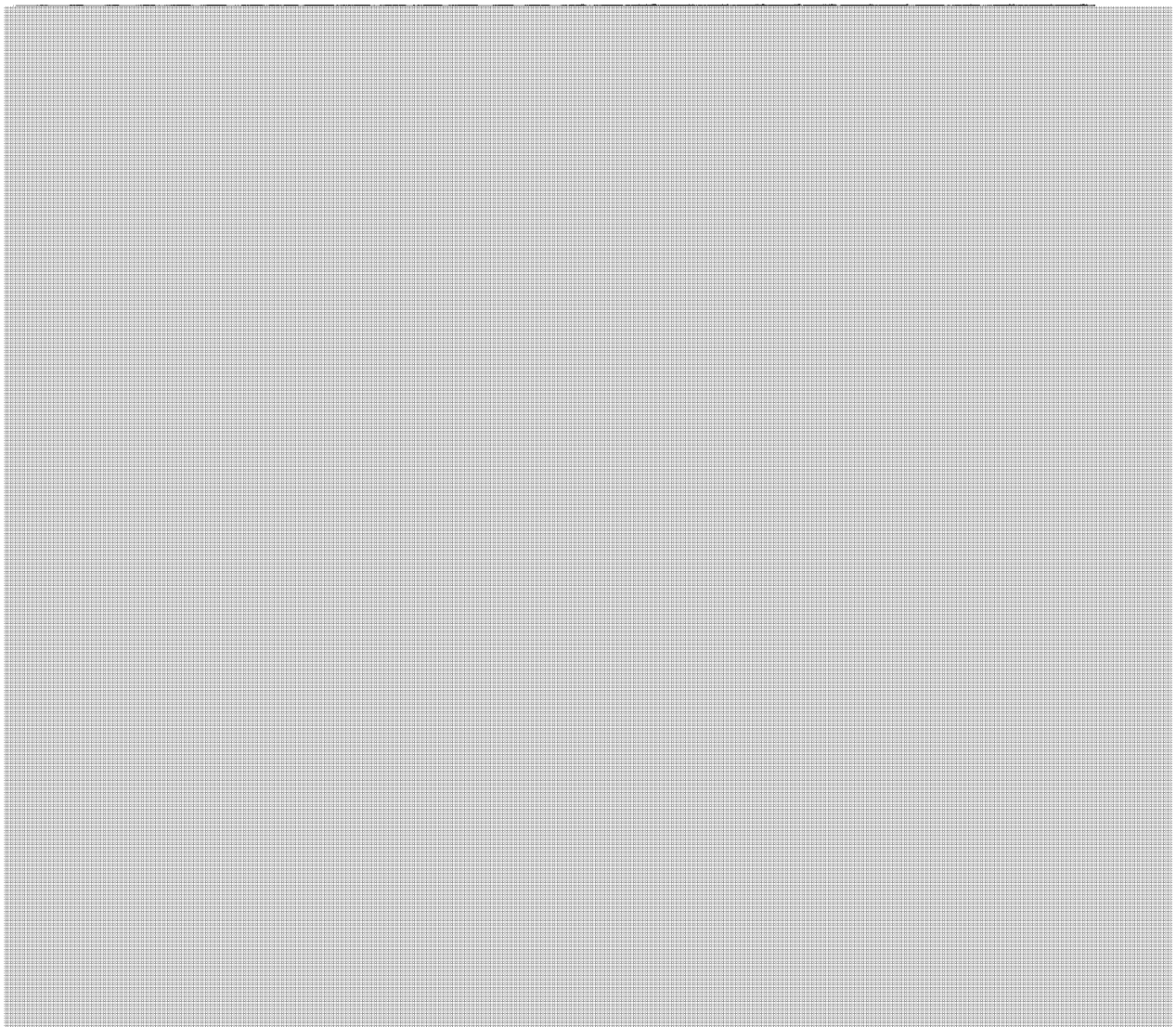
Year	Count
2006	9
2007	8
2008	4
2009	20
2010 (as of May 7)	8

Page 15: [6] Deleted STCHANDL 2010-10-27 3:31:00 PM

The following table shows the quantity of *S. divinorum* products that were seized from 2000 through to 2009.

Page 15: [7] Deleted SDESJARD 2010-10-26 3:48:00 PM

The increase in both the number of enquiries from various municipalities and members of the public and the amount of media interest regarding the availability of *Saliva divinorum* in Canada may be an indication that the recreational use of *S. divinorum* as a hallucinogen is on the rise. However, there are no available statistics that indicate there has been a significant increase in *S. divinorum* use in the Canadian population.




**Page(s) 001584 to\à 001587**

**Is(Are) exempted pursuant to section(s)  
est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**

**Re: Salvia IAS for Review**   
Jocelyn Kula to: Stephanie Chandler

2010-11-01 09:35 AM

Ok I will review then. Can you pls start drafting the NOI while I try and figure out whether we need to go through EC- Science and Risk (see next email)

JK  
Sent by blackberry

Jocelyn Kula  
A/ Director/ Directrice par interim  
Office of Controlled Substances/ Bureau des substances contrôllées  
Stephanie Chandler

----- Original Message -----

**From:** Stephanie Chandler  
**Sent:** 2010-11-01 08:50 AM EDT  
**To:** Jocelyn Kula  
**Subject:** Re: Salvia IAS for Review

Hi Jocelyn,

Yes this version does include all the comments from ODARS. The CSS-WG had no major comments on our adjusted recommendations, but they did have some comments on the body of the IAS (though it had not changed substantially since it was last reviewed by the working group in August).

At the meeting it was also confirmed that, in accordance with the CSS-WG process, once a Notice of Intent has been published for Salvia and public comments received, the IAS will go back to CSS-WG again.

Let me know if you have any questions.

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôllées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

---

Jocelyn Kula                    just to be clear; does this version include the O...                    2010-10-31 10:33:50 PM

---

From:                    Jocelyn Kula/HC-SC/GC/CA  
To:                        Stephanie Chandler/HC-SC/GC/CA@HWC  
Date:                     2010-10-31 10:33 PM  
Subject:                 Re: Salvia IAS for Review

---

just to be clear; does this version include the ODARS comments I was copied on? what happened at the CSS-WG meeting?

JK

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

---

Stephanie Chandler Hi Jocelyn, For your review.

2010-10-29 04:47:13 PM

---

From: Stephanie Chandler/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: CSTD-OCS-DO, Daniel Galarneau/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2010-10-29 04:47 PM  
Subject: Salvia IAS for Review

---

Hi Jocelyn,

For your review.

[attachment "Draft Salvia Divinorum IAS\_Oct 29 2010.doc" deleted by Jocelyn Kula/HC-SC/GC/CA]

Thanks,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca





**Fw: Salvia**  
Jocelyn Kula to: Stephanie Chandler

2010-11-01 09:50 AM

for the file pls

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224  
---- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2010-11-01 01:36 AM ----

From: Christine Roush/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC, Stephanie Szick/HC-SC/GC/CA@HWC, Nicole  
Prentice/HC-SC/GC/CA@HWC  
Date: 2010-10-20 12:31 PM  
Subject: Fw: Salvia

---

FYI - see email below from HPFB. Heidi may be contacting you about this.

Christine Roush  
Senior Communications Advisor/

From: Ken Polk/HC-SC/GC/CA  
To: dave\_stephens@hc-sc.gc.ca  
Cc: Elizabeth Keeping/HC-SC/GC/CA@HWC, Christine Roush/HC-SC/GC/CA@HWC  
Date: 2010-10-20 12:26 PM  
Subject: Fw: Salvia

---

Follow up to MO questions this morning.

Ken Polk  
Senior Communications Executive/ Gestionnaire principal des communications  
Strategic Communications Directorate / Direction générale des communications stratégiques  
Public Affairs, Consultation and Communications Branch / Direction générale des affaires publiques, de  
la consultation et des communications  
Health Canada / Santé Canada

Tel: (613) 941-0698 Cell: (613)219-0903 Fax: (613) 957-8805

---- Forwarded by Ken Polk/HC-SC/GC/CA on 2010-10-20 12:24 PM ----

From: Stephanie Priest/HC-SC/GC/CA  
To: Clarke Olsen/HC-SC/GC/CA@HWC, Graham Howell/HC-SC/GC/CA@HWC  
Cc: HPFB\_ADMO\_EWR, Steven Schwendt/HC-SC/GC/CA@HWC, Heidi  
Jackson/HC-SC/GC/CA@HWC  
Date: 2010-10-20 12:21 PM  
Subject: Salvia

---

Clarke and Graham

Further to your questions this morning about Salvia - I have confirmed with NHPD that my information is correct. Products containing salvia are would only be considered a NHP (and subject to the NHP regulations) if they make a health claim.

- If the ingredient salvia is found in a product AND it the product makes a health claim, then the product would be considered a NHP

- if the ingredient is found in a product BUT DOES NOT make a health claim, then it would NOT be considered a NHP

As I mentioned, we would look at each situation on a case by case basis - there can be gray areas with respect to the claim. You mentioned one of them: if they have a website making a claim or if a retailer is making a claim. We would look at these situations carefully to determine if they are NHP claims. If its a website, we would likely ask that the claim be removed from the website.

- With respect to the status of scheduling Salvia as a controlled substance, we have not been able to reach HECs ADMO this morning. I would suggest that you follow-up directly with Heidi Jackson.

Thanks (and sorry for the delay)

Stephanie

Stephanie Priest  
Executive Director, Issues Management  
Directrice exécutive, Gestion des questions d'intérêt  
ADMO-HPFB/BSMA-DGPSA  
Health Canada/Santé Canada  
tel. 613-952-6237  
fax 613-957-3954



**Fw: hecs bus plng today**

Jocelyn Kula to: Stephanie Chandler, Denis Arsenault  
Cc: Patricia Rapold

2010-11-01 09:52 AM

pls note head's up re salvia. we are all still trying to figure out how the item appears to have made it onto the forward agenda so no need to generate anything yet.....but stay tuned....

JK

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224  
---- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2010-11-01 12:44 AM ----

---

From: Cathy A Sabiston/HC-SC/GC/CA  
To: Suzanne Desjardins/HC-SC/GC/CA@HWC  
Cc: Suzanne Desjardins/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Stephanie Szick/HC-SC/GC/CA@HWC  
Date: 2010-10-27 04:22 PM  
Subject: Re: hecs bus plng today

---

thx very much

Cathy Sabiston  
Director General / Directrice générale  
Controlled Substances & Tobacco Directorate (CSTD)  
Direction des substances contrôlées et de la lutte au tabagisme (DSCLT)  
Health Canada / Santé Canada  
Tel: (613) 941-1977 Fax: (613) 954-2288  
E-mail/courriel: cathy.a.sabiston@hc-sc.gc.ca  
Website/Site web: www.hc-sc.gc.ca

---

Suzanne Desjardins sorry everyone, I should have checked my file...

2010-10-27 03:21:57 PM

---

From: Suzanne Desjardins/HC-SC/GC/CA  
To: Suzanne Desjardins/HC-SC/GC/CA@HWC  
Cc: Cathy A Sabiston/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Stephanie Szick/HC-SC/GC/CA@HWC  
Date: 2010-10-27 03:21 PM  
Subject: Re: hecs bus plng today

---

sorry everyone, I should have checked my files earlier.

FYI

There is a meeting of the HECS Exec Subcommittee on Science Policy, (Chaired by Beth and on which Ivan Ross and I are members), scheduled for this Friday. On the Agenda is Beth's de-brief of the "EC SRM forward agenda". Among the documents sent in preparation for our meeting is the list of proposed topics; Salvia is listed but unscheduled. Salvia is identified as a Natural Health Product with the issue being "potential for abuse/dependence (CDSA discussion with OCS)"; the lead identified is HPFB/HECS. Looking at the list of "what items should be brought to EC-SRM", it is not clear to me why Salvia has been

identified. Also of interest to us would be an issue from Legal services regarding litigation from the perspective of how it affects HC -How HC officials are implicated, resources....(topic also not yet scheduled)

I will let you know what more I learned from my meeting on Friday on this issue and on how the 2 committees are related.

Suzanne

---

Suzanne Desjardins we had reps from HPFB (Marketed products a... 2010-10-27 02:33:09 PM

From: Suzanne Desjardins/HC-SC/GC/CA  
To: Cathy A Sabiston/HC-SC/GC/CA@HWC  
Cc: Jocelyn Kula/HC-SC/GC/CA@HWC, Stephanie Szick/HC-SC/GC/CA@HWC  
Date: 2010-10-27 02:33 PM  
Subject: Re: hecs bus plng today

---

we had reps from HPFB (Marketed products and Natural Health Products) and Inspectorate at our meeting this morning to discuss the scheduling of Salvia and no one raised it.

---

Cathy A Sabiston this is the new name for formerly called SMB ctte... 2010-10-27 01:58:37 PM

From: Cathy A Sabiston/HC-SC/GC/CA  
To: Suzanne Desjardins/HC-SC/GC/CA@HWC  
Cc: Jocelyn Kula/HC-SC/GC/CA@HWC, Stephanie Szick/HC-SC/GC/CA@HWC  
Date: 2010-10-27 01:58 PM  
Subject: Re: hecs bus plng today

---

this is the new name for formerly called SMB cttees. We are guessing that HPFB put it on the list, but I really don't know!

So I guess we have to go to ec cttee now...

Stephanie, follow up with admo, once you hear back from jocelyn on status.

Cathy Sabiston  
Director General / Directrice générale  
Controlled Substances & Tobacco Directorate (CSTD)  
Direction des substances contrôlées et de la lutte au tabagisme (DSCLT)  
Health Canada / Santé Canada  
Tel: (613) 941-1977 Fax: (613) 954-2288  
E-mail/courriel: cathy.a.sabiston@hc-sc.gc.ca  
Website/Site web: www.hc-sc.gc.ca

---

Suzanne Desjardins this is certainly all news to me too (what is EC... 2010-10-27 01:45:53 PM

From: Suzanne Desjardins/HC-SC/GC/CA  
To: Cathy A Sabiston/HC-SC/GC/CA@HWC  
Cc: Jocelyn Kula/HC-SC/GC/CA@HWC, Stephanie Szick/HC-SC/GC/CA@HWC  
Date: 2010-10-27 01:45 PM  
Subject: Re: hecs bus plng today

---

this is certainly all news to me too (what is EC committee?). I wonder who put Salvia on the agenda?

FYI we had a meeting of the Scheduling Committee this morning and discussed both the scheduling

process and the IAS for Salvia. The plan is for Jocelyn to approve the posting on CG1 of a Notice of Intent to regulate it.

Suzanne

Cathy A Sabiston Beth Pieteron attended the new EC committee... 2010-10-27 01:39:11 PM

From: Cathy A Sabiston/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC  
Cc: Stephanie Szick/HC-SC/GC/CA@HWC  
Date: 2010-10-27 01:39 PM  
Subject: hecs bus plng today

---

Beth Pieteron attended the new EC committee on risk and science. They reviewed terms of reference and upcoming forward agendas.

Guess what. Salvia is on it. So ADMO will want to know when we will be "ready" to present.

This appears to be a new mandatory step that we will have to factor into our scheduling assessments.

This is all news to me, Not sure if it is to you as well.

Cathy Sabiston  
Director General / Directrice générale  
Controlled Substances & Tobacco Directorate (CSTD)  
Direction des substances contrôlées et de la lutte au tabagisme (DSCLT)  
Health Canada / Santé Canada  
Tel: (613) 941-1977 Fax: (613) 954-2288  
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Website/Site web: www.hc-sc.gc.ca

Stephanie

# Analysis Summary

DRAFT

## Regulating *Salvia Divinorum* under the CDSA

Regulatory Policy Division  
Office of Controlled Substances  
Controlled Substances and Tobacco and Directorate

October 29, 2010

### CONTENTS

1. APPROVALS
2. ISSUE
3. PURPOSE
4. CONTEXT
5. ASSESSMENT OF RISKS AND BENEFITS
6. IDENTIFICATION AND ANALYSIS OF OPTIONS
7. CONSIDERATIONS
8. RECOMMENDATION(S)
9. CONSULTATIONS
10. IMPLEMENTATION AND EVALUATION

Excellent work!!  
Only minor edits and one question

### 1. APPROVALS

This Issue Analysis Summary is approved.

Jocelyn Kula, A/Director  
Office of Controlled Substances  
Controlled Substances and Tobacco Directorate

[DD/MM/2010]

### 2. ISSUE

Health Canada has received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum* (*S. divinorum*) which is not currently regulated under the *Controlled Drugs and Substances Act* (CDSA). These requests are further to reports from scientific and media sources suggesting that *S. divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has also noted an ongoing media interest regarding the

youth

Q: Are we talking *S. divinorum* (plant) or Salvinorin A (substance) or both?

availability of *S. divinorum* in Canada.

3. PURPOSE

To assess *S. divinorum* against the criteria for the addition of a substance to one of the Schedules to the CDSA, and determine whether this substance should be regulated as a controlled substance in Canada.

have assess and which we are recom

4. CONTEXT

*S. divinorum* is a species of sage which belongs to the mint family, and which is found in the form of dried leaves, extract and plant cuttings. Also called "diviner's sage", the plant is known to induce illusions and hallucinations when chewed or smoked. Salvinorin A, the psychoactive ingredient in *S. divinorum* is a neoclerodane diterpene which is found primarily in the leaves, and to a lesser extent in the stem of the plant.<sup>1</sup>

for schedule I know you get there in the end

*S. divinorum* is widely touted as a "legal" hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs among adolescents and young adults.<sup>2</sup> While very little is known about how and where *S. divinorum* is sold in Canada, it is suspected that it is mainly purchased over the Internet and/or bought at head shops or alternative life style stores, etc. *S. divinorum* cuttings are also available from a number of garden supply companies.

but

*S. divinorum* is a substance not currently scheduled under the CDSA. It can be imported and sold legally in Canada to anyone of any age, anywhere in Canada provided it is not sold as a health product or hallucinogen. In addition, the *S. divinorum* sold in Canada is currently not subject to any specific quality or safety standards.

marketed as a

all the up front is

The use of *S. divinorum* as a psychotropic agent first came to Health Canada's attention in 2002. In 2004, Health Canada received four adverse drug reaction (ADR) reports associated with the use of *S. divinorum* as a hallucinogen, with three being considered non-serious (requiring no medical attention) and the fourth being considered serious (medical intervention was required). The serious ADR report involved the concomitant use of alcohol in a person diagnosed with Attention Deficit Disorder.

Salvia only?

Further to the receipt of the aforementioned ADRs, the Marketed Health Products Directorate (MHPD) and the Natural Health Products Directorate (NHPD) of the Health Products and Food Branch (HPFB) prepared an issue analysis summary (IAS) in November 2005, which recommended that *S. divinorum* and its active ingredient salvinorin A be regulated as controlled substances. This recommendation was maintained when the IAS was updated in November

<sup>1</sup> U.S. Department of Justice Drug Enforcement Administration. 2002. Drugs and Chemicals of Concern: Salvia Divinorum (salvinorin A, divinorin A) URL:

[http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm) Nov 2008

<sup>2</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.

2006.

Later, in December 2005, MHPD and NHPD prepared a Signal Assessment (SA) (updated in June 2007) that eventually led to the preparation of a Health Risk Assessment (HRA), which concluded that *S. divinorum* or salvinorin A-containing health products would constitute a Type II Health Risk according to the Health Hazard Classification of the Recall Policy of the Health Products and Food Branch Inspectorate (HBFBI). Such a risk is defined as “a situation in which the use of, or exposure to, a product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote”.

Further to a discussion with the Assistant Deputy <sup>the</sup> Minister (ADM) of the Healthy Environments and Consumer Safety Branch (HECSB) in April 2007, the ~~the~~ Drug Strategy and Controlled Substances Directorate (DSCSD) (now Controlled Substances and Tobacco Directorate, CSTD) organized a meeting with MHPD, NHPD and HPFBI to discuss *S. divinorum*. HPFBI was to determine appropriate compliance activities regarding *S. divinorum* and consult with the Canada Border Services Agency (CBSA) regarding the movement of products containing *S. divinorum* into and out of Canada.

On September 13, 2007, a further meeting between DSCSD, MHPD, NHPD and HPFBI led to the conclusion that DSCSD would conduct a scheduling assessment of *S. divinorum* in order to explore the possibility of scheduling this substance under the CDSA.

In September 2008, the Director Generals of DSCSD, MHPD, TPD and the HPFBI agreed that media lines and an “It’s Your Health” article on *S. divinorum* would be prepared.

#### **4.1 Relevant Legislative Frameworks in Canada**

##### **4.1.1 Food and Drug Regulations (under the Food and Drugs Act)**

The *Food and Drug Regulations* (F&DR) serve to ensure the safety, efficacy, and quality of health products offered for sale in Canada, including drugs and medical devices. Prior to being given market authorization, a manufacturer must present substantive scientific evidence that their product is safe, efficacious and of high quality. For drugs, Health Canada reviews this information carefully and, if the review is satisfactory, a Notice of Compliance (NOC) is issued and appropriate Drug Identification Numbers (DINs) are assigned.

A “drug” is defined under the F&DR as any substance or mixture of substances manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
  - (b) restoration, correction or modification of organic functions in human beings or animals,
- or



(c) disinfection in premises in which food is manufactured, prepared or kept;

As no products containing *S. divinorum* or its extracts have been reviewed and approved by Health Canada as of October 2010, it is illegal to market *S. divinorum* when it is represented as a drug.

#### 4.1.2 Natural Health Products Regulations (under the Food and Drugs Act)

The *Natural Health Products Regulations* (NHPR) aim to provide Canadians with ready access to natural health products (NHPs) that are safe, effective, and of high quality, while respecting freedom of choice and philosophical and cultural diversity. The NHPR require that all licensed products display a Natural Product Number (NPN), or, in the case of a homeopathic medicine, a Drug Identification Number - Homeopathic Medicine (DIN-HM), on their labels. These numbers are issued once a product is authorized for sale in Canada. A product licence may be obtained pursuant to an application in which the applicant attests to all of the conditions set out in a natural health product monograph prepared and published by the Natural Health Products Directorate. Alternatively, an applicant may submit a product license application that provides evidence of quality, safety and efficacy that is assessed as being sufficient and approved by NHPD by the full submission route. The NHPR also require that all manufacturers, packagers, labelers, and importers have a site license issued on the basis of sufficient evidence of procedures respecting distribution records, product recalls, product handling, storage and delivery, and all other aspects of Good Manufacturing Practices as set out in the NHPR.

The definition of an NHP under the NHPR has both a function and substance component. The function component refers to those substances that are manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
- (b) restoring or correcting organic functions in humans; or
- (c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

The substance component refers to the requirement that all of the medicinal ingredients of an NHP must be substances set out in Schedule 1 (a list of included substances) to the NHPR, a traditional medicine or a homeopathic medicine, and none of the ingredients can be substances set out in Schedule 2, a list of excluded substances which includes any substance listed on Schedules I to V of the CDSA. Section 2(2) of the NHPR excludes those substances (except homeopathic medicines) whose sale is required to be pursuant to a prescription as per Section C.01.043 of the F&DR.

As per section 93(1)(b)(vi) of the NHPR, every natural health product must be labeled with its

authorized recommended use or purpose. In the case of *S. divinorum*, it is generally marketed for its hallucinogenic properties which are considered a modification of an organic function. Therefore products that contain *S. divinorum* and are manufactured, sold or represented for use as a hallucinogen meet the definition of an NHP.

As of October 2010, no products containing *S. divinorum* have been authorized by Health Canada. Therefore no NPNs or DIN-HMs have been issued for such products. Therefore sales of *S. divinorum* are illegal under the NHPR if the product is represented for use as a hallucinogen or if other health claims are made.

#### 4.1.3 Controlled Drugs and Substances Act and its Regulations

The CDSA provides a legislative framework for the control of substances that can alter mental processes and that may produce harm to the health of an individual or to society when diverted or misused. Except as authorized under its regulations, activities such as possession, possession for the purposes of trafficking, trafficking, importation, exportation, possession for the purposes of exportation and production of controlled substances are prohibited under the CDSA.

The substances regulated under the CDSA are grouped into eight Schedules, and each Schedule is associated with particular offences and penalties as described in Part I of the CDSA.

In determining whether a substance should be regulated as a controlled substance, and into which Schedule of the CDSA it should be placed, Health Canada considers a number of factors ; including:

*including implies there are more not listed... 7*

*the following*

- International requirements and trends in ~~the~~ control and/or scheduling;
- Chemical and/or pharmacological similarity to substances listed in the Schedules to the CDSA;
- Legitimate use of the substance, including therapeutic, scientific, industrial <sup>or</sup> ~~or commercial~~ uses;
- Potential for abuse and/or addiction liability;
- Evidence of extent of actual abuse of the substance in Canada and internationally; and
- Risk to personal and public health and safety.

#### 4.2 **Assessment of *S. Divinorum* for Scheduling Purposes**

##### 4.2.1 International Requirements and Trends in the Control and/or Scheduling

At the present time, neither *S. divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and therefore do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

##### ***Australia***

In June 2002, Australia became the first country to prohibit the sale, supply, possession and use of *S. divinorum* and salvinorin A. Both *S. divinorum* and salvinorin A are listed in Schedule 9 of Australia's *Standard for the Uniform Scheduling of Drugs and Poisons* on the basis of "high potential for abuse and risk to public health and safety."<sup>3</sup> Schedule 9 is Australia's most restrictive drug schedule, and includes "substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities."<sup>4</sup>

### **Belgium**

A decree was passed in Belgium on October 22, 2006 which added *S. divinorum* to the list of controlled substances. This list includes substances such as psilocybin mushrooms, khat and peyote cactus.<sup>5</sup>

### **Denmark**

In 2003, Denmark added *S. divinorum* and salvinorin A to their list of "category B" controlled substances, a category which also includes psilocybin mushrooms, cocaine, amphetamine, and several others substances that are only legal for medicinal and scientific purposes. Illegal possession carries a penalty of up to two years in prison.

### **Germany**

*S. divinorum* (plant and plant parts) was added to Appendix I of the *Narcotics Act* in Germany on March 1, 2008, making it illegal to produce, traffic, or possess. The law does not specifically mention salvinorin A.

### **Italy**

On June 25, 2004, the Italian Ministry of Health issued an ordinance prohibiting the sale of *S. divinorum* and its active constituent salvinorin A. On January 11, 2005, the Ministry of Health made possession of *S. divinorum* and salvinorin A illegal by placing them in "Tabella I" of the *Tabella Sostanze Stupefacenti o Psicotrope*.

### **Japan**

On November 9, 2006, the Japanese government added a group of thirty-three drugs to its list of controlled substances, including salvinorin A. The drugs are banned under a revised pharmaceutical law, under which persons involved in their illegal import, production, and sale,

<sup>3</sup> <http://www.tga.gov.au/ndpsc/record/tr200111.pdf>

<sup>4</sup> [http://www.cognitiveliberty.org/news/salvia\\_australia.htm](http://www.cognitiveliberty.org/news/salvia_australia.htm)

<sup>5</sup>

<http://eldd.emcdda.europa.eu/html.cfm/index5176EN.html?pluginMethod=eldd.shownewsdetails&id=20/12/2006BELGIUM:%20New%20substances%20controlled%20include%20mCPP%20and%20khat>

i.e. beyond medical treatment or research purposes, will be subject to up to five years imprisonment or a fine of up to five million yen.

**Spain**

On January 28, 2004, the Spanish Ministry of Health and Consumption issued an order prohibiting the sale of *S. divinorum*. The regulation went into effect on May 6, 2004 and only prohibits activities related to commerce. Possession and/or use are not considered to be criminal offences.

**Other Countries**

It is illegal to possess or sell *S. divinorum* in Croatia, Latvia, Lithuania, Poland, Romania, South Korea and Sweden. In Russia it is illegal to grow or sell *S. divinorum*, but it is legal to possess it. In Estonia, Finland, Iceland and Norway, *S. divinorum* is treated as a medicinal herb and it is illegal to import it without a relevant prescription from a doctor.

**United States of America**

*Administration*

*S. divinorum* and salvinorin A are not included in the Schedules to the United States *Controlled Substances Act*. Although both *S. divinorum* and salvinorin A have been added to a list of chemicals "of concern", ~~this~~ this has no legal implications. According to the National Institute for Drug Abuse, the Drug Enforcement ~~Agency~~ is considering classifying *S. divinorum* and/or salvinorin A as Schedule I drugs. This Schedule includes substances such as LSD and marijuana.

*At the state level, some state legislatures have*  
~~In addition, some individual states have implemented laws restricting its use, sale and/or distribution. As of July 2010, a number of states have enacted legislation placing regulatory controls on *S. divinorum* and/or salvinorin A including Delaware, Georgia, Florida, Hawaii, Illinois, Kansas, Kentucky, Maryland, Mississippi, Missouri, Nebraska, North Dakota, Ohio, Oklahoma, South Dakota, Wisconsin, Virginia, California, Louisiana, Maine, North Carolina, and Tennessee. By way of example, additional details regarding the regulation of *S. divinorum* in these last five states are provided below.~~

*of S. divinorum and/or salvinorin A.*

**California**

As of January 1, 2009, the sale or distribution of *S. divinorum* or salvinorin A, or any substance or material containing *S. divinorum* or salvinorin A, to any person under 18 years of age is a misdemeanor punishable by imprisonment in a county jail for not more than six months, a fine of no more than \$1,000, or both.

**Louisiana**

In 2005, Louisiana passed a bill which prohibits the possession, production, manufacture and distribution of a material, compound, mixture, or preparation intended for human

consumption and that contains a hallucinogenic plant. A "hallucinogenic plant" is defined as "any part or portion" of a plant on a list of forty plants, which includes *S. divinorum*.

### **Maine**

In Maine, *S. divinorum* and salvinorin A are regulated in the same way as tobacco products; adults eighteen years of age or over can legally purchase and use the material, but selling or providing *S. divinorum* or salvinorin A to anyone under the age of eighteen is a criminal offence. Possession by a minor is a civil violation, punishable by a fine, community service, or both.

### **North Carolina**

On December 1, 2009, the North Carolina State Legislature brought a new law into force which made *S. divinorum* and salvinorin A illegal. The only legal *S. divinorum* activities are the growing for aesthetic, landscaping, or decorative purposes or university-affiliated medical or pharmacological research.

### **Tennessee**

On July 1, 2006, Tennessee classified the deliberate production, manufacture, distribution, or possession of the active chemical ingredient in the hallucinogenic plant *S. divinorum* as a Class A misdemeanor. It is not, however, a criminal offence to possess, plant, cultivate, grow, or harvest *S. divinorum* for aesthetic, landscaping, or decorative purposes. The law also does not apply to any dosage that is legally obtainable from a retail establishment without a prescription when (and if) it is recognized by the Food and Drug Administration as a homeopathic drug.

#### **4.2.2 Chemical and/or Pharmacological Similarity to Substances Listed in the Schedules to the CDSA**

The psychoactive ingredient in *S. divinorum* is the neoclerodane diterpene salvinorin A.<sup>6</sup> Another plant which contains psychotropic terpenoids is *Artemisia absinthium* (wormwood).<sup>7</sup> Salvinorin A is a hallucinogen with a distinct structure and it does not interact with the serotonin type-2A receptor or any other molecular target of classical hallucinogens.<sup>8</sup> Instead, the available research suggests that the psychotropic effects of salvinorin A are mediated by its agonistic actions at the

*Diterpenes are a family of substance that contain terpenoids (need same sentence to link 1st 2 sentences)*

<sup>6</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage *Salvia divinorum*. *Life Sci.* 2005 Dec 22;78(5):527-31.

<sup>7</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.

$\kappa$ -opioid (KOR) receptor.<sup>9</sup> Its mechanism of action is therefore unique.<sup>10</sup>

The psychoactive effects of *S. divinorum* vary in onset and duration and include perceptual distortions such as the sensation of becoming an object, having visions of various two-dimensional surfaces, films and membranes, revisiting places of the past (particularly childhood), perceived loss of the body and/or identity, various sensations of motion (being pulled or twisted by a force of some kind), uncontrollable hysterical laughter, and overlapping realities (perceptions of being in more than one place).<sup>11</sup> Laughter, happiness, a sense of well-being and dissociative effects were deemed the most positive aspects of *S. divinorum* by users, second only to the "trip" that the drug elicits.<sup>12</sup> Depersonalization, speaking gibberish, widening of consciousness and subjective illusions of rapid movement, flying or hovering have also been reported.<sup>13</sup>

The psychotomimetic effects of *S. divinorum* closely resemble the schizoid symptoms induced by lysergic acid diethylamide (LSD) or phencyclidine (PCP).<sup>14</sup> Yet, it is said to have only a weak influence on the prevailing mood of the user which differentiates it from other hallucinogens such as LSD and psilocybin.<sup>15</sup> Its strong dissociative effects are often compared to those of ketamine.<sup>16</sup> Users have reported that the psychedelic effects of *S. divinorum* were most similar to those caused by psilocybin mushrooms.<sup>17</sup> However, users familiar with the effects of other hallucinogens agree that despite certain similarities to classical hallucinogens, the visions and overall experience are quite unique.<sup>18</sup>

*S. divinorum* causes an unusually high degree of sedation, weakness and fatigue, and the

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<sup>9</sup> Roth BL, Baner K, Westkaemper R, Siebert D, Rice KC, Steinberg S, Ernsberger P, Rothman RB. Salvinorin A: a potent naturally occurring nonnitrogenous kappa opioid selective agonist. Proc Natl Acad Sci U S A. 2002 Sep 3;99(18):11934-9.

<sup>10</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>11</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>12</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>13</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5 and Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>14</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5.

<sup>15</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>16</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five Salvia divinorum herbal products. Pharmacotherapy. 2006 Sep;26(9):1268-72.

<sup>17</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>18</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6 and González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

increased de-realization is not commonly reported for classical psychedelics.<sup>19</sup> The combination of these effects seems to correlate with that of other KOR agonists such as pentazocine.<sup>20</sup>

The onset and intensity of the effects of *S. divinorum* appear to be related to the route of administration. Traditional uses generally produce mild effects because the leaves are rolled and chewed or crushed and prepared as a foamy infusion whereby the salvinorin A is degraded in the gastrointestinal system before being absorbed into the bloodstream. Hence, the level of effect relates quite closely to the length of time the material spends in the mouth, with the onset of effect generally taking 5-10 minutes. The effects build over the next hour and last for another hour before they begin to subside.<sup>21</sup>

Routes of administration that avoid the hepatic first-pass effect (i.e. inhalation, intravenous, intramuscular and sublingual use) provide the quickest and most intense effect.<sup>22</sup> Salvinorin A can be isolated from the plant to make a powder which can be vaporized and inhaled. The effects felt from vaporizing salvinorin A are experienced in about 30 seconds, last for about 5-10 minutes, and then subside over the next 30 minutes.<sup>23</sup>

Smoking the dried leaves or a concentrated extract using a pipe or bong is by far the most popular method of administration.<sup>24</sup> Dried leaves may also be fortified with a concentrated extract of salvinorin A. A concentrated extract can also be used sublingually. Neither *S. divinorum* nor salvinorin A can be injected because ~~the powder is~~ insoluble in water.<sup>25</sup>

#### 4.2.3 Legitimate Use of the Substance, including (Therapeutic, Scientific, Industrial) ~~or Commercial Uses~~

*S. divinorum* has traditionally been used for spiritual and medicinal purposes by the Mazatec Indians in Oaxaca, Mexico.<sup>26</sup> For medicinal purposes (gastrointestinal problems, headaches,

<sup>19</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>20</sup> Arasteh K, Poudevida S, Farre M, Roset PN, Cami J. Response patterns of the Spanish version of the 49-item short form of the Addiction Research Center Inventory after the use of sedatives, stimulants, and opioids. *Drug Alcohol Depend.* 1999 Jun 1;55(1-2):117-25.

<sup>21</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>22</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.

<sup>23</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>24</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62 and Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>25</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (*divinorin*) A. *J Psychoactive Drugs.* 1994 Jul-Sep;26(3):277-83.

<sup>26</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

rheumatism, anemia and swelling of the stomach) an infusion of the leaves or the leaves themselves are ingested.<sup>27</sup> However, its main use in Mexico today is believed to be for its psychedelic properties in the aid of producing “mystical” or hallucinogenic experiences as part of spiritual rituals.<sup>28</sup>

Although selective KOR agonists have been shown to produce analgesic effects, adverse effects such as psychotomimesis, dysphoria and diuresis have been observed in studies investigating their therapeutic use.<sup>29</sup> In addition, while it has been speculated that KOR agonists may be useful in the treatment of certain psychiatric disorders including Alzheimer’s disease, schizophrenia, dementia and bipolar disorder,~~but~~ there has been no clinical research to support these hypotheses.<sup>30</sup> ~~That said~~ there are presently no recognized medical uses for *S. divinorum* in Canada.

Similarly, there are no known industrial or commercial uses for *S. divinorum* in Canada. Most websites offering *S. divinorum* cuttings and seeds for sale appear to do so in the context of growing the plant for “recreational” purposes, rather than out of horticultural interest or for its esthetic appeal. However, it should be acknowledged that this does not preclude the possibility of a person growing this plant for purely decorative purposes. *S. divinorum* is also marketed as incense. However, there is no evidence that *S. divinorum* has any fragrant properties that would legitimize such a use. Therefore it is believed that the marketing of this plant as an incense is a means to avoid compliance and enforcement actions by Health Canada.

#### 4.2.4 Potential for Abuse and/or Addiction Liability

Salvinorin A is a potent, KOR-selective agonist and in contrast to the euphoria produced by MOR agonists such as morphine, KOR agonists are negatively reinforcing and aversive.<sup>31</sup> In addition, KOR agonists have analgesic properties, but are not associated with respiratory depression like MOR agonists.<sup>32</sup> Finally, while MOR agonists increase the release of dopamine, the activation of KOR decreases dopamine release in the nucleus accumbens.<sup>33</sup> In the case of MOR agonists, the increase of dopamine acts as a positive reinforcer. This action motivates the

<sup>27</sup> Munro, T. The Chemistry of *Salvia divinorum*. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

<sup>28</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage *Salvia divinorum*. *Life Sci.* 2005 Dec 22;78(5):527-31.

<sup>29</sup> Barker RL, Fawcett J, Barkin SJ. 2002. Chronic pain management with a focus on the role of newer antidepressants and centrally acting agents. In: *Pain Management: A Practical Guide for Clinicians*, 6th edition, Weiner RS ed. CRC Press, Boca Raton, FL. pp. 415-34 and Tidgewell et al., 2004. A facile method for the preparation of deuterium labelled salvinorin A: *Biorganic & Medicinal Chemistry Letters*, 14: 5099-5102.

<sup>30</sup> Sheffler DJ & Roth BL. Salvinorin A: the ‘magic mint’ hallucinogen finds a molecular target in the kappa opioid receptor. *Trends Pharmacol Sci.* 2003 Mar;24(3):107-109.

<sup>31</sup> Killinger BA, Peet MM, Baker LE. Salvinorin A fails to substitute for the discriminative stimulus effects of LSD or ketamine in Sprague–Dawley rats. *Pharmacology, Biochemistry & Behaviour.* 2010 May 96; 260-265.

<sup>32</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.

<sup>33</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.



user to use the drug again, which could lead to drug abuse and/or addiction. For KOR agonists, this is not the case.

The aversive effects of KOR agonists suggest that the risk of addiction to *S. divinorum* is negligible. Users have reported the negative effects of *S. divinorum* as: the short duration of action, lack of control over the experience, persisting negative effects (most often anxiety),<sup>34</sup> sweating, chills, increased diuresis, impaired vigilance,<sup>35</sup> and negative after-effects including tiredness, feeling head heavy, dizziness, physical exhaustion, and some degree of malaise or 'hangover' as they 'comedown' from the drug.<sup>36</sup> Despite these reports, very few controlled scientific studies of the physical and psychotropic effects of *S. divinorum* on humans have been carried out and the results have been conflicting. For example, one author states: "Many who have used salvinorin A find the experience extremely unnerving, frightening and overly intense and most have no desire to repeat the experience."<sup>37</sup> However, another study suggested that this is not the experience of all recreational users of *S. divinorum*.<sup>38</sup> Over eighty percent of users surveyed on a web-based questionnaire about their *S. divinorum* use said that they would probably or definitely use *S. divinorum* again.<sup>39</sup>

In addition, some users have noted that they require increasing doses of salvinorin A in order to achieve the desired effect and the stimulated cerebral KOR may act as a mechanism of tolerance.<sup>40</sup> Therefore, it is difficult to predict with certainty its potential for addiction and abuse. In studies that have been conducted, there is conflicting information around the addiction liability of *S. divinorum* in both animals and humans. Further studies in this area and on the KOR mediated decrease of dopamine are also required in order to fully understand the addiction potential of this substance.

While concerns for the potential of abuse were initially considered minimal given that 1 kg of dried leaves only yield 3 to 6 human doses of salvinorin A for oral consumption, it was then discovered that vaporizing and inhaling 200-500 micrograms ~~had~~ profound hallucinogenic

has

<sup>34</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>35</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>36</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>37</sup> Turner DM. *Salvinorin - The Psychedelic Essence of Salvia Divinorum*. Panther Press, San Francisco, CA 1996.

<sup>38</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62, Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5, and Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs*. 1994 Jul-Sep;26(3):277-83.

<sup>39</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>40</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

effects.<sup>41</sup> Given that only small doses of this substance are now necessary to achieve the desired effects through inhalation, the potential for abuse is much higher. Also, the extraction of salvinorin A from the plant is simple, and with care, approximately 1.5 grams of pure salvinorin A per kilogram of dried leaves (8kg of fresh leaves) can be isolated. This is enough for 2000 oral doses.<sup>42</sup>

#### 4.2.5 Evidence of Extent of Actual Abuse of the Substance in Canada and Internationally

In Canada, the prevalence of use of *S. divinorum* has recently been documented. Questions about the use of salvia were included in the 2009 Ontario Student Drug Use and Health Survey, the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey. [In some cases it is not clear if responses indicate the use of *S. divinorum* or salvinorin A given the use of the term "salvia".] *would make this a footnote id.*

*It should be noted that...*

The results from the 2009 Ontario Student Drug Use and Health Survey were published on November 18, 2009 and indicate that:

- Among all responding students in Ontario, 4.4% reported using *S. divinorum* at least once in the past year. In comparison, 58.2% indicated they had used alcohol, 25.6% indicated they had used cannabis and 5.0% indicated they had used hallucinogens other than LSD and PCP in the past year;
- Males (6.2%) were significantly more likely than females (2.3%) to report using *S. divinorum*;
- There is significant grade variation, with *S. divinorum* use most likely among 11<sup>th</sup> graders (8.6%) and 12<sup>th</sup> graders (8.4%); and

The results of the 2008-2009 Youth Smoking Survey were published on May 31, 2010 and indicate that:

- 4.9% of students stated that they had used salvia in the last twelve months. In comparison, 53.0% indicated they had used alcohol, 27.3% indicated they had used cannabis and 6.9% indicated they had used other hallucinogens in the last twelve months;
- 2.6% of students in Grades 7-9 and 7.0% of students in Grades 10-12 had used salvia in the last twelve months; and
- Males (6.6%) were more likely to have used salvia in the past twelve months compared to females (3.2%).

The Canadian Alcohol and Drug Use Monitoring Survey specifically examined salvia for the first time in 2009. An estimated 1.6% of Canadians, aged 15 years and older, reported that they

<sup>41</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>42</sup> Valdès LJ 3rd. Salvia divinorum and the unique diterpene hallucinogen, Salvinorin (divinorin) A. J Psychoactive Drugs. 1994 Jul-Sep;26(3):277-83.

Inclusion,

had used salvia in their lifetime, and 0.2% reported using it in the past-year. In comparison, the prevalence of past-year cannabis use among Canadians 15 years of age and older was 10.6%, while 1.2% of respondents reported using cocaine or crack in the past 12 months, 0.9% ecstasy and 0.7% illicit hallucinogens. Salvia appears ~~however to~~ be a substance that is tried largely by youth with a 7.3% prevalence of lifetime use.

According to the 2009 Monitoring the Future survey, <sup>the</sup> annual prevalence of use of *S. divinorum* among 12th graders in the United States is 5.7%. The American Substance Abuse and Mental Health Services Administration's 2006 National Survey on Drug Use and Health found that, of respondents aged 12 or older, 1.8 million had used *S. divinorum* at least once in their lifetime and 756,000 had used the substance in the past year. Among youth aged 12 to 17, males were more likely than females to have used *S. divinorum* in the past year (0.9% vs. 0.3%).

Health Canada's Drug Analysis Services (DAS) has identified salvinorin A in a number of samples seized by law enforcement, ranging from 9 samples in 2006 to 20 samples in 2009. It is, however, difficult to determine how this data reflects the extent of actual abuse of salvinorin A in Canada, given that it is not an illegal substance and would likely only be seized accidentally or during the seizure of other ~~illicit~~ substances.

controlled (not all controlled subs are illicit)

The National Forensic Laboratory Information System (NFLIS) and the System to Retrieve Information from Drug Evidence (STRIDE) in the United States are Drug Enforcement Agency (DEA) databases that collect scientifically verified data on analyzed samples in state and local forensic labs as well as samples from DEA labs. While in 2000 no seized samples were found to contain *S. divinorum* or salvinorin A, 70 samples tested positive in 2008. Once again, it is difficult to determine how this data can be used to reflect the actual extent of abuse of *S. divinorum* and salvinorin A in the United States as ~~both these substances are not~~ listed in the *Controlled Substances Act*.

Agency Admini stration

neither is

The increase in both the number of enquiries to Health Canada from various municipalities and members of the public and the amount of media interest regarding the availability of *S. divinorum* in Canada may be an indication that the recreational use of *S. divinorum* as a hallucinogen is on the rise. However, it may ~~only~~ reflect an increased awareness of the phenomenon,

rather than an <sup>also</sup> increased incidence of use.

#### 4.2.6 Risk to Personal and Public Health and Safety

The potential for harm to the user and/or other individuals is primarily related to the hallucinogenic properties of the substance. As this substance is typically smoked, there is no risk of infectious disease transmission as is the case when a drug is injected. Users may get up and walk around without apparent awareness of their movements, behaviour or surroundings, and distinction between self and surroundings is often lost. At doses greater than 1mg of salvinorin A, out of body experiences are frequent and loss of consciousness has been reported.<sup>43</sup> There is little information regarding the social behaviours of persons under the influence of *S. divinorum* products, and what risks their activities such as operating a motorized vehicle may pose to the general public. There is also very little data regarding the toxicity, teratogenicity or

<sup>43</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

other long-term effects of *S. divinorum* use.<sup>44</sup>

As far as law enforcement is concerned, the Department has only received a limited number of communications indicating concern with respect to *S. divinorum*. The Royal Canadian Mounted Police (RCMP) has stated that while *S. divinorum* is readily available, it has not become a popular drug in Canada, probably due to its aversive effects such as anxiety and introversion.

A handful of case reports regarding physiological and psychotropic effects of *S. divinorum* use have been published in the scientific/medical literature. For example, an international case report described the perceptions of a 19 year-old man after inhaling *S. divinorum* smoke. The peak psychotropic effects, including prickling of the skin, fever-like hot flashes, muscular tremor, and depersonalization, were reached in less than five minutes after inhalation of an unknown amount of smoke from burning dried leaves.<sup>45</sup> Another report involved a 15-year-old male who presented to psychiatric emergency services with acute onset of paranoia, déjà vu, blunted affect, difficulties in thought processing and slowed speech after smoking *S. divinorum* over an unknown period of time. During his hospitalization all symptoms improved significantly except the feeling of déjà vu. Based on this case presentation, the author suggested that the feelings of déjà vu may be a long-term effect of *S. divinorum* use.<sup>46</sup> However, given that this is the only case report in which déjà vu was associated with the use of *S. divinorum*, more reports are needed to substantiate this finding.

In addition to the above-mentioned reports, in 2006, a case was reported in the U.S. in which a 17-year-old boy committed suicide after smoking *S. divinorum* for an unknown period of time.<sup>47</sup>

It should be noted that alcohol and general depression were the main confounders in this case. After this case was reported, the state of Delaware passed a law which classified *S. divinorum* as a Schedule I controlled substance along with other hallucinogenic substances.

Like many drugs of abuse, users are often unaware of the potency and adulterants in the product they purchase. A study by Wolowich *et al.* (2006), showed that the salvinorin A content in five out of five *S. divinorum* products was falsely indicated on the label and 4 out of 5 products contained unidentified adulterants (i.e. vitamin E, caffeine).<sup>48</sup>

There are also several reports of domestic adverse reactions related to the use of *S. divinorum* that have been received through the Canada Vigilance database. However, this does not reflect true incidence due to under-reporting.

## 5. ASSESSMENT OF RISKS AND BENEFITS

s.21(1)(a)

s.21(1)(b)

<sup>44</sup> Grundmann O, Phipps SM, Zadezensky I, Butterweck V. *Salvia divinorum* and Salvinorin A: An Update on Pharmacology and Analytical Methodology. *Planta Med* 2007 Jun;73:1039-1046.

<sup>46</sup> Singh S. (2007) Adolescent salvia substance abuse. *Addiction*. 102, 823-824.

<sup>47</sup> <http://www.kvbc.com/Global/story.asp?S=4893692>

<sup>48</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

**Page(s) 001610 to\à 001610**

**Is(Are) exempted pursuant to section(s)  
est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**

## 7. CONSIDERATIONS

s.21(1)(a)

s.21(1)(b)

The NHPR are limited in their capacity to control the availability of *S. divinorum* in that *S. divinorum* products are often declared as incense and therefore cannot be considered unapproved natural health products. In addition, compliance and enforcement actions such as voluntary stop-sales, forfeiture, destruction, and administrative seizure, cannot be implemented unless the marketing of the product indicates that it is to be sold for human consumption in order to modify an organic function. Unlicensed natural health products are also permitted to be imported provided they are for personal use only.

Non-regulatory options for the control of *S. divinorum*, such as the development of an educational campaign to highlight the risks associated with using this plant, were also considered. However, the risks associated with this substance, as well as the confusion concerning its enforcement as a natural health product only when it is sold for use with a health claim, do not make this option viable.

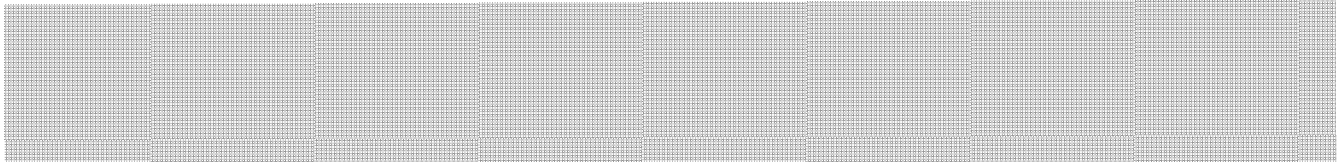
*S. divinorum* meets the criteria for scheduling a substance under the CDSA. While neither the plant nor its main active component salvinorin A are scheduled under any of the UN Drug Control Conventions, a number of countries and American states have taken steps to control the distribution and use of these substances. *S. divinorum* and salvinorin A are pharmacologically similar to other substances included in Schedule III to the CDSA, such as LSD and psilocybin. There are also currently no legitimate therapeutic, commercial or industrial uses for *S. divinorum*. While the addiction potential of *S. divinorum* appears to be low, there is a significant potential for its abuse as a 'legal' hallucinogen. There is very little information with regards to the long-term effects of *S. divinorum* use. There is also evidence of abuse, particularly by Canadian youth and potential for individual health risks as well as risks to public health and safety.

of use (abuse same chronic to me)

the use of roses

In light of a recommendation to include *S. divinorum* under Schedule III to the CDSA, it is also recommended that the main psychoactive ingredient of this plant, salvinorin A, be scheduled. Salvinorin A can easily be extracted from *S. divinorum* and this substance gives the plant its hallucinogenic properties. Therefore, salvinorin A ~~results in~~ the same risks as *S. divinorum* and should also be controlled under the CDSA in the same manner as *S. divinorum*.

## 8. RECOMMENDATIONS



## 9. CONSULTATIONS

The Drug Analysis Services (DAS) was contacted in order to provide any data available regarding the identification of salvinorin A in samples submitted by law enforcement.

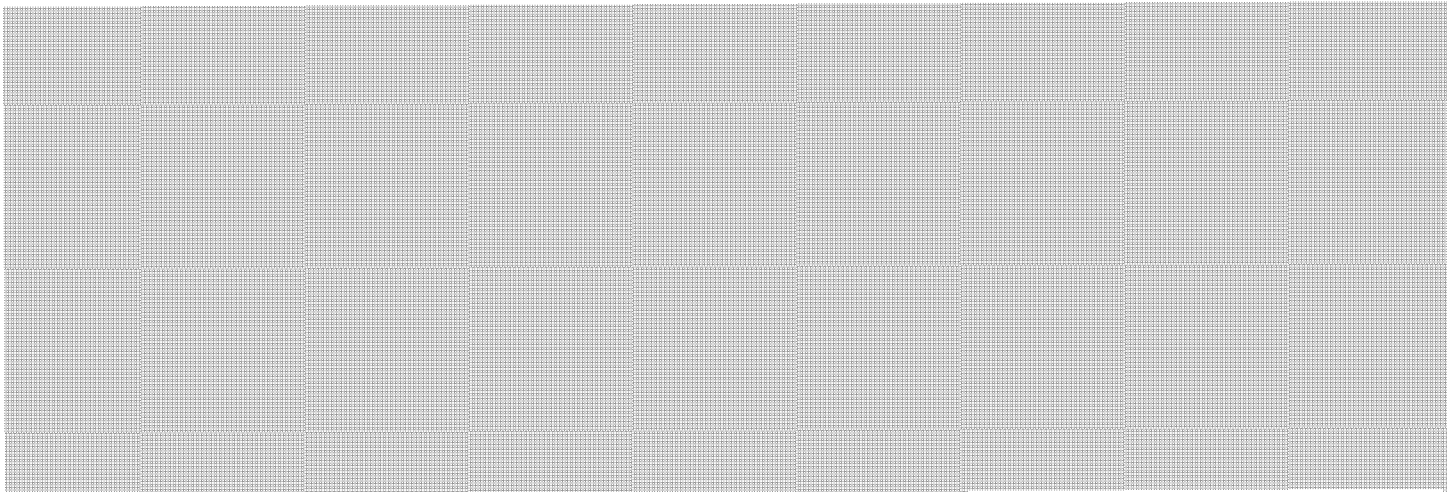
s.21(1)(a)  
s.21(1)(b)

The Royal Canadian Mounted Police (RCMP) was contacted in order to establish their views with respect to *S. divinorum* use in Canada. The RCMP advised that *S. divinorum* is readily available and law enforcement agencies have no legal means to prevent its sale.

OCS has received a number of correspondences from Canada Border Services Agency (CBSA) officers concerning a lack of information regarding the status of *S. divinorum* and how the plant should be treated at the border. CBSA officers have also expressed concern regarding the plant's hallucinogenic properties. At present, only shipments of *S. divinorum* that are represented for sale as health products that modify organic functions can be refused for import under the NHPR.

OCS brought *S. divinorum* to the Controlled Substances Scheduling Working Group (CSS-WG) in August 2010 to discuss the possibility of regulatory control of this substance. After assessing the available information against the six criteria listed in the Context section of this Issue Analysis Summary, the CSS-WG recommended that *S. divinorum* be included under Schedule III to the CDSA.

## 10. IMPLEMENTATION AND EVALUATION





Spacing !!!

\* Not sure what happened here... looks fine on my computer.

s.21(1)(a)

s.21(1)(b)





**Re: Question on Salvia**

Jocelyn Kula to: Lisa MacKay

2010-11-01 11:31 AM

Cc: Bruna Brands, Hanan Abramovici, Lisa MacKay, Suzanne  
Desjardins, Stephanie Chandler

Hi Lisa

According to our files, we started getting media enquiries on salvia in 2002, so from my perspective, that is when we would have started a file on it, and hence when we became aware of it as a psychotropic substance. I am not surprised that the date when MHPD became aware is different as to my knowledge, MHPD only became involved in salvia at all, when it received the four ADR reports that we sometimes reference .....

Suzanne- not sure what is on your files?

JK

---

Jocelyn Kula

Acting Director/ Directrice par intérim

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs

Health Canada/ Santé Canada

Tel: (613) 952-2177 Fax: (613) 946-4224

Lisa MacKay

Hello all, A question has come in from Chris Tur...

2010-11-01 11:03:38 AM

From: Lisa MacKay/HC-SC/GC/CA  
To: Suzanne Desjardins/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Hanan  
Abramovici/HC-SC/GC/CA@HWC, Bruna Brands/HC-SC/GC/CA@HWC  
Cc: Lisa MacKay/HC-SC/GC/CA@HWC  
Date: 2010-11-01 11:03 AM  
Subject: Question on Salvia

Hello all,

A question has come in from Chris Turner (DG MHPD) - The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention in the **spring of 2005**

MHPD first became aware of this in the "spring of 2005" is that the same for HECSB?

Thank you

Lisa Mackay

It's Your Health Project Manager/Gestionnaire du projet Votre santé et vous

Consumer Information Bureau / Bureau d'information aux consommateurs

Marketing and Communications Services Directorate/Direction des services de marketing et de  
communications

Public Affairs, Consultation and Communications Branch/ Direction générale des affaires publiques, de la  
consultation et des communications

Health Canada | Santé Canada

Tel 613.954.0105



**Fw: October 19th EC - Science and Risk Management**

Jocelyn Kula to: Stephanie Chandler

Cc: Daniel Galarneau, Denis Arsenault

2010-11-01 02:20 PM

FYI (and phew!)

---

Jocelyn Kula

Acting Director/ Directrice par intérim

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs

Health Canada/ Santé Canada

Tel: (613) 952-2177 Fax: (613) 946-4224

----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2010-11-01 02:20 PM -----

From: Suzanne Desjardins/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Date: 2010-11-01 02:19 PM  
Subject: Fw: October 19th EC - Science and Risk Management

---

as per my previous email

Suzanne

----- Forwarded by Suzanne Desjardins/HC-SC/GC/CA on 2010-11-01 02:19 PM -----

From: Suzanne Desjardins/HC-SC/GC/CA  
To: Cathy A Sabiston/HC-SC/GC/CA@HWC  
Date: 2010-10-29 12:11 PM  
Subject: Re: Fw: October 19th EC - Science and Risk Management

Hi Cathy,

I am just returning from the HECS-Science Policy meeting that Beth Chairs. The forward agenda for the EC-SRM meeting was discussed. Beth does not know how items were identified but she believed that one input was the combination of the forward agenda from the 2 committees that have been merged (i.e. SMB-Risk and SMB science). In any case, she will ask that Salvia be removed from the agenda at this time. If there is a desire later for Salvia to go to the Committee, we could make a request to that effect. Items will not have to go through HECS-Science before they go to EC-SRM (this will rather be, I think, for HECS Exec to decide), but HECS-Science could discuss whether a specific item or issue should be brought to EC-SRM and make recommendations in that regard.

Suzanne

---

Cathy A Sabiston FYI. I believe Beth is the HECSB representative,... 2010-10-29 11:22:23 AM

---

From: Cathy A Sabiston/HC-SC/GC/CA  
To: CSTD-Directors  
Cc: CSTD-DGO  
Date: 2010-10-29 11:22 AM  
Subject: Fw: October 19th EC - Science and Risk Management

FYI.

I believe Beth is the HECSB representative, so if we have issues I can go through her.

001615



**Fw: For approval: URGENT MEDIA REQUEST - Salvia (CTV News Halifax)**

Denis Arsenault to: Jeannine Ritchot

2010-11-04 01:18 PM

Cc: Jocelyn Kula, Stephanie Chandler

Hi Jeannine,

See our suggested revisions below.

Denis

Denis Arsenault, A/Manager / Gestionnaire p.i.

Regulatory Policy Division /

Division des politiques réglementaires,

Office of Controlled Substances /

Bureau des substances contrôlées,

Health Canada / Santé Canada

Tel/Tél: (613) 957-6828

Fax / Télécopieur : (613) 946-4224

E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca

----- Forwarded by Denis Arsenault/HC-SC/GC/CA on 2010-11-04 01:14 PM -----

From: Stephanie Chandler/HC-SC/GC/CA

To: Denis Arsenault/HC-SC/GC/CA@HWC

Date: 2010-11-04 01:11 PM

Subject: Fw: For approval: URGENT MEDIA REQUEST - Salvia (CTV News Halifax)

For your review. Effects of salvia come straight from the IYH. I also added a few sentences that we used in the last media request to clarify when salvia is considered an NHP.

Stephanie

#### **1 - Has salvia been on Health Canada's radar and why?**

A1 - Health Canada is aware of salvia and has noted media interest regarding the availability of *Salvia divinorum* in Canada.

Health Canada will continue to collect and study information about *S. divinorum* as it becomes available and is currently assessing whether the regulation of *Salvia divinorum* and/or Salvinorin A under the *Controlled Drugs and Substances Act* is warranted, and to consult with law enforcement and health officials domestically and internationally in order to determine the best way to manage the risks associated with its availability in Canada.

Health Canada is currently assessing whether the regulation of *Salvia divinorum* and/or Salvinorin A under the *Controlled Drugs and Substances Act* is warranted.

#### **2 - What are the effects of salvia?**

A2 - *S. divinorum* is known to have both physical and mental effects. The effects of *S. divinorum*, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness

- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

Health Canada does not recommend the use of products containing *S. divinorum* and/or salvinorin A because very little is known about these substances and their potential effects on the brain and/or body, and their impact on physical and mental functions.

**3 - Is it legal or illegal to sell salvia in Canada? Does this include products sold in stores and/or on the internet?**

**4 - If it is legal or has to be authorised, is this product in fact authorised for sale in Canada?**

**5 - If illegal and in stores, are there any restrictions on salvia that are currently being enforced?**

A3/4/5 - When salvia products are sold for the purposes of modifying brain functions (i.e. for their hallucinogenic effects), they meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*. To date, Health Canada has not licensed for sale any drug or Natural Health Product which contains salvia as an ingredient.

It is a contravention of the *Food and Drugs Act* and the *Natural Health Products Regulations* to sell Natural Health Products in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN) on the label. The sale of unauthorised natural health products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

~~Health Canada will continue to collect and study information about *S. divinorum* as it becomes available, and to consult with law enforcement and health officials domestically and internationally in order to determine the best way to manage the risks associated with its availability in Canada.~~

Complaints about the sale of unauthorized products containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate by calling 1-800-267-9675.

----- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2010-11-04 01:03 PM -----

From: Denis Arsenault/HC-SC/GC/CA  
To: Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2010-11-04 01:00 PM  
Subject: Fw: For approval: URGENT MEDIA REQUEST - Salvia (CTV News Halifax)

For review.

Denis

Denis Arsenault, A/Manager / Gestionnaire p.i.  
Regulatory Policy Division /  
Division des politiques réglementaires,  
Office of Controlled Substances /  
Bureau des substances contrôlées,  
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E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca

----- Forwarded by Denis Arsenault/HC-SC/GC/CA on 2010-11-04 01:00 PM -----

From: Jocelyn Kula/HC-SC/GC/CA  
To: "Denis Arsenault" <denis.arsenault@hc-sc.gc.ca>, "Jeannine Ritchot" <jeannine.ritchot@hc-sc.gc.ca>  
Date: 2010-11-04 12:18 PM  
Subject: Fw: For approval: URGENT MEDIA REQUEST - Salvia (CTV News Halifax)

---

Not crazy about the line re domestic and international law enforcement agencies etc as we are not doing that per se. Think we shld just cut that out and move straight to the part about assessing for scheduling...

For Q2, text is accurate but doesn't really respond to question about effects. There is stuff on effects in IYH we could use.

JK  
Sent by blackberry

Jocelyn Kula  
A/ Director/ Directrice par interim  
Office of Controlled Substances/ Bureau des substances contrôllées  
Nicole Prentice

----- Original Message -----

**From:** Nicole Prentice  
**Sent:** 2010-11-04 12:07 PM EDT  
**To:** Jeannine Ritchot; Jocelyn Kula  
**Cc:** Christine Roush; Paul Spendlove; Denis Arsenault; CSTD-OCS-DO  
**Subject:** For approval: URGENT MEDIA REQUEST - Salvia (CTV News Halifax)

Hi Jeannine,

Below is an urgent media response for approval by 12:45 at the latest as this is due at 2pm today. These proposed responses were drafted using the salvia media lines (that are in the works) and a previously approved media response from a few weeks ago which was thoroughly discussed between HPFB and HECS.

Thanks in advance and sorry for the short notice,  
Nicole

\*\*\*\*\*

### 1 - Has salvia been on Health Canada's radar and why?

A1 - Health Canada is aware of salvia and has noted media interest regarding the availability of *Salvia divinorum* in Canada.

Health Canada will continue to collect and study information about *S. divinorum* as it becomes available, and to consult with law enforcement and health officials domestically and internationally in order to determine the best way to manage the risks associated with its availability in Canada.

Health Canada is currently assessing whether the regulation of *Salvia divinorum* and/or Salvinorin A under the *Controlled Drugs and Substances Act* is warranted.

### 2 - What are the effects of salvia?

A2 - Health Canada does not recommend the use of products containing *S. divinorum* and/or salvinorin A because very little is known about these substances and their potential effects on the brain and/or body, and their impact on physical and mental functions.

### 3 - Is it legal or illegal to sell salvia in Canada? Does this include products sold in stores and/or on the

internet?

4 - If it is legal or has to be authorised, is this product in fact authorised for sale in Canada?

5 - If illegal and is stores, are there any restrictions on salvia that are currently being enforced?

A3/4/5 - To date, Health Canada has not licensed for sale any drug or Natural Health Product which contains salvia as an ingredient.

It is a contravention of the *Food and Drugs Act* and the *Natural Health Products Regulations* to sell Natural Health Products in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN) on the label. The sale of unauthorised natural health products containing *S. divinorum* and/or salvinatorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

Health Canada will continue to collect and study information about *S. divinorum* as it becomes available, and to consult with law enforcement and health officials domestically and internationally in order to determine the best way to manage the risks associated with its availability in Canada.

Complaints about the sale of unauthorized products containing *S. divinorum* and/or salvinatorin A can be referred to the Health Products and Food Branch Inspectorate by calling 1-800-267-9675.

**Nicole Prentice**

Junior Communications Officer | Agente junior des Communications  
Regulatory Communications and Media Relations Division | Division des communications réglementaires et des relations avec les médias  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la consultation et des communications  
Health Canada | Santé Canada  
Tel: 613.941.3107  
Fax: 613.948.8085

----- Forwarded by Nicole Prentice/HC-SC/GC/CA on 2010-11-04 12:04 PM -----

From: Christelle Legault/HC-SC/GC/CA  
To: Elizabeth Keeping/HC-SC/GC/CA@HWC, Nicole Prentice/HC-SC/GC/CA@HWC, Christine Roush/HC-SC/GC/CA@HWC  
Cc: Dave Stephens/HC-SC/GC/CA  
Date: 2010-11-04 11:02 AM  
Subject: URGENT MEDIA REQUEST - Salvia (CTV News Halifax)

Please see request below on salvia.

**Deadline:** By 2pm today.

Thank you, -- Christelle

\*\*\*\*\*

\*\*\* Previous response used to answer a similar media request dated October 20:

**Q1 - Est-ce illégal ou simplement pas encore autorisé au Canada? (L'article cite la GRC qui dit qu'il ne peut rien faire auprès des acheteurs de salvia aussi longtemps que le gouvernement n'a pas légiféré pour rendre le produit illégal.)**

**Q2 - Est-ce que la vente du salvia est toujours autorisé ou non au Canada?**

Health Canada does not recommend the use of products containing *S. divinorum* and/or salvinorin A because very little is known about these substances and their potential effects on the brain and/or body, and their impact on physical and mental functions.

To date, Health Canada has not licensed for sale any drug or Natural Health Product which contains salvia as an ingredient.

It is a contravention of the *Food and Drugs Act* and the *Natural Health Products Regulations* to sell Natural Health Products in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN) on the label. The sale of unauthorized natural health products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

Complaints about the sale of unauthorized products containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate by calling 1-800-267-9675.

Health Canada is currently assessing whether the regulation of *Salvia divinorum* and/or Salvinorin A under the *Controlled Drugs and Substances Act* is warranted.

**Approved by / Approuvé par:**  
Jocelyn Kula, A/Director, OCS  
Cathy A Sabiston, DG, CSTD  
Dave Stephens, Comms Executive, assigned to HECS  
Heidi Jackson, Director, HECS ADMO

Christelle Legault  
Media Relations Officer | Agente des relations avec les médias  
Regulatory Communications and Media Relations Division |  
Division des communications réglementaires et des relations avec les médias  
Public Affairs, Consultation and Communications Branch |  
Direction générale des affaires publiques, de la consultation et des communications  
Health Canada | Santé Canada  
Tel. | Tél.: 613.957.2988 Fax | Téléc.: 613.960.0208

**s.19(1)**

---- Forwarded by Christelle Legault/HC-SC/GC/CA on 2010-11-04 10:59 AM ----



### Media Enquiry - Demande médiatique

Name/Nom : [REDACTED]	Media/Média : CTV News Halifax
Telephone/Téléphone : [REDACTED]	Language/Langue : English-anglais
Cell Telephone/Téléphone cellulaire : [REDACTED]	Fax/Télécopieur :
Email/Courriel : [REDACTED]	

Date and Time Received  
Date et Heure de réception : 2010-11-04 10:53:15 AM

Date Completed  
Date d'achèvement :

**Subject/Objet :** Controlled Substances/Substances contrôlées, Natural Health Products/Produits de santé naturels

**Question:**

Add to the Question/ajouter a la question

2010-11-04 10:53:16 AM (Christelle Legault)

CTV News in Halifax

s.19(1)

**Issue:** Salvia

**Questions:**

- 1 - Has salvia been on Health Canada's radar and why?
- 2 - What are the effects of salvia?
- 3 - Is it legal or illegal to sell salvia in Canada? Does this include products sold in stores and/or on the internet?
- 4 - If it is legal or has to be authorised, is this product in fact authorised for sale in Canada?
- 5 - If illegal and is stores, are there any restrictions on salvia that are currently being enforced?

**Deadline:** 2:00pm (3pm Atlantic)

**Response/Réponse :**

Add to the Response/ajouter a la réponse

**Action Taken/Mesures prises :**

Add to the Action Taken/ajouter au mesures prises

2010-11-04 10:59:27 AM (Christelle Legault)

Request sent to Beth Keeping, Christine Roush, Nicole Prentice, Dave Stephens.

Interview with spokesperson granted/Entrevue avec porte-parole accordé:  Yes-Oui  No-Non

Branch/Direction générale :

Spokesperson/Porte-parole :

Reporter's Deadline

Heure de tombée du journaliste :

Priority/Priorité : Regular

Telephone/Téléphone :

Story Run Date

Date de parution de l'article :

Status/Rapport de situation : Follow-up

**Comment/Commentaire :**

**Attachments/Pièces jointes :**

**Related Clippings/Coupures connexes :**

Media Relations Officer/Agente de relations avec les médias : Christelle Legault

Edit History / Historique des révisions



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VanAlstyne/OU=HC-SC/O=GC/C=CA

**Re: Fw: For approval: URGENT MEDIA REQUEST - Salvia (CTV News Halifax)** 

Denis Arsenault to: Stephanie Chandler

2010-11-04 01:50 PM

Thanks for checking on this

D

Stephanie Chandler

----- Original Message -----

**From:** Stephanie Chandler

**Sent:** 2010-11-04 01:32 PM EDT

**To:** Jeannine Ritchot

**Cc:** Denis Arsenault

**Subject:** Re: Fw: For approval: URGENT MEDIA REQUEST - Salvia (CTV News  
Halifax)

Hi Jeannine,

Will you be forwarding this to Comms, or would you like us to?

Stephanie

Stephanie Chandler

Junior Regulatory Project Officer

Regulatory Policy Division/ Division de la politique réglementaire

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs

Health Canada/ Santé Canada

Tel: (613) 946-0124, Fax: (613) 946-4224

E-Mail: stephanie.chandler@hc-sc.gc.ca

Jeannine Ritchot

Merci! Jeannine R. Ritchot

2010-11-04 01:22:57 PM

**From:** Jeannine Ritchot/HC-SC/GC/CA

**To:** Denis Arsenault/HC-SC/GC/CA@HWC

**Cc:** Jocelyn Kula/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC

**Date:** 2010-11-04 01:22 PM

**Subject:** Re: Fw: For approval: URGENT MEDIA REQUEST - Salvia (CTV News Halifax)

Merci!

Jeannine R. Ritchot

Director/Directrice

Medical Cannabis/Cannabis médical

Office of Controlled Substances/Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/Direction Générale, Santé environnementale et  
sécurité des consommateurs

Health Canada/Santé Canada

Denis Arsenault

Hi Jeannine, See our suggested revisions below.

2010-11-04 01:18:09 PM



**Fw: CTV Halifax - Lack of HC regulation making salvia use difficult to control -  
Nov 5 2010, 6:15PM**  
Denis Arsenault to: Stephanie Chandler

2010-11-08 10:03 AM

FYI

Denis

Denis Arsenault, A/Manager / Gestionnaire p.i.  
Regulatory Policy Division /  
Division des politiques réglementaires,  
Office of Controlled Substances /  
Bureau des substances contrôlées,  
Health Canada / Santé Canada  
Tel/Tél: (613) 957-6828  
Fax / Télécopieur : (613) 946-4224  
E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca

— Forwarded by Denis Arsenault/HC-SC/GC/CA on 2010-11-08 10:02 AM —

From: HC\_Media\_SC/HC-SC/GC/CA  
To:  
Date: 2010-11-08 09:47 AM  
Subject: CTV Halifax - Lack of HC regulation making salvia use difficult to control - Nov 5 2010, 6:15PM  
Sent by: Nicolas Frate

Distribution group/Groupe de distribution: Controlled Substances - Substances contrôlées -  
HECSB/DGSESC, Natural Health Products - Produits de santé naturels - HPFB/DGPSA,

CTV Halifax  
Fri Nov 5 2010  
6:15 PM AT

**Lack of HC regulation making salvia use difficult to control**

THIS NEXT STORY IS ABOUT SOMETHING CALLED SALVIA. IT'S NOT A DRUG, BUT SOME KIDS ARE USING IT TO GET HIGH AND HEALTH CANADA WANTS IT MAKE IT MORE DIFFICULT TO GET, BUT THE FACT THAT IT'S LEGAL MAKES IT DIFFICULT TO CONTROL. KELLAND SUNDAHL HAS THE STORY.

Reporter: THE TRIPS VARY.

THE GRASS IS THE HAIR OF A MUPPET.

Reporter: THE HIGH DOESN'T LAST LONG, BUT IT CAN PACK A POWERFUL PUNCH. OUT OF BODY EXPERIENCES, UNCONTROLLABLE LAUGHTER, AND MEMORY LOSS.

CRAZY AND INTENSE, LASTS TEN MINUTES OR SOMETHING.

Reporter: JEFF HASN'T TRIED THE DRUG BEFORE BUT KNOWS PEOPLE WHO HAVE.

I HEARD OF PEOPLE NOT HAVING AN EFFECT, AND OTHERS THAT WERE SCARED TO DEATH FROM IT.

Reporter: IT CAN BE SOLD AS A NATURAL HEALTH PRODUCT BUT MUST BE AUTHORIZED BY HEALTH CANADA, BUT IF YOU ASK POLICE OFFICERS, THEY'LL SAY IT'S NOT LISTED AS A BANNED SUBSTANCE OR DRUG. HEALTH CANADA IS LOOKING AT REGULATING SALVIA BUT UNTIL THAT IT CAN BE FOUND IN SMOKE SHOPS. IT'S SOLD IN SMALL VIALS AND CAN BE SMOKED.

IT'S NOT A PLEASANT HIGH.

Reporter: MARY LANDRY WORKS THROUGH THE IWK CHOICES PROGRAM IN HALIFAX. SHE'S ONLY EVER RUN ACROSS A FEW TEENS WHO TRIED SALVIA.

IF HEALTH CANADA IS FINDING A REASON TO DO WHAT THEY'RE DOING, IT'S PROBABLY FOR A GOOD CAUSE AND PROBABLY SHOULD CONTINUE DOING WHAT THEY'RE DOING TO PROMOTE HEALTH.

HOW DOES IT FEEL?

Reporter: EVEN IF HEALTH CANADA'S STANCE ISN'T ENOUGH TO DETER SOME PEOPLE, THE EXPENSIVE PRICE OF THE HERB MAY BE. KELLAND SUNDAHL, "CTV NEWS," HALIFAX.

-END-

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Thank you.

Media Monitoring Team

Health Canada

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Merci.

L'Équipe de surveillance des médias

Santé Canada



**Rescheduled: CSS-WG Meeting**

**2010-11-16 Tue 10:30 AM - 12:00**

**PM**

Attendance is **optional** for Stephanie Chandler

Chair: **Tiffany Thornton/HC-SC/GC/CA**

Location: **123 Slater Street, Rm 629B**

**Tiffany Thornton** has rescheduled this meeting. You have not yet responded.

① This meeting has been rescheduled - please confirm your attendance. If you have agenda items for the meeting please send them to me. The Rm for the meeting is 629B (same as before).

Thanks and sorry for the inconvenience.

Tiffany

---

Required: Colette Strnad/HC-SC/GC/CA@HWC, Collin Pinto/HC-SC/GC/CA@HWC, Courtney Smith/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, Evelyn Soo/HC-SC/GC/CA@HWC, Hanan Abramovici/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Robin Marles/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC, Tanja Kalajdzic/HC-SC/GC/CA@HWC, Tiana Branch/HC-SC/GC/CA@HWC

Optional: Isabel Shanahan/HC-SC/GC/CA@HWC, Laura Cooney/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC, Valence Nebie/HC-SC/GC/CA@HWC

**Description**

Hi everyone,

Please mark your calendars. The Agenda for the next meeting and the Record of Discussion from October 27 to follow shortly. Please find attached (from Robin)

- the most recent versions of the Salvia divinorum HRA and IAS documents prepared by MHPD and NHPD and
- background information on "morning glory"

Thanks,  
Tiffany

\*\*\*\*\*



Health Risk Assessment of Salvia divinorum as a Health Product 2010-08-25.doc



Salvia divinorum IAS 2006-11-03.doc

At the last CSS-WG meeting we reviewed the deck "Scheduling Substances under the *Controlled Drugs and Substances Act*". On slide 7, I pointed out that "morning glory" was identified as a plant with psychoactive properties but that may be a bit misleading because the psychoactive species are not the common morning glory that people have in their gardens. I promised I would provide details by e-mail.

The psychoactive "morning glory" plant, species name *Turbina corymbosa* (L.) Raf., Convolvulaceae, widely published synonym *Rivea corymbosa* (L.) Hallier f., is better known in the scientific literature by

its Mexican Nahuatl name of "Ololiuqui". Horticulturally it has the English common names "Christmaspops" or "Christmasvine." The seeds were consumed in water traditionally by the Mexican Chinamec, Mazatec, Mixtec and Zapotec peoples as a narcotic hallucinogen for purposes of divination by traditional healers. Hallucinations occur during the somnambulistic stage of intoxication.

The psychoactive properties are due to biosynthesis of ergoline alkaloids by fungi of the order Clavicipitales (related to ergot) that colonize the adaxial (upper) leaf surface and seeds of certain members of the morning glory family, especially *Turbina corymbosa* and *Ipomoea asarifolia*. A closely related fungus is found on *Ipomoea violacea*. The fungus-derived ergoline alkaloids: chanoclavine, lysergic acid-alpha-hydroxyethylamide, lysergic acid amide, and ergonovine, accumulate in the leaves and seeds of the host plant. The fungi are seed-transmitted to the next generation of plants.

The common garden morning glory is *Ipomoea purpurea* (L.) Roth. Additional horticultural species include *I. pes-caprae*, *I. pandurata*, *I. carnea*, *I. cairica*, *I. quamoclit*, *I. tricolor*, *I. hederifolia*, *I. nil*, *I. aquatica*, *Convolvulus tricolor*, *Argyreia nervosa*, and *Merremia tuberosa*. The wild morning glory or bindweed plants that infest our gardens as noxious weeds are *Convolvulus arvensis* L. (small-flowered) and *Calystegia sepium* (L.) R.Br. (greater bindweed).



Markert et al ergoline alkaloids fungi and Convolvulaceae.pdf

## Health Risk Assessment of *Salvia divinorum* as a Health Product

Marketed Health Products Directorate and Natural Health Products Directorate

revised August 25, 2010

### Issue:

In the last several years, Health Canada has become aware of the use of the plant *Salvia divinorum* and its main active ingredient, salvinorin A, as recreational hallucinogens and their promotion on web sites as “legal alternatives” to illicit drugs. In certain areas of Mexico but not in Canada, this plant has been used traditionally for religious as well as for health purposes.

### Purpose:

This health risk assessment was undertaken to determine the potential risks to health from the use of *Salvia divinorum* and salvinorin A as health products and to help guide potential compliance and enforcement actions to be taken by Health Canada on products available on the Canadian market that contain *Salvia divinorum* or its active constituents.

### Introduction:

*Salvia divinorum* Epling & Játiva is a herb in the mint family (Lamiaceae), native to Mexico. It is also known by a number of common names such as Diviner's Sage, Magic Sage, Mexican Sage, Sage of the Seers, and Herba Maria (Natural Medicines Comprehensive Database 2007). The plant has been used in traditional healing and spiritual practices by the Mazatec Indians of Oaxaca, Mexico (Diaz, 1976).

Salvinorin A (Figure 1), the main hallucinogenic ingredient in *Salvia divinorum*, is a non-nitrogenous neoclerodane diterpene acting as a high-affinity and selective  $\kappa$ -opioid receptor agonist (Chavkin et al. 2004).

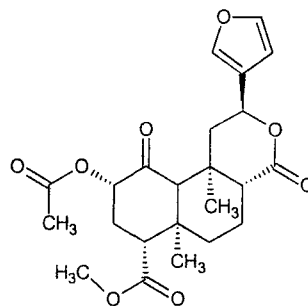


Figure 1. Salvinorin A

## **Regulatory Context:**

### **Uses:**

Health Canada has received four reports of adverse reactions involving psychotropic effects, associated with the use of *Salvia divinorum*. There have been several reports (scientific articles, case reports, media enquiries/articles) which indicate that *Salvia divinorum* has the potential for abuse, and is being used by adolescents and young adults for its hallucinogenic properties. In addition, *Salvia* is being widely touted on internet sites aimed at these population groups, as a “legal” alternative to street drugs.

In Canada, neither the herb *Salvia divinorum*, nor its active constituents such as salvinin A, are listed in any Schedule to the *Controlled Drugs and Substances Act* (CDSA), nor any Schedule of the *Food and Drugs Act and Regulations*. *Salvia divinorum* meets the definition of a natural health product (NHP) if marketed in Canada with health claims. However, the current use and advertising of *Salvia divinorum* as a recreational hallucinogen does not meet the intent of the functional component of the definition of a natural health product. In addition, as a hallucinogen and potential drug of abuse, Health Canada’s Office of Controlled Substances (OCS) has placed *Salvia divinorum* on its list of substances to monitor. As part of this action, the OCS will collect relevant information specific to this herb and its active constituents, in relation to its psychotropic use.

Since *Salvia divinorum* in some circumstances meets the definition of a NHP and is not listed in any Schedule to the CDSA, nor any Schedule of the *Food and Drugs Act* or its Regulations, it is appropriate to assess the health risk associated with the use of *Salvia divinorum*, when used as a health product.

### **Traditional Use:**

#### Non-Psychoactive Use:

When consumed orally, *Salvia divinorum* has been used traditionally to treat diarrhoea, constipation, anaemia, headache, rheumatism and alcohol addiction, as well as for regulation of urination. It is also used topically in traditional settings for treating ulcers of the skin (Natural Medicines Comprehensive Database, 2007; Valdes et al., 1982).

#### Psychoactive Use:

*Salvia divinorum* has been used traditionally by the Mazatec people of Oaxaca, Mexico, for religious ceremonies, in order to produce “mystical” and hallucinogenic experiences. The psychoactive effects can be produced by chewing the leaves, or by inhalation of the smoke from the leaves.



## **Non-Traditional Use:**

### Non-Psychoactive Use:

No information is available on *Salvia divinorum*-containing products currently marketed for health-related purposes. Some research, however, suggests therapeutic potential for salvinorin A (see Therapeutic Potential section, below).

### Psychoactive Use:

The main non-traditional use of *Salvia divinorum* relates to its psychoactive properties and use as a street drug. The hallucinogenic properties can be achieved by a variety of means, and products available commercially for such purposes include dried leaves, extracts, plant cuttings, tinctures, tablets, essence and leaf juice. Products can be taken orally (tablets, leaves extract), sublingually (tincture) and by inhalation (smoking of dried leaves, extract), to experience hallucinogenic effects.

## **Hazard Assessment and Characterisation:**

### Pharmacokinetics:

The main active constituent of *Salvia divinorum*, both from the perspective of psychoactive and potential therapeutic use, appears to be the diterpene salvinorin A.

The pharmacokinetics of salvinorin A have not been studied extensively; however, it is apparent that when taken orally, the hallucinogenic effects depend on absorption by the oral mucosa, as salvinorin A is largely inactivated in the gastrointestinal tract (Siebert, 1994). Although some psychotropic activity has been noted after drinking the leaf juice, the effects are much more mild compared to the chewing of the leaves (Siebert, 1994). Siebert (1994) administered 2 mg of encapsulated salvinorin A to human subjects. Swallowing the capsules produced no detectable psychotropic activity. Thus, the most effective way (orally) to use the plant or its purified constituents to achieve hallucinogenic effects is to ensure the salvinorin A remains in the mouth for a period of time, allowing buccal absorption. Other studies on the pharmacokinetics and potential therapeutic effects of salvinorin A have relied on non-oral routes of exposure (Schmidt et al., 2005; McCurdy et al., 2006).

It should be noted that since salvinorin A is postulated as the phytochemical in *Salvia divinorum* that has potential therapeutic effect, the plant and its extracts may only be effective when administered non-orally. More research is required to clarify the potential therapeutic uses of *Salvia divinorum*. More detail is provided below.

### Toxicology studies on *Salvia divinorum* and salvinorin A:

No studies appear to have been performed to determine the adverse effects of *Salvia divinorum*, or its chemical constituents, in humans.

With regard to animal toxicity studies, only one published report is available. Mowry et al. (2003) examined the short term effects of salvinorin A in rats. Swiss-Webster rats of both sexes, 4-6 months of age, were administered salvinorin A by intraperitoneal injection at doses of 0 (vehicle control), 400, 800, 1600, 3200 and 6400 ug/kg/day for 14 days. A total of 114 animals were used, specific numbers in each group were not reported. The authors did not observe any effects on cardiac conduction (PR or QT intervals), heart rate, body temperature or galvanic skin response. In a separate study, a nonsignificant rise in pulse pressure was observed after 20 and 40 minutes of salvinorin A exposure in anesthetized rats administered a single dose of 1600 ug/kg. In the repeat-dose study, no histologic differences were noted at any salvinorin A doses for either sex in the liver, spleen, kidney, bone marrow or brain tissue. The authors concluded that while salvinorin A is a potent hallucinogen, it has relatively low toxicity.

Mowry et al. (2003) also noted a literature report of a single dose of 1g/kg bw of an extract of *Salvia divinorum*, injected in mice (specific route unknown), where no toxic effects were noted. The actual reference provided by Mowry et al. for this study (Valdes et al., 1984), does not make mention of the actual dose, route of administration, or animal species employed, but notes that this administration produced behavioural patterns resembling the intoxication in humans.

Longer terms studies on the potential toxic effects of salvinorin A, or the whole plant, are not available, and no specialized studies (eg. teratology studies) appear to have been published in the scientific literature to date.

#### Psychotropic effects and mechanism of action:

The psychotropic effects induced by salvinorin A include altered perception, hallucinations, ataxia, depersonalization, hysterical laughter, incoherent speech and unconsciousness (Siebert DJ, 1994). Onset and intensity of the effects of salvinorin A depend on the dose and route of administration. A route that avoids the hepatic first-pass effect (sublingual, inhalation) produces rapid and intense effects.

The effects of *Salvia divinorum* can last up to two hours after absorption through the oral mucosa, while effects of inhaled salvia can last up to 30 minutes. A minimum dose of 200-500 µg of purified salvinorin A, or 0.1 - 0.5 g of dried leaves of *Salvia divinorum* were shown to produce intense psychoactive affects when inhaled (Bucheler et al., 2005).

Various studies have claimed that the psychotropic effects of *Salvia divinorum* closely resemble the symptoms of schizophrenia induced by other drugs such as LSD, phencyclidine or ketamine (Hansen et al., 1988; Javitt and Zukin, 1991; Valdes, 1994).

Salvinorin A has been shown to be a potent agonist of the kappa-opioid receptor (Chavkin et al., 2004). Research has shown that the hallucinogenic effects of salvinorin A are mediated through its kappa-opioid receptor agonist activity (Zhang et al, 2005).

Salvinorin A is structurally different from other naturally occurring classical hallucinogens such as mescaline, psilocybin and lysergic acid diethylamide. Typical doses of other hallucinogens (LSD, mescaline and psilocybin) required to produce hallucinogenic effects are 50-250 ug, 100

mg and 5 mg, respectively (Wolowich et al., 2006), while a minimum dose of 200-500 µg of purified salvinorin A can produce intense psychoactive affects, when vapourised and inhaled (Natural Medicines Comprehensive Database, 2007). Therefore, salvinorin A has more potency compared to mescaline and psilocybin, both of which are controlled substances in Canada. The Natural Medicines Comprehensive Database (2007) notes that “salvinorin A is the most potent hallucinogen known.”

Adverse reactions associated with the use of *Salvia divinorum*:

Domestic reports: See the appendix for detailed causality assessments of the adverse reaction reports submitted to Health Canada. Health Canada has received four reports of adverse reactions (ARs) associated with the use of *Salvia divinorum*. All of these ARs involved psychotropic effects. Out of the four AR reports, three cases involving inhalation were associated with hallucinogenic effects and were considered to be non-serious reactions. The fourth case, however, was considered serious and was associated with the oral use of the chemical constituent salvinorin A. As well, it should be noted that, in this case report, salvinorin A was consumed in a therapeutic drug form (one tablet containing 57 mg of salvinorin A), although this commercially available product was meant to provide psychotropic, rather than therapeutic, effects. In this particular case, the product produced the effects when combined with alcohol.

Summary of Canadian domestic AR cases associated with *Salvia divinorum* or salvinorin A

Total number of cases	4
Route of exposure	Oral (1) & Inhalation (3)
Age range	16 yrs - 56 yrs
Gender	2 male, 2 female
Causality	oral - 1 possible; inhalation - 2 possible, 1 probable

International reports: Two case reports of salvia abuse have been published in the scientific literature.

- (1) An international case report involving *Salvia divinorum* was published in which a young man (19 years of age) described his perceptions after inhaling the smoke from *Salvia divinorum*. The peak psychotropic effects, including prickling of the skin, fever-like hot flashes, muscular tremor, and depersonalization, were reached in less than five minutes after inhalation of an unknown amount of dried leaves (Bucheler et al., 2005).
- (2) Most recently, another published case of *Salvia divinorum* abuse involved a 15-year-old male who presented to psychiatric emergency services with acute onset of paranoia, déjà vu, blunted affect, thought blocking and slowed speech, after smoking *Salvia divinorum* over an unknown period of time. During his hospitalization all symptoms improved

significantly except the feeling of déjà vu. Based on this case presentation, the author suggested that the feelings of déjà vu may be considered long-term effects of Salvia use (Singh, 2007). However, given that this is the only case report in which déjà vu was associated with the use of *Salvia divinorum*, more reports are needed to substantiate this finding.

In addition to the above-mentioned case reports, in 2006, a case report was reported in the US in which a 17-year-old boy committed suicide after smoking *Salvia divinorum* for unknown period of time (<http://www.kvbc.com/Global/story.asp?S=4893692>). Alcohol and general depression were the main confounders in this case. As a result of this case, however, the state of Delaware passed a law outlawing *Salvia divinorum*, and classifying it as a Schedule I controlled substance with other hallucinogenic substances (<http://www.jointogether.org/news/headlines/inthenews/2006/youths-death-inspires.html>). It should be noted that suicidal symptoms were also observed in one of the four domestic cases of *Salvia divinorum* abuse reported to Health Canada.

#### Dose-response assessment

The dose-response for non-psychoactive adverse effects of *Salvia divinorum* or salvinorin A, by any route of administration, either in animals or humans, is unknown. No statistically significant findings were noted in the only available study (Mowry et al., 2003), in which NOELs of 1600 ug/kg bw and 6400 ug/kg bw/day were noted for acute physiologic effects, and short-term histological effects, respectively, using intraperitoneal injection. No longer term studies are available.

The intensity of the psychotropic effects in humans, induced by *Salvia divinorum*, has been noted as dose-dependent; however, a quantitative dose-response assessment has not been carried out. It is known, however, that the minimum dose required to produce hallucinogenic effects by inhalation is about 200 ug salvinorin A (Bucheler et al., 2005).

#### Potential for Dependence, Addiction, and Abuse

It is well known that *Salvia divinorum* or purified salvinorin A can produce various psychotropic effects (altered perception, hallucinations, ataxia, hysterical laughter, and incoherent speech) in humans. As noted above, the intensity of the psychological effects induced by salvinorin A is dose-dependent: high doses can produce extreme effects, such as depersonalisation with loss of reality, and intense psychosis which could be enough for users to harm themselves or others unintentionally (Siebert, 1994). In addition, the symptoms associated with *Salvia divinorum* are expected to be similar to those seen with other hallucinogens, although the duration of effects can be much shorter, depending on the route of exposure (inhalation vs. buccal absorption).

Drug dependence is a physiologic state where continued administration of the drug is necessary to prevent withdrawal; it can be of two types, physical and/or psychological. Dependence can be

influenced by certain receptor types, such as opioid receptors. The existence of three major groups of opioid receptors (mu, delta and kappa) in the central nervous system is well documented (Suzuki and Misawa 1997). There exist complicated interactions among opioid receptor types. The activation of the kappa opioid receptor suppresses physical and psychological dependence produced by mu and delta opioid receptor agonists, but the activation of the delta opioid receptor potentiates the dependence of mu opioid receptor agonists. Various studies provide arguments to support substantial roles for mu-opioid receptors and the possible involvement of delta-opioid receptors in the development of physical and psychological dependence produced by morphine (Narita et al. 2001; Suzuki and Misawa 1997). Most of the drugs used clinically that are mu-opioid analgesics are habit-forming. While both receptor types (delta and mu) provide analgesia, only stimulation of the mu-opioid receptors lead to tolerance and dependency. Opioid agonists (stimulators) such as morphine and other drugs (meperidine, diphenoxylate, methadone, dextromethorpan, codeine, fentanyl, heroin, and tetrahydrocannabinol) exert their activity mainly at the mu receptor (Gaveriaux-Ruff and Kieffer 2002; Narita et al. 2001; Pasternak 2003; Suzuki and Misawa 1997). Using in vitro methods, Margolis et al. (2003) demonstrated that the mechanism of action of kappa opioid receptor agonists may involve direct inhibition of midbrain (ventral tegmental area) dopaminergic neurons, that play a critical role in motivation and reinforcement of goal-directed behaviours, and are excited by addictive substances such as morphine. It is well known that mu and delta opioid receptor agonists produce psychological dependence, while kappa opioid receptor agonists produce an aversive effect, i.e. dysphoria rather than euphoria (Kumor et al. 1986; Rothman et al. 2000). The activation of kappa-receptors also leads to the suppression of mu/delta-mediated side effects such as dependence and respiratory depression.

Salvinorin A is unique in that it is a potent, non-nitrogenous, selective kappa opioid agonist, distinct in its actions from other known opioid receptor agonists. It appears to be devoid of the mainly mu receptor-mediated side effects such as dependence and respiratory depression associated with morphine and its analogues. It may, thus, be possible to use salvinorin A to treat heroin, cocaine, alcohol and amphetamine dependency, depressive illness, and even excessive marijuana use. Being defined by its selectivity for the kappa class of opioid receptor, salvinorin A has the potential to offer a non-habit forming alternative to addictive drugs. It may also reduce the effects of physical and emotional dependence by its antidepressive action (Hanes, 2001).

Although *Salvia divinorum* does not appear to cause dependency, it has the potential for abuse/misuse, especially by young adults. Health Canada has received four domestic case reports of adverse reactions (ARs) associated with the use of *Salvia divinorum* (three inhaled and one oral). In addition, Health Canada is aware of several media reports published on the issue of *Salvia divinorum*, specifically its presence on the market as a legal alternative to illicit drugs. This has prompted the concern of police (eg. Saskatoon Star-Phoenix, December 21, 2006). Furthermore, there are two international cases of salvia abuse published in scientific journals. However, it is important to note that accumulated case reports cannot be used to determine the incidence of a reaction, nor the risk associated with use of a product, because of the unknown number of individuals exposed to the product and because of the significant under-reporting of ARs. In any case, it should be noted that the Canadian Adverse Drug Reaction Monitoring

Program is not an appropriate tool to obtain information concerning adverse reactions associated with the use of *Salvia divinorum* as a street drug.

It has been suggested that *Salvia divinorum* is the most marketed herbal substances available for use as a legal alternative to illicit drugs of abuse, among adolescents and young adults (Siemann et al., 2006; Dennehy et al., 2005). In 2000, a large number of *Salvia divinorum* plants were seized at a large scale plantation in Switzerland, which suggest that its use is increasing as a recreational drug in Europe (Giroud et al, 2000). Several countries (Australia, Denmark, Finland, Italy, Norway, Sweden and some states of the US) have either banned or included *Salvia divinorum* in their list of *controlled substances*.

The above evidence would suggest that any therapeutic products containing *Salvia divinorum* and/or salvinorin A could be misused or abused for their potential psychotropic activities.

### **Therapeutic potential of *Salvia divinorum* and salvinorin A**

Recent studies have suggested that salvinorin A acts at kappa opioid receptor sites (Chavkin et al. 2004; Valdes 1994; Roth et al. 2002). Selective kappa receptor agonists have been shown to produce analgesic effects with potential for reduced tolerance and dependence (Tidgewell et al., 2004). Animal studies have shown that salvinorin A has short-acting anti-nociceptive effects which operate via kappa opioid receptors (McCurdy et al., 2006). Considering the functional interaction between opioid receptor types noted above, the co-administration of morphine-like compounds with kappa-receptor agonists, such as salvinorin A, may constitute a preferable and superior approach to the treatment of pain with fewer side effects (Narita et al., 2001).

There have been significant advances in studies on the role of kappa opioid receptor agonists in producing aversive effects and in the potential modulation of withdrawal from other substances such as morphine, cocaine, THC, alcohol, and in other non-opioid addictions (Cui et al. 2000; Hahn et al. 2000; Mori et al. 2002; Raffa et al. 2003; Rosin et al. 1999; Rothman et al. 2000; Schenk et al. 1999; Tao et al. 1994). As noted above, it may, thus, be possible to use salvinorin A to treat heroin, cocaine, alcohol and amphetamine dependency, clinical depression, and even excessive marijuana use. Because of its selectivity for the kappa class of opioid receptor, salvinorin A has the potential to offer a non-habit forming alternative to these drugs, and may also reduce the effects of physical and emotional dependence by its antidepressive action (Hanes, 2001). Nevertheless, salvinorin A is a well recognised hallucinogen in its own right.

One study suggests that the salvinorin A may be used as a novel molecular candidate for the development of antipsychotic drugs and could be used to treat psychiatric (schizophrenia, bipolar depression) and neuropsychiatric disorders (Alzheimer's disease, dementia) (Sheffler and Roth, 2003).

It should be noted that the above-mentioned therapeutic potentials of *Salvia divinorum* are extrapolated from the results of preliminary investigations, and therefore, much more evidence is needed to substantiate the therapeutic use of *Salvia divinorum* or salvinorin A.

### **Exposure Assessment:**

It is not feasible to assess the exposure to *Salvia divinorum* or salvinorin A from the use of health products, as such products do not appear to exist in Canada, currently. Based on currently available information, however, it is possible that any therapeutic doses of this plant or its active constituents may produce adverse psychoactive effects (see below).

### **Risk Characterization:**

Although little scientific information exists regarding dose-response for *Salvia divinorum* or salvinorin A, risks associated with their use can be assessed in a qualitative manner.

The single toxicological study in animals alludes to the low toxicity of salvinorin A, at least with respect to certain physiological and histological effects. No information, however, is available on the potential long-term effects of exposure to *Salvia divinorum* or salvinorin A, and no studies have looked at the potential for other effects such as teratogenicity.

The psychotropic, and potentially therapeutic effects, elicited by salvinorin A are dependant on the route of exposure. Inhalation and buccal absorption are the most efficient; however, the bioavailability is greatly reduced when ingested without prolonged contact with the oral mucosa.

It is unknown if any potentially therapeutic effects of *Salvia divinorum* /salvinorin A would be achieved via inhalation or ingestion. Although the psychotropic effects appear to be dose-dependent, without more information on the dose-response of the hallucinogenic or therapeutic effects of *Salvia divinorum* or salvinorin A, the risk cannot be fully characterized. However, since the hallucinogenic and potentially therapeutic effects are both dependant on salvinorin A's affinity for the kappa opioid receptor, it is possible that any exposure to the plant or its active constituents, at a dose required for therapeutic use, may result in some degree of psychoactivity. Although selective kappa receptor agonists have been shown to produce analgesic effects, adverse effects such as psychotomimesis, dysphoria and diuresis have been observed in studies investigating their therapeutic use (Barker et al. 2002; Tidgewell et al., 2004). Thus, the potential for psychoactivity, and therefore abuse, with any future therapeutic use of *Salvia divinorum* or salvinorin A, cannot be discounted at the present time.

### **Summary and Conclusions:**

Salvinorin A appears to have low acute and short-term toxicity, although only one limited toxicological study in animals was identified in the scientific literature. No long-term studies have been published, and the long-term safety of this compound has not yet been established. The scientific literature does not support the possibility of developing dependency with *Salvia divinorum* use; however, its use has the potential for misuse or abuse. *Salvia divinorum* and salvinorin A have the ability to induce dose-dependent, moderate to severe hallucinogenic effects in humans, depending on the route of administration.

The fact that a clear dose-response has not been established for the potential therapeutic benefits of salvinorin A, and that the psychotropic and potentially therapeutic actions rely on the same mechanism of action, suggest that any therapeutic activity established in the future may also produce unwanted psychotropic effects. Therefore, the psychotropic activity of *Salvia divinorum* and salvinorin A may lead to the abuse of any health products proposed in the future.

In addition to the above, one of the potential therapeutic uses of salvinorin A is in the treatment of addiction to illicit drugs such as cocaine and heroin. Such potential use should be carried out under the supervision of a qualified physician.

#### Recommendations:

Based on the above assessment, *Salvia divinorum* or salvinorin A-containing health products should be restricted from over-the-counter use. Should any such (unauthorized) health products be found on the Canadian market, they should be removed from sale. Such products would constitute a Type II Health Risk, defined as "A situation in which there is a reasonable probability that the use of, or exposure to, a product, will cause moderate or mild adverse health consequences."

Health products containing *Salvia divinorum* or salvinorin A would meet criteria A (requirement for direct practitioner supervision), C (potential or known undesirable or severe side effects at normal therapeutic doses), and H (possess a dependence or abuse potential that is likely to lead to harmful non-medicinal use) of Schedule F of the *Food and Drug Regulations*. Thus, it is recommended that if such therapeutic products were identified, they should be classified as Schedule F products, precluding them from being Natural Health Products, or regulated under *the Natural Health Products Regulations*.

#### Authors:

Marketed Health Products Directorate: Dr. Shahid Perwaiz, Dr. Scott Jordan

Natural Health Products Directorate: ~~XXXXXXXX~~

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APPENDIX  
CAUSALITY ASSESSMENTS OF ADVERSE REACTIONS

Updated May 22, 2007

FINAL

Natural Health Product: *Salvia divinorum*

Purpose of the assessment:

To review the adverse reactions<sup>1</sup> associated with the use of *Salvia divinorum*. (Domestic case reports are reviewed with respect to causality<sup>2</sup> and seriousness<sup>3</sup>)

Date of review commenced:  
May 2005 - ongoing monitoring

Medical evaluator(s):  
Dr. T. Desjarlais-Renaud

Approved:  
Dr. M. Murty (Sept. 9/05; revised May 22, 2007)

#### Search Strategy:

Adverse reactions suspected to be associated with *Salvia divinorum* were searched, using the search term *Salvia divinorum* in the Canadian Adverse Drug Reaction Monitoring Program (includes reports received and entered into the database from January 01, 1997 to May 3, 2005)]

#### Executive summary:

There are 4 domestic Canadian case reports of neuropsychiatric adverse effects associated with the use of *Salvia divinorum* (3 “non-serious” cases associated with inhalation route of administration and 1 “serious” case associated with oral ingestion).

The ‘serious’ case of psychosis associated with oral use was confounded by concomitant alcohol and therefore, the causality assignment is “Possible”.

One of the inhaled cases was assessed as ‘probable’ but the reaction was not ‘serious’.

**Conclusion:** In the serious case, *Salvia* was sold in a drug form, a tablet containing 57 or 72 mg of Salvinorin-A. In this case concomitant use of *Salvia* and alcohol most likely contributed to the adverse reaction of psychosis.

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<sup>1</sup> Natural Health Product Regulations: <http://canadagazette.gc.ca/partII/2003/20030618/html/sor196-e.html>

An **adverse reaction** is defined as a noxious and unintended response to a natural health product that occurs at any dose used or tested for the diagnosis, treatment or prevention of a disease or for modifying an organic function.  
(*réaction indésirable*)

<sup>2</sup> Based on the WHO causality algorithm unless otherwise specified. (See appendix for WHO algorithm)

<sup>3</sup> Natural Health Product Regulations: <http://canadagazette.gc.ca/partII/2003/20030618/html/sor196-e.html>

A **serious adverse reaction** means a noxious and unintended response to a natural health product that occurs at any dose and that requires in-patient hospitalization or a prolongation of existing hospitalization, that causes congenital malformation, that results in persistent or significant disability or incapacity, that is life threatening or that results in death. (*réaction indésirable grave*):

In the 3 non serious cases, there was disorientation and hallucination after taking one "puff" of Salvia divinorum.

From a clinical perspective, the main concern is the easy access, availability in retail outlets to adolescents without controls and the potential for misuse, as suggested by the AR case report of prolonged psychosis in an adolescent. Additionally, the hallucinogenic effects of Salvia may put individuals in life-threatening situations for themselves and others (driving while under the influence of Salvia). Although the case was confounded by alcohol and details of "intervention" were not specified in the report, it is likely that the Salvia component had contributed significantly to the psychosis, requiring restraint, observation/monitoring prior to the incarceration. Psychosis is a medically significant event and causality remains "Possible" and "Serious".

It is important to note that CADRMP is not the proper tool for monitoring the risk associated with Salvia in this context, because CADRMP is not designed or promoted for the collection of street drug effects. Rather, CADRMP is designed and promoted for the collection of adverse reactions associated with health products, and Salvia used in the current context would not be considered a health product.

Further monitoring and public education are necessary to regulate and possibly restrict Salvia divinorum.

Total domestic AR case reports associated with the use of Salvia divinorum up to May 31, 2005

Source of ADRs	# of cases report	route		psychosis	hallucination disorientation	Causality certain	Causality probable	Causality possible	Serious	Fatal outcome
CADRMP	4	oral	1	1				1	1	0
		inhalation	3		3		1	2	0	0

Summary of Causality Assessment of reaction associated with the use of *Salvia divinorum*

Case ID	Age/gender	Date/Adverse reaction (AR)	Suspect drug/Product name	Route/Dose/Freq.	Time to onset AR/Exposure time period	Possible Confounders	Outcome	Causality	Serious (Y/N)
177866 consumer Jan 12, 2005	27yr/ F	-Unknown - Disorientation, hallucination, not recognizing people around her.	<i>Salvia divinorum</i> Puff encens spécial	Inhalation	1 puff taken	No	Recovered (Effect lasted 5 minutes)	Probable	No

Case summary no 0177866

A 27 year old woman experienced disorientation, not recognizing people in the room, hallucination for a duration of approximately 5 minutes after taking one puff of *Salvia divinorum*. The product called *Puff encens spécial* obtained from a boutique called "L'Ecologique" was inhaled thru a pipe. Patient reported prior use of mescaline and LSD and that the effect of those were not as bad ("moins pires"). The patient was on no other medications. This is not an unexpected reaction to *Salvia divinorum*.

There is no evidence from the case report that she had recently taken other hallucinogenic substances.

The causality was assigned as probable.

The adverse reaction judged as not serious.

Case ID reporter date received	Age/ gender	Date/ Adverse reaction (AR)	Suspect drug/ Product name	Route/ Dose/ Freq.	Time to onset AR/ Exposure time period	Possible Confou nders	Outco me	Caus ality	Seri ous (Y/ N)
1778 65  consumer  Jan 12, 2005	28y r/M	-Unknown - Disorientati on, hallucinatio n, - foaming at the mouth	<i>Salvia divinoru m</i> Puff encens spécial	Inhala tion	1 puff taken	No -no other medicat ions -past med history - unknow n	Recov ered (Effect lasted 5 minute s)	Possi ble	No

Case summary no 0177865

A 28 year old man experienced disorientation, foaming at the mouth, hallucination for a duration of approximately 5 minutes after taking one puff of *Salvia divinorum*. The product called *Puff encens spécial* obtained from a boutique called "L'Ecologique" was inhaled thru a pipe. There was no concomitant medication. Past medical history is unknown. This is not an unexpected reaction to *Salvia divinorum*.

The causality was assigned as possible.  
The adverse reaction judged as not serious.

Case ID reporter date received	Age/ gender	Date/ Adverse reaction (AR)	Suspect drug/ Product name	Route/ Dose/ Freq.	Time to onset AR/ Exposure time period	Possible Confou nders	Outco me	Caus ality	Seri ous (Y/ N)
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Case ID reporter date received	Age/ gender	Date/ Adverse reaction (AR)	Suspect drug/ Product name	Route/ Dose/ Freq.	Time to onset AR/ Exposure time period	Possible Confounders	Outcome	Causality	Serious (Y/ N)
179969  consumer  Feb. 17, 2005	56yr/F	-Unknown - Disorientation, hallucination, does not recognize husband	<i>Salvia divinorum</i> Al sasia encens special	Inhalation	1 puff taken	Unknown	Recovered (total effect 30 minutes)	Possible	No

Case summary no 0179969

A 56 year old woman experienced 30 minutes of disorientation and vivid hallucination after taking 1 puff of *Salvia divinorum*. The reaction was very intense for 10 minutes and then decreased in intensity. The past medical history, concomitant medication and NHP usage are unknown. This is not an unexpected reaction to *Salvia divinorum*.

The causality was assigned as possible.  
The adverse reaction judged as not serious.

Case ID reporter date received	Age/ gender/ weight	Date/ Adverse reaction (AR)	Suspect drug/ Product name	Route/ Dose/ Freq.	Time to onset AR/ Exposure time period	Possible Confounders	Outcome	Causality	Serious (Y/ N)
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Case ID	Age / gender/ weight	Date/ Adverse reaction (AR)	Suspect drug/ Product name	Route/ Dose/ Freq.	Time to onset AR/ Exposure time period	Possible Confounders	Outcome	Causality	Serious (Y/N)
0185128  Consumer (parent)  May 31, 2005	16yr/M  150 lbs	March 29, 2005/ -drug induced psychosis -incoherent -suicidal - restrained -threatened to kill police officers -amnesia (does not remember any of these events) -jailed	Salvia/ aka Maria Pastora	oral/ 1 tablet "the 30\$ pill" 57mg *	single dose	Yes  <u>Concomitant intake of:</u> Alcohol ("few drinks")  <u>Concomitant condition:</u> ADD	Recovered	Possible	Yes

Case summary no 0185128:

On March 23, 2005, a 16 year old male experienced drug induced psychosis: was incoherent, was suicidal, needed to be restrained, threatened to kill police officers, was jailed and had amnesia of these events after taking a single tablet of *Salvia* ( aka Maria Pastra). He had also consumed a few drinks of alcohol. He had an underlying Attention Deficit Disorder (ADD) but was not receiving medication for this. He had previously taken *Salvia* "on its own" (route of administration unknown) with no adverse reaction.

Additional information obtained through the ADR specialist:

\* Follow up request for more information obtained July 28 2005, confirmed that the tablet was oral "30 \$ pill" purchased "behind the counter" at Bob Headquarters<sup>4</sup> in Manitoba. This outlet

<sup>4</sup><http://www.bobhq.com/public/index.htm>

sells a Salvia 10x containing 57 mg of Salvinorin-A for 29.98\$ and a Salvia 20x containing 72 mg of Salvinorin-A for 39.98\$.

Further information received August 18 2005: When Salvia was taken previously, it was the same dose (30\$ pill orally). The only thing different was that on previous occasions, the patient did not have alcohol with it.

This is a case where there was no adverse reaction with previous use of *Salvia* (same dosage, same distributor, same route of administration) but when associated with alcohol, it had a severe adverse reaction.

The causality was assigned as possible with alcohol as a confounder.

The adverse reaction was judged as serious because it required intervention.

## Appendix

### WHO algorithm of Causality Categories:

1	Probably/Likely:	a clinical event, including laboratory test abnormality, with a reasonable time sequence to administration of the drug, unlikely to be attributed to concurrent disease or other drugs or chemicals, and which follows a clinically reasonable response on withdrawal (dechallenge). Rechallenge information is not required to fulfil this definition.
2	Possible:	a clinical event, including laboratory test abnormality, with a reasonable time sequence to administrations of the drug, but which could also be explained by concurrent disease or other drugs or chemicals. Information on drug withdrawal may be lacking or unclear.
3	Unlikely	A clinical event, including laboratory test abnormality, with a temporal relationship to drug administration which makes a causal relationship improbable, and in which other drugs, chemicals or underlying disease provide plausible explanations.
4	Conditional/Unclassified	A clinical event, including laboratory test abnormality, reported as an adverse reaction, about which more data are essential for a proper assessment or the additional data are under examination.
5	Unassessable/Unclassifiable	A report suggesting an adverse reaction which cannot be judged because information is insufficient or contradictory, and which cannot be supplemented or verified.

## **NHPD AND MHPD ISSUE ANALYSIS SUMMARY**

### ***Salvia divinorum* Regulatory Authority and Health Risks**

**Prepared by:** Jacinta Roberts and Robin Marles, NHPD, and Shahid Perwaiz, MHPD

**Draft Date:** June 24, 2004

**Draft Revised:** July 15, 2004

**Finalized:** July 15, 2004

**Updated:** November 3, 2006

#### **ISSUES**

1. Which regulatory authority is most appropriate for *Salvia divinorum* under various conditions of use?
2. What are the risks to consumers of this substance?

#### **BACKGROUND AND ISSUE ANALYSIS**

##### ***Salvia divinorum* as a Health Product**

*Salvia divinorum* Epling & Játiva is an herb in the mint family (Lamiaceae), native to Mexico, that is smoked as a hallucinogen. As a substance it falls under Item 1 of Schedule 1 (inclusion list) to the *Natural Health Products Regulations*, which includes: "a plant or plant material, an alga, a bacterium, a fungus or a non-human animal material."

The main active ingredient of *Salvia divinorum* is a neoclerodane diterpene compound called salvinorin A, which currently falls under Schedule 1, item 2: "an extract or isolate of a substance described in item 1, the primary molecular structure of which is identical to that which it had prior to its extraction or isolation."

In Canada neither the herb, *Salvia divinorum*, nor its active ingredients, such as salvinorin A, are listed in any Schedule to the *Controlled Drugs and Substances Act* (CDSA), nor any Schedule of the *Food and Drugs Act* or its Regulations that would remove it from the purview of the *Natural Health Products Regulations*.

*Salvia divinorum* and its active constituents therefore meet the substance aspect of the regulatory definition of a natural health product.

Whether or not *Salvia divinorum* products meet the function aspect of the regulatory definition of a natural health product depends on the purpose for which the product is being manufactured, sold, or represented for use. According to Section 1(1) of the *Natural Health Products Regulations*, a natural health product means a substance that is manufactured, sold, or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
- (b) restoring or correcting organic functions in humans; or
- (c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

*Salvia divinorum* has traditional medicinal uses among the native peoples of Mexico, e.g. for the treatment of topical ulcers (Díaz 1976), to help normalize eliminatory functions (diarrhoea/ constipation and urination), anemia, headaches, rheumatism, and alcohol addiction, in addition to its use as a hallucinogen in divination rituals (Valdés et al. 1982).

With respect to potential modern uses, there is one human case study from Australia suggesting a possible antidepressant effect (Hanes 2001).

Since *Salvia divinorum* and salvinin A under some conditions of use meet both the functional and substance portions of the definition of a natural health product and are not currently subject to any regulatory exclusions, if associated with a health claim finished products containing these substances could be considered to be natural health products (NHPs).

Until such time as the herb and its active constituent are scheduled under the CDSA or Schedule F to the *Food and Drug Regulations*, the NHPD has jurisdiction to receive a Product Licence Application for a therapeutic use. However, the safety assessment will be sufficiently rigorous to protect consumers' health, particularly with respect to the following safety factors:

- “Does the medicinal ingredient or product have a demonstrated potential for addiction, abuse or severe dependency that is likely to lead to harmful non-medicinal use?”
- “Does the medicinal ingredient or product have known adverse effects at the recommended or therapeutic dosage level?”
- “Does the medicinal ingredient or product have a therapeutic effect based on recently established pharmacological concepts, the consequences of which have not yet been fully established?”
- “Does the medicinal ingredient or product possess a high level of risk relative to expected benefits?”

The answers to these questions are as follows:

- Despite the fact that it is being used as a hallucinogen, the potential for *Salvia divinorum* to cause addiction or dependence is likely to be very low since it affects the brain in way that is quite different from other hallucinogens such as heroin or LSD.
- Nevertheless, *Salvia divinorum* alters perception and could potentially trigger withdrawal symptoms in people suffering from other addictions.
- It is subject to abuse as a street drug.
- It acts on the brain in a way that is quite novel and for which the consequences have not yet been fully established.

For all those reasons, the risks of *Salvia divinorum* use compared to any expected benefits suggest that if it were to be regulated as a health product, it should require a prescription under the *Food and Drug Regulations*, rather than being regulated as an over-the-counter natural health product.

### ***Salvia divinorum as a Hallucinogen***

As with many other NHP substances, there are other uses for the herb that may in future be more appropriately regulated under a different framework.

*Salvia divinorum* is used as a hallucinogen in traditional divination rituals (Valdés et al. 1982) and is being widely touted on internet sites aimed at young adults and adolescents as a "legal" alternative street drug.

The current use and advertising of *Salvia divinorum* as a recreational hallucinogen does not meet the intent of the function component of the *Natural Health Products Regulations*' definition of a natural health product. Nevertheless, even if it is being sold without labelled claims as leaf material in a plastic baggy, it is being represented for use in "modifying organic functions in humans" so from a compliance perspective *Salvia divinorum* falls under the jurisdiction of the *Food and Drugs Act*.

As a hallucinogen and drug of abuse, Health Canada's Office of Controlled Substances has placed *Salvia divinorum* on its list of substances to monitor. As part of this action, the Office of Controlled Substances will collect relevant information specific to this herb and its active constituents.

### ***Salvia divinorum in Other Regulatory Jurisdictions***

In the U.S. Congress, *Salvia divinorum* was the subject of a bill (H.R.5607) entitled "To amend the Controlled Substances Act to place Salvinorin A in Schedule I" introduced on October 10, 2002, seeking to place the herb and its active constituent salvinorin A onto U.S. Controlled Substances Act Schedule 1 (drugs or other substances with a high potential for abuse, with no currently accepted medical use in treatment in the United States, and with respect to which there is a lack of accepted safety for use under medical supervision). Since November 11, 2002, the bill has been referred to the Subcommittee on Crime, Terrorism, and Homeland Security (<http://thomas.loc.gov/cgi-bin/bdquery/z?d107:HR05607:@@L&summ2=m&>, accessed June 24, 2004). Currently, the FDA considers street drug alternatives such as *Salvia divinorum* to be unapproved new drugs and misbranded drugs under sections 505 and 502 of the Act (<http://www.fda.gov/cder/guidance/3602fnl.pdf>, accessed May 26, 2004) and has issued warning letters to a number of firms. Thus it appears that the U.S. has sufficient regulatory authority already to achieve the necessary level of control.

Both the herb and the active ingredient are listed on Schedule 9 of Australia's Standard for the Uniform Scheduling of Drugs and Poisons on the basis of "high potential for abuse and risk to public health and safety," but no substantiation of this risk was provided (<http://www.tga.health.gov.au/ndpsc/record/rr200111upd8.pdf>, accessed May 26, 2004). They are both also in Category B of the Danish list of controlled substances (<http://www.retsinfo.dk/delfin/html/b2003/0071405.htm>, accessed May 26, 2004).

### ***Scientific Details of the Potential of Salvia divinorum for Abuse***

*Salvia divinorum* is smoked to induce visual hallucinations, the diversity of which are described by its users to be similar to those induced by other hallucinogens such as

mescaline or psilocybin. Since neither *Salvia divinorum* nor any of its active ingredients are specifically listed in the *Controlled Drugs and Substances Act*, nor any Schedule of the *Food and Drugs Act* or its Regulations in Canada, some on-line botanical companies and drug promotional sites have advertised the herb as a legal alternative to other plant hallucinogens like mescaline. The objective of this section is to provide background on whether or not *Salvia divinorum* has the potential to induce dependence effects.

Salvinorin A (there are B and C forms) is a hallucinogen when vaporized and inhaled. Salvinorin A is a highly efficacious *kappa*-opioid receptor agonist of clinical interest for treatment and etiological studies of depression, dementia, bipolar disorder, and schizophrenia (Chavkin et al. 2004, Roth et al. 2002). Chemically, salvinorin A is a psychotropic diterpenoid.

Other plants with similar properties include *Cannabis sativa*, which contains the phenolic active principle, tetrahydrocannabinol (THC), and *Artemisia absinthium*, also known as wormwood and used to make the liqueur asbinthe, which contains the monoterpene active principle, thujone.

A dose of 200 to 500 micrograms of salvinorin A produces profound hallucinations when smoked. Its effects in the open field test in mice and locomotor activity tests in rats are similar to those of mescaline. A large body of evidence links the action of hallucinogenic agents (LSD, mescaline) to effects at serotonin (5-HT) receptor sites in the central nervous system (Aghajanian and Marek 1999). Salvinorin A's actions in the brain are not well elucidated. However, recent tissue testing (in vitro assays) have suggested that salvinorin A acts at the *kappa* opiate receptor site (Chavkin et al. 2004; Valdes 1994; Roth et al. 2002). Effects associated with *kappa* opioid receptor activation include analgesia, sedation, and dysphoria (Barker et al. 2002). Using in vitro methods, Margolis et al. (2003) have found evidence that the mechanism of action of *kappa* opiate receptor agonists may involve direct inhibition of midbrain (ventral tegmental area) dopaminergic neurons that play a critical role in motivation and reinforcement of goal-directed behaviours, and have also been implicated in the addictive process initiated by drugs such as morphine.

Drug dependence is a physiologic state where continued administration of the drug is necessary to prevent withdrawal; it can be of two types, physical and/or psychological dependence. The existence of three major groups of opioid receptors (*mu*, *delta* and *kappa*) in the central nervous system is well documented (Suzuki and Misawa 1997). There are complicated interactions among opioid receptor types. The activation of the *kappa* opioid receptor suppresses physical and psychological dependence on *mu* and *delta* opioid receptor agonists, but the activation of the *delta* opioid receptor potentiates the dependence on *mu* opioid receptor agonists. Various studies provide arguments to support substantial roles for *mu*-opioid receptors and the possible involvement of *delta*-opioid receptors in the development of physical and psychological dependence on morphine (Narita et al. 2001; Suzuki and Misawa 1997).

Most of the drugs used clinically that are mu-opioid analgesics are habit-forming. While both receptor types (delta and mu) provide analgesia, only the mu-opioid receptors lead to tolerance and dependency. Opioid agonists (stimulators) such as morphine and other drugs (meperidine, diphenoxylate, methadone, dextramethorpan, codeine, fentanyl, heroin, and tetrahydrocannabinol) exert their activity mainly at the mu receptor (Gaveriaux-Ruff and Kieffer 2002; Narita et al. 2001; Pasternak 2003; Suzuki and Misawa 1997). From behavioural, biochemical and molecular biological studies, it is suggested so far that development of physical dependence on morphine results predominantly from an activation of mu 1 and mu 2 opioid receptors which cause functional changes in Gi/o, adenylate cyclase, protein kinases A and C, beta-adrenoceptor and NMDA receptor in the locus coeruleus. However, activation of the mesolimbic dopamine system may lead to psychological dependence on opioids (Narita et al. 2001; Suzuki and Misawa 1997).

It is well known that mu and delta opioid receptor agonists produce psychological dependence, while kappa opioid receptor agonists produce an aversive effect, i.e. dysphoria rather than euphoria (Kumor et al. 1986; Rothman et al. 2000). Recently, there have been significant advances in studies on the role of kappa opioid receptor agonists in producing an aversive effect of other stimulants such as morphine, cocaine, THC, alcohol, and in other non-opioid addictions (Cui et al. 2000; Hahn et al. 2000; Collins et al. 2001; Mori et al. 2002; Raffa et al. 2003; Rosin et al. 1999; Rothman et al. 2000; Schenk et al. 1999; Tao et al. 1994). The activation of kappa-receptors also leads to the suppression of unpleasant mu/delta-mediated side effects such as dependence and respiratory depression. Considering the functional interaction between opioid receptor types, the co-administration of morphine-like compounds with kappa-receptor agonists may constitute a preferable and superior approach to the treatment of pain with fewer side effects (Narita et al., 2001).

Salvinorin A is unique in that it is a potent, non-nitrogenous, selective kappa opioid agonist distinct in its actions from other known opioid agonists. Therefore, it appears to be devoid of the mainly mu receptor-mediated side effects such as dependence and respiratory depression associated with morphine and its other analogues. It may thus be possible to use salvinorin A to treat heroin, cocaine, alcohol and amphetamine dependency, depression, and even excessive marijuana use. Being defined by its selectivity for the kappa class of opioid receptor, salvinorin A has the potential to offer a non-habit forming alternative. It may also reduce the effects of physical and emotional dependence by its antidepressive action (Hanes, 2001).

In conclusion, on the basis of available scientific literature, the potential addiction or dependence effects of *Salvia divinorum* are expected to remain very low because of the following:

- Most of the drugs which cause dependence and addiction are mu-opioid agonists, while salvinorin A acts as a full agonist at kappa opioid receptors and appears to possess no mu opioid receptor activity.

- Kappa opioid receptor agonists are characterized as being able to modulate dependence-related behavioural effects of drugs like morphine and cocaine rather than causing dependence.
- There have been no cases of dependence on *Salvia divinorum* or salvinorin A reported in the scientific literature.
- The precise mechanism of interaction between salvinorin A and the brain to produce its hallucinogenic effects remains unclear.
- The toxicity of salvinorin A is relatively low, even at doses many times greater than what humans are exposed to (Mowry et al., 2003).
- Many individuals have reported experiencing negative effects (bitter taste, unpredictable and occasionally disturbing short-term mental effects) during their first experience with *Salvia divinorum* and indicate that they would not use it a second time.

#### ***Canadian Reports of Adverse Reactions to Salvia divinorum Products***

The Canadian Adverse Drug Reaction Monitoring Program within the Marketed Health Products Directorate (MHPD) has received four reports of adverse reactions (ARs) associated with products said to contain *Salvia divinorum*, used for its hallucinatory effects. MHPD has conducted causality assessments on the four Canadian case reports associated with the use of *Salvia divinorum* products. All the reported ARs relate to neuropsychological effects. Specifically, three cases (27 year-old female, 56 year-old female, 28 year-old male) were associated with inhalation of *Salvia divinorum* with reported brief hallucinogenic effects, which were considered to be non-serious reactions requiring no medical intervention. The fourth case was associated with the oral consumption of tablets said to contain *Salvia divinorum* and concomitant use of alcohol in a 16 year-old male, with reported adverse reactions of psychosis and amnesia which were considered to be serious and required medical intervention.

#### **PRESENT HEALTH CANADA ACTIONS:**

1. Adverse reactions to *Salvia divinorum* or salvinorin A reported through the Canadian Adverse Drug Reaction Monitoring Program (CADRMP) and those reported in the United States and other jurisdictions are being monitored continuously, recognizing that it is unlikely that adverse reaction reports for these substances will be adequately documented due to *Salvia divinorum*'s use primarily as an hallucinogen. Some information might also be available from Poison Control Centres but there is apparently no uniform means for communication between Poison Control Centres at this time.
2. Health Canada's Office of Controlled Substances has placed *Salvia divinorum* on its list of substances to monitor. As part of this action, the Office of Controlled Substances is collecting relevant information specific to this herb and its active constituents.
3. A Customs Lookout is already in place and should be continued to restrict importation.



4. *Salvia divinorum* and its active principles are being represented for use in modifying organic functions in humans and are therefore classified as health products that fall under the jurisdiction of the *Food and Drugs Act*. To protect the health of Canadians, they are subject to compliance actions by the Health Products and Food Branch Inspectorate in accordance with their Policy 0001.

**NEXT STEPS:**

1. If the information collected warrants further action, the Office of Controlled Substances will assess *Salvia divinorum* against the criteria used for adding substances to the appropriate schedule of the *Controlled Drugs and Substances Act*. These criteria include:
  - international requirements and trends in control/scheduling;
  - chemical and pharmacological similarity to other drugs listed in the CDSA;
  - dependence potential;
  - likelihood of abuse/misuse;
  - extent of abuse/misuse in Canada;
  - danger to public health and safety, and
  - legitimate use in Canada.
2. If *Salvia divinorum* is added to one of the Schedules to the *Controlled Drugs and Substances Act* it will become subject to compliance actions by the federal, provincial, and municipal police forces instead of the HPFB Inspectorate.

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**Media Lines**  
**Salvia divinorum**

**Issue**

Since 2006, Health Canada has noted ongoing media interest regarding the availability of *Salvia divinorum* in Canada. Health Canada has also received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum*, particularly given reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties.

Key msg now is that we ~~have~~ are taking steps -

**Key Messages:**

• Canadians should not use products containing *S. divinorum* and/or salvinorin A because very little is known about the substance and its potential effects on the brain and/or body, and its impact on physical and mental functions.

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• Because of their hallucinogenic properties, products containing *S. divinorum* and/or salvinorin A meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*.

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It is illegal to sell NHPs in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN). The illegal sale of products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*.

• Health Canada has studied the available information about *S. divinorum* and has analyzed the options available to manage the risks associated with the availability of this substance in Canada. Health Canada has determined that a Notice of Intent to schedule *S. divinorum* and salvinorin A under the *Controlled Drugs and Substances Act (CDSA)* will be issued. The purpose of this Notice will be to inform stakeholders and other interested parties of Health Canada's proposal to regulate these substances as controlled substances, as well as to allow the public to provide comments on the proposal.

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**Supplementary Messages:**

***Salvia divinorum* as a controlled substance:**

• In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are currently regulated under the *Controlled Drugs and Substances Act (CDSA)*.

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- Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and thus, do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.
- Several countries (Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) have placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Although some individual U.S. states have implemented laws restricting its use, sale and/or distribution, *Salvia divinorum* and salvinorin A are not regulated under the federal *Controlled Substances Act* in the United States.

#### Questions and Answers:

##### **Q1 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why isn't it illegal?**

A1 – Because *S. divinorum* meets the definition of a Natural Health Product (NHP) under the Natural Health Product Regulations, it is illegal to manufacture, sell or provide products containing *S. divinorum* and/or salvinorin A without their being authorized by Health Canada prior to sale. Health Canada has reviewed the available information regarding *Salvia divinorum*, including the prevalence of its use in Canada, and plans to issue a Notice of Intent to include *S. divinorum* and salvinorin A in one of the schedules to the *Controlled Drugs and Substances Act (CDSA)*. The purpose of this Notice will be to inform stakeholders and other interested parties of Health Canada's proposal to regulate these substances as controlled substances, as well as to allow the public to provide comments on the proposal.

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##### **Q2 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?**

A2 – The *Natural Health Products Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *Salvia divinorum*.

##### **Q3 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A3 – *Salvia divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. Complaints about the illegal sale of drugs containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

##### **Q4 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum* as a controlled substance. What does that involve and what stage is it at?**

A4 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act (CDSA)* is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada has reviewed the available information regarding *Salvia divinorum*, including the prevalence of its use in Canada, and plans to issue a Notice of Intent to include *S. divinorum* and salvinorin A in one of the schedules to the *Controlled Drugs and Substances Act (CDSA)*. The purpose of this Notice will be to inform stakeholders and other interested parties of Health Canada's proposal to regulate these substances as controlled substances, as well as to allow the public to provide comments on the proposal.

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**Q5 – Didn't an internal report from Health Canada's Marketed Health Products Directorate recommend that *Salvia divinorum* be scheduled under the CDSA? Why has that recommendation not been acted upon?**

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A5 – See A4

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A6 – Health Canada has received four domestic adverse reaction reports related to the use of *Salvia divinorum* as a hallucinogen through the Canada Vigilance database. The number of reports and the nature of reactions reported are, however, not adequate to fully characterize the risk of similar reactions among the general population

***If pressed on whether Health Canada has issued any kind of warning to Canadians about *Salvia divinorum****

A - Health Canada is developing an It's Your Health (IYH) article on *Salvia divinorum* to help inform the general public about the risks associated with the use of this substance.

### **Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

Data from the 2008-2009 Youth Smoking Survey indicates that:

- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;
- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year; and.
- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using Salvia in their lifetime (0.2% in the past year); and
- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that:

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;
- 5.4% of students (grades 7-12) ever used *S. divinorum*; and
- the use of *S. divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

**Prepared by:** Cheryl Tremblay and Denis Arsenault, OCS, CSTD

**Input by:** Lisa Mackay IYH/PACCB, Suzanne Desjardins HECSB/ODARS, Hanan Abramovici HECSB/ODARS, Bruna Brands HECSB/ODARS, Jocelyn Kula, HECSB/OCS, Robin Marles HPFB/NHPD, Maggie Graham HPFB/NHPD, Stephanie Collins HPFB/NHPD, Mano Murty HPFB/MHPD, Robert Leitch HPFB/MHPD, Shahid Perwaiz HPFB/MHPD, Collin Pinto, HPFB/HPFBI

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Anne Lamar, ADM, PACCB (pending)  
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### Media Lines *Salvia divinorum*

#### Issue

Since 2006, Health Canada has noted ongoing media interest regarding the availability of *Salvia divinorum* in Canada. Health Canada has also received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum*, particularly given reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties.

#### Key Messages:

- Canadians should not use products containing *S. divinorum* and/or salvinorin A because very little is known about the substance and its potential effects on the brain and/or body, and its impact on physical and mental functions.
- Because of their hallucinogenic properties, products containing *S. divinorum* and/or salvinorin A meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*.
- It is illegal to sell NHPs in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN). The illegal sale of products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*.
- Health Canada has studied the available information about *S. divinorum* and has analyzed the options available to manage the risks associated with the availability of this substance in Canada. Health Canada has determined that a Notice of Intent to schedule *S. divinorum* and salvinorin A under the *Controlled Drugs and Substances Act* (CDSA) will be issued. The purpose of this Notice will be to inform stakeholders and other interested parties of Health Canada's proposal to regulate these substances as controlled substances, as well as to allow the public to provide comments on the proposal.

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#### Supplementary Messages:

##### *Salvia divinorum as a controlled substance:*

- In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are currently regulated under the *Controlled Drugs and Substances Act* (CDSA).

- Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and thus, do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.
- Several countries (Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) have placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Although some individual U.S. states have implemented laws restricting its use, sale and/or distribution, *Salvia divinorum* and salvinorin A are not regulated under the federal *Controlled Substances Act* in the United States.

### Questions and Answers:

#### Q1 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why isn't it illegal?

A1 – Because *S. divinorum* meets the definition of a Natural Health Product (NHP) under the *Natural Health Product Regulations*, it is illegal to manufacture, sell or provide products containing *S. divinorum* and/or salvinorin A without their being authorized by Health Canada prior to sale. Health Canada has reviewed the available information regarding *Salvia divinorum*, including the prevalence of its use in Canada, and plans to issue a Notice of Intent to include *S. divinorum* and salvinorin A in one of the schedules to the *Controlled Drugs and Substances Act (CDSA)*. The purpose of this Notice will be to inform stakeholders and other interested parties of Health Canada's proposal to regulate these substances as controlled substances, as well as to allow the public to provide comments on the proposal.

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#### Q2 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?

A2 – The *Natural Health Products Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *Salvia divinorum*.

#### Q3 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?

A3 – *Salvia divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. Complaints about the illegal sale of drugs containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

#### Q4 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum* as a controlled substance. What does that involve and what stage is it at?

A4 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act (CDSA)* is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada has reviewed the available information regarding *Salvia divinorum*, including the prevalence of its use in Canada, and plans to issue a Notice of Intent to include *S. divinorum* and salvinorin A in one of the schedules to the *Controlled Drugs and Substances Act* (CDSA). The purpose of this Notice will be to inform stakeholders and other interested parties of Health Canada's proposal to regulate these substances as controlled substances, as well as to allow the public to provide comments on the proposal.

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A - Health Canada is developing an It's Your Health (IYH) article on *Salvia divinorum* to help inform the general public about the risks associated with the use of this substance.

### **Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

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PCO (pending)

Comments from David

## **Salvia divinorum**

### **Issue**

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff, incense special, and salvia.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs. As of [REDACTED] 2010 Health Canada has not authorized for sale any products containing *S. divinorum*.

Health Canada recommends that you avoid using this plant because very little is known about the effects it may have on your body and/or brain functions. There is also no way to predict how it will affect you with each use.

### **Risks Associated with the Use of *Salvia divinorum***

*S. divinorum* is known to have both physical and mental effects. The effects of *S. divinorum*, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product
- how much is used
- the purity of the product (products that contain *S. divinorum* may be mixed with other substances)
- how it is taken, for example, whether the product is chewed, swallowed or smoked
- the user's mood and expectations

While scientists know which brain receptors are targeted by the active ingredient, salvinorin A, very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or if it can cause permanent damage
- how it interacts with other substances, including other drugs, natural health products and alcohol
- the potential of *S. divinorum* to produce physical dependence and/or addiction

### Minimizing Your Risk

Hallucinogens like *S. divinorum* work by modifying functions in the brain. Health Canada recommends that you avoid using *S. divinorum* because very little is known about the effects it may have on your body and/or brain functions. There is also no way to predict how it will affect you with each use. Just because a drug is plant-based or “natural”, does not mean that it is safe.

Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs, such as marijuana, cocaine, ecstasy, LSD and other substances that distort reality. See the “*Need More Info?*” section below for links to resources that can help you with this.

### Legal Status of *Salvia divinorum*

#### In Canada

Because of their hallucinogenic properties, products containing *S. divinorum* or salvinorin A meet the definition of a Natural Health Product (NHP) in accordance with the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*. It is illegal to sell drugs or NHPs in Canada, unless they have been reviewed and authorized for sale by Health Canada. In the case of NHPs, they need to be labelled with one of the following:

- a Natural Product Number (NPN); or
- an Exemption Number (EN); or
- a Drug Identification Number - Homeopathic Medicine Number (DIN-HM).

As of [REDACTED] 2010 no products containing *S. divinorum* or salvinorin A have been authorized by Health Canada for sale. The sale of unauthorized drugs and NHPs is illegal, and may be subject to compliance and enforcement actions by the Department.

Neither *S. divinorum* nor salvinorin A are currently regulated under the *Controlled Drugs and Substances Act* (CDSA). Health Canada has reviewed the available information regarding *Salvia divinorum*, and plans to issue a Notice of Intent to include *S. divinorum* and salvinorin A in one of the schedules to the CDSA. The purpose of this Notice will be to inform interested parties of Health Canada’s proposal to regulate these substances as controlled substances, as well as to allow the public to provide comments on the proposal.

#### In Other Countries

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Several countries including but not limited to Australia, Belgium, Germany, Italy, Japan, etc., have placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on their sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution. For example, in some states it is illegal for *S. divinorum* to be sold to anyone under the age of 18.

### Background

The leaves of this plant have been used traditionally by the Mazatec people for medicinal and mystical purposes.

Products that claim to contain *S. divinorum* or its main active ingredient, salvinorin A are widely available on the Internet and are sold in various "head shops" and natural food stores. The products are sold in a number of forms, including fresh or dried leaves, liquids or seeds and plant cuttings for growing purposes.

Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, less than 2% of Canadians age 15 and older reported having used *S. divinorum* at least once in their lifetime. Youth, ages 15-24 were much more likely to have used it than adults. The results from the *Canadian 2008-2009 Youth Smoking Survey* show that 5% of 15yr olds have used *S. divinorum* in the past year. For more information on these surveys, see the *Need More Info* section below.

### Health Canada's Role

Health Canada continues to collect and consider safety information regarding *S. divinorum* and will continue to consult with key stakeholders including health officials in other countries and law enforcement officials here at home. This will assist in determining Health Canada's future approach to the regulation of *S. divinorum* in Canada. Health Canada also continues to monitor the sale of unauthorized health products, including those that contain *S. divinorum* or its main active ingredient salvinorin A, and will take appropriate action when the department becomes aware of any unauthorized health products that may pose a risk to Canadians.

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### Need More Info?

- Complaints about the illegal sale of drugs containing *S. divinorum* can be made to the **Health Products and Food Branch Inspectorate** at: [http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_44\\_consumer\\_consommateur\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_44_consumer_consommateur_cp-pc-eng.php)  
Tel: 1-800-267-9675.

since we are moving forward with scheduling, our role is to continue to collect info but more important to use the DOJ regarding our intent to control under the CDSA.

- You can report any adverse reactions to the Canada Vigilance Program by one of the following three ways:  
Report online at the MedEffect™ Canada website at: <http://www.hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>  
Call toll-free at 1-866-234-2345  
Complete a Canada Vigilance Reporting Form and either:  
Fax toll-free to 1-866-678-6789  
Mail to: Canada Vigilance Program  
Health Canada  
AL 0701C  
Ottawa, ON K1A 0K9  
To have postage pre-paid, download the postage paid label from the MedEffect™ Canada website. The Canada Vigilance Reporting Form and the adverse reaction reporting guidelines may also be obtained via this website at : [http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei\\_form-eng.php](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei_form-eng.php)
- For information about the Government of Canada's Anti-Drug Strategy, go to: [www.nationalantidrugstrategy.gc.ca/](http://www.nationalantidrugstrategy.gc.ca/)  
The Prevention section on this site has a number of helpful resources for parents, including:
  - **Tips on Talking to Your Teenager**, at: [www.hc-sc.gc.ca/hc-ps/pubs/adp-apd/talk-aborder/index-eng.php](http://www.hc-sc.gc.ca/hc-ps/pubs/adp-apd/talk-aborder/index-eng.php)
  - **What to Do if Your Teen is Using Drugs**, at:  
[www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html](http://www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html)
  - Health Canada's **Not4Me** youth drug prevention section at:  
<http://www.hc-sc.gc.ca/hc-ps/drugs-drogués/youth-jeunes/facts-faits/index-eng.php>
- Information on natural health products and the Natural Health Products Regulations can be found at: [www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php)

For more on the surveys that have collected information about *Salvia divinorum* use in Canada, see:

- **The 2008-2009 Youth Smoking Survey**, at:  
<http://www.yss.uwaterloo.ca/index.cfm?section=5&page=288>
- **The 2009 Canadian Alcohol and Drug Use Monitoring Survey**, at:  
<http://www.hc-sc.gc.ca/hc-ps/drugs-drogués/stat/index-eng.php>
- **The 2009 Ontario Student Drug Use and Health Survey**, at:  
[http://www.camh.net/News\\_events/News\\_releases\\_and\\_media\\_advisories\\_and\\_backgrounders/osduhs2009\\_advisory.html](http://www.camh.net/News_events/News_releases_and_media_advisories_and_backgrounders/osduhs2009_advisory.html)

Additional Resources:

- U.S. Drug Enforcement Administration: **Drugs and Chemicals of Concern: *Salvia divinorum* and Salvinorin A** at:  
[www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)

- U.S. Department of Health & Human Services, **National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006** at:  
[www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf](http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf)
- For additional articles on health and safety issues go to the **It's Your Health** web section at: [www.healthcanada.gc.ca/iyh](http://www.healthcanada.gc.ca/iyh)

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

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Comments from: HECSB - CSTD (OCS&ODARS) & HPFB – NHPD, MHPD & HPFBI

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HECSB comms: Christine Roush, Bronwyn Cline  
HPFB-NHPD: Valerie Hurry, Robin Marles, Maggie Graham, Stephanie Collins  
HPFB-MHPD: Scott Jordan, Robert Leitch, Mano Murty, Shahid Perwaiz  
HPFBI : Collin Pinto  
HPFB comms: Elizabeth Keeping, Blossom Leung

## **Salvia divinorum**

### **Issue**

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Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs. As of [REDACTED] 2010 Health Canada has not authorized for sale any products containing *S. divinorum*.

Health Canada recommends that you avoid using this plant because very little is known about the effects it may have on your body and/or brain functions. There is also no way to predict how it will affect you with each use.

### **Risks Associated with the Use of *Salvia divinorum***

*S. divinorum* is known to have both physical and mental effects. The effects of *S. divinorum*, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product
- how much is used
- the purity of the product (products that contain *S. divinorum* may be mixed with other substances)
- how it is taken, for example, whether the product is chewed, swallowed or smoked
- the user's mood and expectations

While scientists know which brain receptors are targeted by the active ingredient, salvinorin A, very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or if it can cause permanent damage
- how it interacts with other substances, including other drugs, natural health products and alcohol
- the potential of *S. divinorum* to produce physical dependence and/or addiction

### Minimizing Your Risk

Hallucinogens like *S. divinorum* work by modifying functions in the brain. Health Canada recommends that you avoid using *S. divinorum* because very little is known about the effects it may have on your body and/or brain functions. There is also no way to predict how it will affect you with each use. Just because a drug is plant-based or “natural”, does not mean that it is safe.

Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs, such as marijuana, cocaine, ecstasy, LSD and other substances that distort reality. See the “*Need More Info?*” section below for links to resources that can help you with this.

### Legal Status of *Salvia divinorum*

#### In Canada

Because of their hallucinogenic properties, products containing *S. divinorum* or salvinorin A meet the definition of a Natural Health Product (NHP) in accordance with the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*. It is illegal to sell drugs or NHPs in Canada, unless they have been reviewed and authorized for sale by Health Canada. In the case of NHPs, they need to be labelled with one of the following:

- a Natural Product Number (NPN); or
- an Exemption Number (EN); or
- a Drug Identification Number - Homeopathic Medicine Number (DIN-HM).

As of [REDACTED] 2010 no products containing *S. divinorum* or *salvinorin A* have been authorized by Health Canada for sale. The sale of unauthorized drugs and NHPs is illegal, and may be subject to compliance and enforcement actions by the Department.

Neither *S. divinorum* nor salvinorin A are currently regulated under the *Controlled Drugs and Substances Act* (CDSA). Health Canada has reviewed the available information regarding *Salvia divinorum*, and plans to issue a Notice of Intent to include *S. divinorum* and salvinorin A in one of the schedules to the CDSA. The purpose of this Notice will be to inform interested parties of Health Canada’s proposal to regulate these substances as controlled substances, as well as to allow the public to provide comments on the proposal.

#### In Other Countries

Deleted: its

Deleted: Health Canada is currently considering the available information to determine whether regulation as a controlled substance is warranted.

Several countries including but not limited to Australia, Belgium, Germany, Italy, Japan, etc., have placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on their sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution. For example, in some states it is illegal for *S. divinorum* to be sold to anyone under the age of 18.

## Background

The leaves of this plant have been used traditionally by the Mazatec people for medicinal and mystical purposes.

Products that claim to contain *S. divinorum* or its main active ingredient, salvinorin A are widely available on the Internet and are sold in various "head shops" and natural food stores. The products are sold in a number of forms, including fresh or dried leaves, liquids or seeds and plant cuttings for growing purposes.

Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, less than 2% of Canadians age 15 and older reported having used *S. divinorum* at least once in their lifetime. Youth, ages 15-24 were much more likely to have used it than adults. The results from the *Canadian 2008-2009 Youth Smoking Survey* show that 5% of 15yr olds have used *S. divinorum* in the past year. For more information on these surveys, see the *Need More Info* section below.

## Health Canada's Role

Health Canada continues to collect and consider safety information regarding *S. divinorum* and will continue to consult with key stakeholders including health officials in other countries and law enforcement officials here at home. This will assist in determining Health Canada's future approach to the regulation of *S. divinorum* in Canada. Health Canada also continues to monitor the sale of unauthorized health products, including those that contain *S. divinorum* or its main active ingredient salvinorin A, and will take appropriate action when the department becomes aware of any unauthorized health products that may pose a risk to Canadians.

← should we re-state info re: NOI here?

Deleted: decision-making regarding

## Need More Info?

- Complaints about the illegal sale of drugs containing *S. divinorum* can be made to the **Health Products and Food Branch Inspectorate** at: [http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_44\\_consumer\\_consommateur\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_44_consumer_consommateur_cp-pc-eng.php)  
Tel: 1-800-267-9675.

- You can report any adverse reactions to the Canada Vigilance Program by one of the following three ways:  
Report online at the MedEffect™ Canada website at: <http://www.hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>  
Call toll-free at 1-866-234-2345  
Complete a Canada Vigilance Reporting Form and either:  
Fax toll-free to 1-866-678-6789  
Mail to: Canada Vigilance Program  
Health Canada  
AL 0701C  
Ottawa, ON K1A 0K9  
To have postage pre-paid, download the postage paid label from the MedEffect™ Canada website. The Canada Vigilance Reporting Form and the adverse reaction reporting guidelines may also be obtained via this website at : [http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei\\_form-eng.php](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei_form-eng.php)
- For information about the Government of Canada's Anti-Drug Strategy, go to: [www.nationalantidrugstrategy.gc.ca/](http://www.nationalantidrugstrategy.gc.ca/)  
The Prevention section on this site has a number of helpful resources for parents, including:
  - **Tips on Talking to Your Teenager**, at: [www.hc-sc.gc.ca/hc-ps/pubs/adp-apd/talk-aborder/index-eng.php](http://www.hc-sc.gc.ca/hc-ps/pubs/adp-apd/talk-aborder/index-eng.php)
  - **What to Do if Your Teen is Using Drugs**, at: [www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html](http://www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html)
  - Health Canada's **Not4Me** youth drug prevention section at: <http://www.hc-sc.gc.ca/hc-ps/drugs-drogues/youth-jeunes/facts-faits/index-eng.php>
- Information on natural health products and the Natural Health Products Regulations can be found at: [www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php)

For more on the surveys that have collected information about *Salvia divinorum* use in Canada, see:

- **The 2008-2009 Youth Smoking Survey**, at: <http://www.yss.uwaterloo.ca/index.cfm?section=5&page=288>
- **The 2009 Canadian Alcohol and Drug Use Monitoring Survey**, at: <http://www.hc-sc.gc.ca/hc-ps/drugs-drogues/stat/index-eng.php>
- **The 2009 Ontario Student Drug Use and Health Survey**, at: [http://www.camh.net/News\\_events/News\\_releases\\_and\\_media\\_advisories\\_and\\_backgrounders/osduhs2009\\_advisory.html](http://www.camh.net/News_events/News_releases_and_media_advisories_and_backgrounders/osduhs2009_advisory.html)

Additional Resources:

- U.S. Drug Enforcement Administration: **Drugs and Chemicals of Concern: *Salvia divinorum* and Salvinorin A** at: [www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)

- U.S. Department of Health & Human Services, **National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006** at:  
[www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf](http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf)
- For additional articles on health and safety issues go to the **It's Your Health** web section at: [www.healthcanada.gc.ca/iyh](http://www.healthcanada.gc.ca/iyh)

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

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Catalogue#

ISBN#

Version/date: Draft 17. September 8, 2010.


PACCB IYH - Lisa Mackay: 613-954-0105 – [Lisa.Mackay@hc-sc.gc.ca](mailto:Lisa.Mackay@hc-sc.gc.ca)

Comments from: HECSB - CSTD (OCS&ODARS) & HPFB – NHPD, MHPD & HPFBI

Contacts: HECSB: Jocelyn Kula, Stephanie Chandler, Suzanne Desjardin, Denis Arsenault, Hanan Abramovici, Bruna Brands  
HECSB comms: Christine Roush, Bronwyn Cline  
HPFB-NHPD: Valerie Hurry, Robin Marles, Maggie Graham, Stephanie Collins  
HPFB-MHPD: Scott Jordan, Robert Leitch, Mano Murty, Shahid Perwaiz  
HPFBI : Collin Pinto  
HPFB comms: Elizabeth Keeping, Blossom Leung





**Re: Salvia IAS**   
Tiffany Thornton to: Stephanie Chandler

2010-11-17 12:32 PM

Thanks Stephanie, all will note that when I circulate.

Tiffany

Stephanie Chandler Hi Tiffany, Here is the current IAS for salvia. A... 2010-11-17 09:44:47 AM

From: Stephanie Chandler/HC-SC/GC/CA  
To: Tiffany Thornton/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC, Tiana Branch/HC-SC/GC/CA@HWC  
Date: 2010-11-17 09:44 AM  
Subject: Re: Salvia IAS

---

Hi Tiffany,

Here is the current IAS for salvia. As previously stated I have yet to incorporate some changes from the Director, OCS (so it has not been approved) and it will be updated again pending comments from the NOI. [attachment "Draft Salvia Divinorum IAS\_Oct 29 2010.doc" deleted by Tiffany Thornton/HC-SC/GC/CA]

Regards,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

Tiffany Thornton Hi Stephanie, Thanks for your note. 2010-11-16 04:48:15 PM

From: Tiffany Thornton/HC-SC/GC/CA  
To: Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2010-11-16 04:48 PM  
Subject: Re: Salvia IAS

---

Hi Stephanie,

Thanks for your note.

Based on what I heard today I think Suzanne would like to see the comments based on the last CSS-WG meeting (Oct 27th) that were provided to you. In addition, she would like to see whether or not the IAS has incorporated all the changes thus far that have been given throughout the entire review process to see if these have been integrated into the current document.

Suzanne is aware that the document has not receive approval and the NOI comments have not been incorporated. As a result, can you send me the most recent version you have.

Let me know if you have any further questions.  
Tiffany

---

Stephanie Chandler    Hi Tiffany, Denis mentioned to me that Suzann...    2010-11-16 03:55:42 PM

From:            Stephanie Chandler/HC-SC/GC/CA  
To:                Tiffany Thornton/HC-SC/GC/CA@HWC  
Date:             2010-11-16 03:55 PM  
Subject:          Salvia IAS

---

Hi Tiffany,


Denis mentioned to me that Suzanne stated at today's CSS-WG meeting (sorry I couldn't attend due to a scheduling conflict) that she would like for the group to see an updated version of the IAS. I recall from the last meeting that Suzanne felt that ODARS did not have time to provide in depth comments with regard to the scientific sections of the IAS and would provide comments at a later date. I haven't received any other comments, so I'm wondering if ODARS would like to provide them before I send you the latest version of the IAS? I am happy to provide the current IAS (though please keep in mind it is not the final version as NOI comments will be incorporated). I also have to incorporate some grammatical changes from Jocelyn before she officially approves it.

Regards,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca



**Re: Fw: Salvia products**   
Daniel Galarneau to: Stephanie Chandler  
This message is digitally signed.

2010-11-17 03:19 PM

Fine

*Daniel Galarneau*

Head, Regulatory Affairs Section – Chef, Section de la réglementation  
Office of Controlled Substances -- Bureau des substances contrôlées  
Controlled Substances and Tobacco Directorate – Direction des substances contrôlées et de la lutte au tabagisme  
Healthy Environments and Consumer Safety Branch -- Direction Générale de la Santé Environnementale et de la  
Sécurité des Consommateurs  
Tel: (613) 946-6521  
Fax: (613) 946-4224

Stephanie Chandler Revised as discussed. For your review. Thanks, 2010-11-17 02:56:16 PM

From: Stephanie Chandler/HC-SC/GC/CA  
To: Daniel Galarneau/HC-SC/GC/CA@HWC  
Date: 2010-11-17 02:56 PM  
Subject: Fw: Salvia products

Revised as discussed. For your review.

[attachment "Salvia Media Lines\_Nov17\_SC.doc" deleted by Daniel Galarneau/HC-SC/GC/CA]

Thanks,

Stephanie

----- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2010-11-17 02:55 PM -----

From: Stephanie Chandler/HC-SC/GC/CA  
To: Daniel Galarneau/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2010-11-17 09:26 AM  
Subject: Fw: Salvia products

Hi Daniel,

For your review. Denis stated yesterday that you should approve this on his behalf before we send this to the DO. (Comms would like it by the end of the week.)

[attachment "Salvia Media Lines\_Nov16\_SC.doc" deleted by Stephanie Chandler/HC-SC/GC/CA]  
[attachment "IYH Salvia divinorum\_v19 Nov 16\_SC.doc" deleted by Stephanie Chandler/HC-SC/GC/CA]

Thanks,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et

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E-Mail: stephanie.chandler@hc-sc.gc.ca

----- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2010-11-17 09:24 AM -----

From: Denis Arsenault/HC-SC/GC/CA  
To: Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2010-11-15 03:14 PM  
Subject: Fw: Salvia products

---

Hi Stephanie,

For action.

Denis

---

Denis Arsenault, A/Manager / Gestionnaire p.i.

Regulatory Policy Division /

Division des politiques réglementaires,

Office of Controlled Substances /

Bureau des substances contrôlées,

Health Canada / Santé Canada

Tel/Tél: (613) 957-6828

Fax / Télécopieur : (613) 946-4224

E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca

----- Forwarded by Denis Arsenault/HC-SC/GC/CA on 2010-11-15 03:13 PM -----

From: Nicole Prentice/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC, Christine Roush/HC-SC/GC/CA@HWC, Paul Spendlove/HC-SC/GC/CA@HWC  
Date: 2010-11-15 02:47 PM  
Subject: Salvia products

---

Hi Jocelyn,

Below are the salvia media lines and IYH article. This is not urgent, but if possible can you revise these lines and the IYH article regarding the NOI and possible scheduling by the end of this week so we can move these products along? Cathy would like to get the lines going at the very least so we can limit the amount of media enquiries on salvia in her inbox.

On a side note, I sent these back to HPFB as well so they can correct the wording re: illegal vs. in contravention of etc...

If you have any issues or concerns, please let me know.

Thanks.

[attachment "Salvia Media Lines\_Sept30.doc" deleted by Stephanie Chandler/HC-SC/GC/CA]

[attachment "IYH Salvia divinorum\_v18 clean Oct 1.doc" deleted by Stephanie Chandler/HC-SC/GC/CA]

**Nicole Prentice**

Junior Communications Officer | Agente junior des Communications

Regulatory Communications and Media Relations Division | Division des communications

réglementaires et des relations avec les médias  
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Tel: 613.941.3107  
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# Issue Analysis Summary

DRAFT

## Scheduling *Salvia Divinorum* under the CDSA

Regulatory Policy Division  
Office of Controlled Substances

Controlled Substances and Tobacco and Directorate

November 17, 2010

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### CONTENTS

1. APPROVALS
2. ISSUE
3. PURPOSE
4. CONTEXT
5. ASSESSMENT OF RISKS AND BENEFITS
6. IDENTIFICATION AND ANALYSIS OF OPTIONS
7. CONSIDERATIONS
8. RECOMMENDATION(S)
9. CONSULTATIONS
10. IMPLEMENTATION AND EVALUATION

#### 1. APPROVALS

This Issue Analysis Summary is approved.

Jocelyn Kula, A/Director  
Office of Controlled Substances  
Controlled Substances and Tobacco Directorate

[DD/MM/2010]

#### 2. ISSUE

Health Canada has received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum* (*S. divinorum*) under the *Controlled Drugs and Substances Act* (CDSA). These requests are further to reports from scientific and media sources suggesting that *S. divinorum* is being used by youth specifically for its hallucinogenic properties. Health Canada has also noted an ongoing media interest regarding the availability of *S. divinorum* in Canada.

Deleted: ,

Deleted: which is not currently regulated

Deleted: adolescents and young adults

1

### 3. PURPOSE

To assess *S. divinorum* against the criteria for the addition of a substance to one of the Schedules to the CDSA, and determine whether this substance should be regulated as a controlled substance in Canada.

### 4. CONTEXT

*S. divinorum* is a species of sage which belongs to the mint family, and which is found in the form of dried leaves, extracts and plant cuttings. Also called "diviner's sage", the plant is known to induce illusions and hallucinations when chewed or smoked. Salvinorin A, the psychoactive ingredient in *S. divinorum* is a neoclerodane diterpene which is found primarily in the leaves, and to a lesser extent in the stem of the plant.<sup>1</sup>

*S. divinorum* is widely touted as a "legal" hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs among adolescents and young adults.<sup>2</sup> While very little is known about how and where *S. divinorum* is sold in Canada, it is suspected that it is mainly purchased over the Internet and/or bought at head shops or alternative life style stores, etc. *S. divinorum* cuttings are also available from a number of garden supply companies.

*S. divinorum* is a substance not currently scheduled under the CDSA. It can be imported and sold legally in Canada to anyone of any age, anywhere in Canada provided it is not sold as a health product or marketed as a hallucinogen. In addition, the *S. divinorum* sold in Canada is currently not subject to any specific quality or safety standards.

The use of *S. divinorum* as a psychotropic agent first came to Health Canada's attention in 2002. In 2004, Health Canada received four adverse drug reaction (ADR) reports associated with the use of *S. divinorum* as a hallucinogen, with three being considered non-serious (requiring no medical attention) and the fourth being considered serious (medical intervention was required). The serious ADR report involved the concomitant use of alcohol in a person diagnosed with Attention Deficit Disorder.

Further to the receipt of the aforementioned ADRs, the Marketed Health Products Directorate (MHPD) and the Natural Health Products Directorate (NHPD) of the Health Products and Food Branch (HPFB) prepared an issue analysis summary (IAS) in November 2005, which recommended that *S. divinorum* and its active ingredient salvinorin A be regulated as controlled substances. This recommendation was maintained when the IAS was updated in November

<sup>1</sup> U.S. Department of Justice Drug Enforcement Administration. 2002. Drugs and Chemicals of Concern: Salvia Divinorum (salvinorin A, divinorin A) URL: [http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm) Nov 2008

<sup>2</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.

2006.

Later, in December 2005, MHPD and NHPD prepared a Signal Assessment (SA) (updated in June 2007) that eventually led to the preparation of a Health Risk Assessment (HRA), which concluded that *S. divinorum* or salvinorin A-containing health products would constitute a Type II Health Risk according to the Health Hazard Classification of the Recall Policy of the Health Products and Food Branch Inspectorate (HBFBI). Such a risk is defined as “a situation in which the use of, or exposure to, a product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote”.

Further to a discussion with the Assistant Deputy Minister (ADM) of the Healthy Environments and Consumer Safety Branch (HECSB) in April 2007, the (then) Drug Strategy and Controlled Substances Directorate (DSCSD) (now the Controlled Substances and Tobacco Directorate, CSTD) organized a meeting with MHPD, NHPD and HPFBI to discuss *S. divinorum*. HPFBI was to determine appropriate compliance activities regarding *S. divinorum* and consult with the Canada Border Services Agency (CBSA) regarding the movement of products containing *S. divinorum* into and out of Canada.

On September 13, 2007, a further meeting between DSCSD, MHPD, NHPD and HPFBI led to the conclusion that DSCSD would conduct a scheduling assessment of *S. divinorum* in order to explore the possibility of scheduling this substance under the CDSA.

In September 2008, the Director Generals of DSCSD, MHPD, TPD and the HPFBI agreed that media lines and an “It’s Your Health” article on *S. divinorum* would be prepared.

#### **4.1 Relevant Legislative Frameworks in Canada**

##### **4.1.1 Food and Drug Regulations (under the Food and Drugs Act)**

The *Food and Drug Regulations* (F&DR) serve to ensure the safety, efficacy, and quality of health products offered for sale in Canada, including drugs and medical devices. Prior to being given market authorization, a manufacturer must present substantive scientific evidence that their product is safe, efficacious and of high quality. For drugs, Health Canada reviews this information carefully and, if the review is satisfactory, a Notice of Compliance (NOC) is issued and appropriate Drug Identification Numbers (DINs) are assigned.

A “drug” is defined under the F&DR as any substance or mixture of substances manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
- (b) restoration, correction or modification of organic functions in human beings or animals, or



- (c) disinfection in premises in which food is manufactured, prepared or kept;

As no products containing *S. divinorum* or its extracts have been reviewed and approved by Health Canada as of October 2010, it is illegal to market *S. divinorum* when it is represented as a drug.

#### 4.1.2 Natural Health Products Regulations (under the Food and Drugs Act)

The *Natural Health Products Regulations* (NHPR) aim to provide Canadians with ready access to natural health products (NHPs) that are safe, effective, and of high quality, while respecting freedom of choice and philosophical and cultural diversity. The NHPR require that all licensed products display a Natural Product Number (NPN), or, in the case of a homeopathic medicine, a Drug Identification Number - Homeopathic Medicine (DIN-HM), on their labels. These numbers are issued once a product is authorized for sale in Canada. A product licence may be obtained pursuant to an application in which the applicant attests to all of the conditions set out in a natural health product monograph prepared and published by the Natural Health Products Directorate. Alternatively, an applicant may submit a product license application that provides evidence of quality, safety and efficacy that is assessed as being sufficient and approved by NHPD by the full submission route. The NHPR also require that all manufacturers, packagers, labelers, and importers have a site license issued on the basis of sufficient evidence of procedures respecting distribution records, product recalls, product handling, storage and delivery, and all other aspects of Good Manufacturing Practices as set out in the NHPR.

The definition of an NHP under the NHPR has both a function and substance component. The function component refers to those substances that are manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
- (b) restoring or correcting organic functions in humans; or
- (c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

The substance component refers to the requirement that all of the medicinal ingredients of an NHP must be substances set out in Schedule 1 (a list of included substances) to the NHPR, a traditional medicine or a homeopathic medicine, and none of the ingredients can be substances set out in Schedule 2, a list of excluded substances which includes any substance listed on Schedules I to V of the CDSA. Section 2(2) of the NHPR excludes those substances (except homeopathic medicines) whose sale is required to be pursuant to a prescription as per Section C.01.043 of the F&DR.

As per section 93(1)(b)(vi) of the NHPR, every natural health product must be labeled with its

authorized recommended use or purpose. In the case of *S. divinorum*, it is generally marketed for its hallucinogenic properties which are considered a modification of an organic function. Therefore products that contain *S. divinorum* and are manufactured, sold or represented for use as a hallucinogen meet the definition of an NHP.

As of October 2010, no products containing *S. divinorum* have been authorized by Health Canada. Therefore no NPNs or DIN-HMs have been issued for such products. Therefore sales of *S. divinorum* are illegal under the NHPR if the product is represented for use as a hallucinogen or if other health claims are made.

#### 4.1.3 Controlled Drugs and Substances Act and its Regulations

The CDSA provides a legislative framework for the control of substances that can alter mental processes and that may produce harm to the health of an individual or to society when diverted or misused. Except as authorized under its regulations, activities such as possession, possession for the purposes of trafficking, trafficking, importation, exportation, possession for the purposes of exportation and production of controlled substances are prohibited under the CDSA.

The substances regulated under the CDSA are grouped into eight Schedules, and each Schedule is associated with particular offences and penalties as described in Part I of the CDSA.

In determining whether a substance should be regulated as a controlled substance, and into which Schedule of the CDSA it should be placed, Health Canada considers the following factors;

- International requirements and trends in the control and/or scheduling;
- Chemical and/or pharmacological similarity to substances listed in the Schedules to the CDSA;
- Legitimate use of the substance, including therapeutic, scientific, industrial or commercial uses;
- Potential for abuse and/or addiction liability;
- Evidence of extent of actual abuse of the substance in Canada and internationally; and
- Risk to personal and public health and safety.

**Deleted:** a number of

**Deleted:** including

**Comment [S1]:** JK suggested we remove 'the'; however this is how this factor is written in CSS-WG documents so I have left as is

**Comment [S2]:** Same comment as above

#### 4.2 **Assessment of *S. Divinorum* for Scheduling Purposes**

##### 4.2.1 International Requirements and Trends in the Control and/or Scheduling

At the present time, neither *S. divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and therefore do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

##### ***Australia***

In June 2002, Australia became the first country to prohibit the sale, supply, possession and use of *S. divinorum* and salvinorin A. Both *S. divinorum* and salvinorin A are listed in Schedule 9 of Australia's *Standard for the Uniform Scheduling of Drugs and Poisons* on the basis of "high potential for abuse and risk to public health and safety."<sup>3</sup> Schedule 9 is Australia's most restrictive drug schedule, and includes "substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities."<sup>4</sup>

### **Belgium**

A decree was passed in Belgium on October 22, 2006 which added *S. divinorum* to the list of controlled substances. This list includes substances such as psilocybin mushrooms, khat and peyote cactus.<sup>5</sup>

### **Denmark**

In 2003, Denmark added *S. divinorum* and salvinorin A to their list of "category B" controlled substances, a category which also includes psilocybin mushrooms, cocaine, amphetamine, and several others substances that are only legal for medicinal and scientific purposes. Illegal possession carries a penalty of up to two years in prison.

### **Germany**

*S. divinorum* (plant and plant parts) was added to Appendix I of the *Narcotics Act* in Germany on March 1, 2008, making it illegal to produce, traffic, or possess. The law does not specifically mention salvinorin A.

### **Italy**

On June 25, 2004, the Italian Ministry of Health issued an ordinance prohibiting the sale of *S. divinorum* and its active constituent salvinorin A. On January 11, 2005, the Ministry of Health made possession of *S. divinorum* and salvinorin A illegal by placing them in "*Tabella I*" of the *Tabelle Sostanze Stupefacenti o Psicotrope*.

### **Japan**

On November 9, 2006, the Japanese government added a group of thirty-three drugs to its list of controlled substances, including salvinorin A. The drugs are banned under a revised

<sup>3</sup> <http://www.tga.gov.au/ndpsc/record/r200111.pdf>

<sup>4</sup> [http://www.cognitiveliberty.org/news/salvia\\_australia.htm](http://www.cognitiveliberty.org/news/salvia_australia.htm)

<sup>5</sup> <http://eldd.emcdda.europa.eu/html.cfm/index5176EN.html?pluginMethod=eldd.shownewsdetails&id=20/12/2006BELGIUM:%20New%20substances%20controlled%20include%20mCPP%20and%20khat>

pharmaceutical law, under which persons involved in their illegal import, production, and sale, i.e. beyond medical treatment or research purposes, will be subject to up to five years imprisonment or a fine of up to five million yen.

**Spain**

On January 28, 2004, the Spanish Ministry of Health and Consumption issued an order prohibiting the sale of *S. divinorum*. The regulation went into effect on May 6, 2004 and only prohibits activities related to commerce. Possession and/or use are not considered to be criminal offences.

**Other Countries**

It is illegal to possess or sell *S. divinorum* in Croatia, Latvia, Lithuania, Poland, Romania, South Korea and Sweden. In Russia it is illegal to grow or sell *S. divinorum*, but it is legal to possess it. In Estonia, Finland, Iceland and Norway, *S. divinorum* is treated as a medicinal herb and it is illegal to import it without a relevant prescription from a doctor.

**United States of America**

*S. divinorum* and salvinorin A are not included in the Schedules to the United States *Controlled Substances Act*. Although both *S. divinorum* and salvinorin A have been added to a list of chemicals "of concern", this has no legal implications. According to the National Institute for Drug Abuse, the Drug Enforcement Administration is considering classifying *S. divinorum* and/or salvinorin A as Schedule I drugs. This Schedule includes substances such as LSD and marijuana.

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At the state level, some state legislatures have implemented laws restricting the use, sale and/or distribution of *S. divinorum* and/or salvinorin A. As of July 2010, a number of states have placed regulatory controls on *S. divinorum* and/or salvinorin A including Delaware, Georgia, Florida, Hawaii, Illinois, Kansas, Kentucky, Maryland, Mississippi, Missouri, Nebraska, North Dakota, Ohio, Oklahoma, South Dakota, Wisconsin, Virginia, California, Louisiana, Maine, North Carolina, and Tennessee. By way of example, additional details regarding the regulation of *S. divinorum* in these last five states are provided below.

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**California**

As of January 1, 2009, the sale or distribution of *S. divinorum* or salvinorin A, or any substance or material containing *S. divinorum* or salvinorin A, to any person under 18 years of age is a misdemeanor punishable by imprisonment in a county jail for not more than six months, a fine of no more than \$1,000, or both.

**Louisiana**

In 2005, Louisiana passed a bill which prohibits the possession, production, manufacture and distribution of a material, compound, mixture, or preparation intended for human consumption and that contains a hallucinogenic plant. A "hallucinogenic plant" is defined as "any part or portion" of a plant on a list of forty plants, which includes *S. divinorum*.

### **Maine**

In Maine, *S. divinorum* and salvinorin A are regulated in the same way as tobacco products; adults eighteen years of age or over can legally purchase and use the material, but selling or providing *S. divinorum* or salvinorin A to anyone under the age of eighteen is a criminal offence. Possession by a minor is a civil violation, punishable by a fine, community service, or both.

### **North Carolina**

On December 1, 2009, the North Carolina State Legislature brought a new law into force which made *S. divinorum* and salvinorin A illegal. The only legal *S. divinorum* activities are the growing for aesthetic, landscaping, or decorative purposes or university-affiliated medical or pharmacological research.

### **Tennessee**

On July 1, 2006, Tennessee classified the deliberate production, manufacture, distribution, or possession of the active chemical ingredient in the hallucinogenic plant *S. divinorum* as a Class A misdemeanor. It is not, however, a criminal offence to possess, plant, cultivate, grow, or harvest *S. divinorum* for aesthetic, landscaping, or decorative purposes. The law also does not apply to any dosage that is legally obtainable from a retail establishment without a prescription when (and if) it is recognized by the Food and Drug Administration as a homeopathic drug.

#### **4.2.2 Chemical and/or Pharmacological Similarity to Substances Listed in the Schedules to the CDSA**

The psychoactive ingredient in *S. divinorum* is the neoclerodane diterpene salvinorin A.<sup>6</sup> As a diterpene, salvinorin A is part of a family of substances that contain terpenoids. Another plant which contains psychotropic terpenoids is *Artemisia absinthium* (wormwood).<sup>7</sup> Salvinorin A is a hallucinogen with a distinct structure and it does not interact with the serotonin type-2A receptor or any other molecular target of classical hallucinogens.<sup>8</sup> Instead, the available research suggests

<sup>6</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage *Salvia divinorum*. *Life Sci.* 2005 Dec 22;78(5):527-31.

<sup>7</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.

that the psychotropic effects of salvinorin A are mediated by its agonistic actions at the  $\kappa$ -opioid (KOR) receptor.<sup>9</sup> Its mechanism of action is therefore unique.<sup>10</sup>

The psychoactive effects of *S. divinorum* vary in onset and duration and include perceptual distortions such as the sensation of becoming an object, having visions of various two-dimensional surfaces, films and membranes, revisiting places of the past (particularly childhood), perceived loss of the body and/or identity, various sensations of motion (being pulled or twisted by a force of some kind), uncontrollable hysterical laughter, and overlapping realities (perceptions of being in more than one place).<sup>11</sup> Laughter, happiness, a sense of well-being and dissociative effects were deemed the most positive aspects of *S. divinorum* by users, second only to the "trip" that the drug elicits.<sup>12</sup> Depersonalization, speaking gibberish, widening of consciousness and subjective illusions of rapid movement, flying or hovering have also been reported.<sup>13</sup>

The psychotomimetic effects of *S. divinorum* closely resemble the schizoid symptoms induced by lysergic acid diethylamide (LSD) or phencyclidine (PCP).<sup>14</sup> Yet, it is said to have only a weak influence on the prevailing mood of the user which differentiates it from other hallucinogens such as LSD and psilocybin.<sup>15</sup> Its strong dissociative effects are often compared to those of ketamine.<sup>16</sup> Users have reported that the psychedelic effects of *S. divinorum* were most similar to those caused by psilocybin mushrooms.<sup>17</sup> However, users familiar with the effects of other hallucinogens agree that despite certain similarities to classical hallucinogens, the visions and overall experience are quite unique.<sup>18</sup>

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<sup>9</sup> Roth BL, Baner K, Westkaemper R, Siebert D, Rice KC, Steinberg S, Ernsberger P, Rothman RB. Salvinorin A: a potent naturally occurring nonnitrogenous kappa opioid selective agonist. *Proc Natl Acad Sci U S A*. 2002 Sep 3;99(18):11934-9.

<sup>10</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>11</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>12</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>13</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5 and Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>14</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>15</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>16</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five Salvia divinorum herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

<sup>17</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>18</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6 and González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

*S. divinorum* causes an unusually high degree of sedation, weakness and fatigue, and the increased de-realization is not commonly reported for classical psychedelics.<sup>19</sup> The combination of these effects seems to correlate with that of other KOR agonists such as pentazocine.<sup>20</sup>

The onset and intensity of the effects of *S. divinorum* appear to be related to the route of administration. Traditional uses generally produce mild effects because the leaves are rolled and chewed or crushed and prepared as a foamy infusion whereby the salvinorin A is degraded in the gastrointestinal system before being absorbed into the bloodstream. Hence, the level of effect relates quite closely to the length of time the material spends in the mouth, with the onset of effect generally taking 5-10 minutes. The effects build over the next hour and last for another hour before they begin to subside.<sup>21</sup>

Routes of administration that avoid the hepatic first-pass effect (i.e. inhalation, intravenous, intramuscular and sublingual use) provide the quickest and most intense effect.<sup>22</sup> Salvinorin A can be isolated from the plant to make a powder which can be vaporized and inhaled. The effects felt from vaporizing salvinorin A are experienced in about 30 seconds, last for about 5-10 minutes, and then subside over the next 30 minutes.<sup>23</sup>

Smoking the dried leaves or a concentrated extract using a pipe or bong is by far the most popular method of administration.<sup>24</sup> Dried leaves may also be fortified with a concentrated extract of salvinorin A. A concentrated extract can also be used sublingually. Neither *S. divinorum* nor salvinorin A can be injected because the powder is insoluble in water.<sup>25</sup>

#### **4.2.3 Legitimate Use of the Substance, including Therapeutic, Scientific, Industrial or Commercial Uses**

*S. divinorum* has traditionally been used for spiritual and medicinal purposes by the Mazatec

**Comment [S3]:** Have not changed title as suggested by JK because this wording is in accordance with the agreed upon CSS-WG factors for scheduling

<sup>19</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>20</sup> Arasteh K, Poudevida S, Farre M, Roset PN, Cami J. Response patterns of the Spanish version of the 49-item short form of the Addiction Research Center Inventory after the use of sedatives, stimulants, and opioids. *Drug Alcohol Depend.* 1999 Jun 1;55(1-2):117-25.

<sup>21</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>22</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.

<sup>23</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>24</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62 and Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>25</sup> Valdés LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (*divinorin*) A. *J Psychoactive Drugs.* 1994 Jul-Sep;26(3):277-83.

Indians in Oaxaca, Mexico.<sup>26</sup> For medicinal purposes (gastrointestinal problems, headaches, rheumatism, anemia and swelling of the stomach) an infusion of the leaves or the leaves themselves are ingested.<sup>27</sup> However, its main use in Mexico today is believed to be for its psychedelic properties in the aid of producing “mystical” or hallucinogenic experiences as part of spiritual rituals.<sup>28</sup>

Although selective KOR agonists have been shown to produce analgesic effects, adverse effects such as psychotomimesis, dysphoria and diuresis have been observed in studies investigating their therapeutic use.<sup>29</sup> In addition, while it has been speculated that KOR agonists may be useful in the treatment of certain psychiatric disorders including Alzheimer’s disease, schizophrenia, dementia and bipolar disorder, there has been no clinical research to support these hypotheses.<sup>30</sup> There are presently no recognized medical uses for *S. divinorum* in Canada.

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Similarly, there are no known industrial or commercial uses for *S. divinorum* in Canada. Most websites offering *S. divinorum* cuttings and seeds for sale appear to do so in the context of growing the plant for “recreational” purposes, rather than out of horticultural interest or for its esthetic appeal. However, it should be acknowledged that this does not preclude the possibility of a person growing this plant for purely decorative purposes. *S. divinorum* is also marketed as incense. However, there is no evidence that *S. divinorum* has any fragrant properties that would legitimize such a use. Therefore it is believed that the marketing of this plant as an incense is a means to avoid compliance and enforcement actions by Health Canada.

#### 4.2.4 Potential for Abuse and/or Addiction Liability

Salvinorin A is a potent, KOR-selective agonist and in contrast to the euphoria produced by MOR agonists such as morphine, KOR agonists are negatively reinforcing and aversive.<sup>31</sup> In addition, KOR agonists have analgesic properties, but are not associated with respiratory depression like MOR agonists.<sup>32</sup> Finally, while MOR agonists increase the release of dopamine,

<sup>26</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>27</sup> Munro, T. The Chemistry of Salvia divinorum. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

<sup>28</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage Salvia divinorum. *Life Sci.* 2005 Dec 22;78(5):527-31.

<sup>29</sup> Barker RL, Fawcett J, Barkin SJ. 2002. Chronic pain management with a focus on the role of newer antidepressants and centrally acting agents. In: *Pain Management: A Practical Guide for Clinicians*, 6th edition, Weiner RS ed. CRC Press, Boca Raton, FL. pp. 415-34 and Tidgewell et al., 2004. A facile method for the preparation of deuterium labelled salvinorin A: *Biorganic & Medicinal Chemistry Letters*, 14: 5099-5102.

<sup>30</sup> Sheffler DJ & Roth BL. Salvinorin A: the ‘magic mint’ hallucinogen finds a molecular target in the kappa opioid receptor. *Trends Pharmacol Sci.* 2003 Mar;24(3):107-109.

<sup>31</sup> Killinger BA, Peet MM, Baker LE. Salvinorin A fails to substitute for the discriminative stimulus effects of LSD or ketamine in Sprague-Dawley rats. *Pharmacology, Biochemistry & Behaviour.* 2010 May 96; 260-265.

<sup>32</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman’s The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.



the activation of KOR decreases dopamine release in the nucleus accumbens.<sup>33</sup> In the case of MOR agonists, the increase of dopamine acts as a positive reinforcer. This action motivates the user to use the drug again, which could lead to drug abuse and/or addiction. For KOR agonists, this is not the case.

The aversive effects of KOR agonists suggest that the risk of addiction to *S. divinorum* is negligible. Users have reported the negative effects of *S. divinorum* as: the short duration of action, lack of control over the experience, persisting negative effects (most often anxiety),<sup>34</sup> sweating, chills, increased diuresis, impaired vigilance,<sup>35</sup> and negative after-effects including tiredness, feeling head heavy, dizziness, physical exhaustion, and some degree of malaise or 'hangover' as they 'comedown' from the drug.<sup>36</sup> Despite these reports, very few controlled scientific studies of the physical and psychotropic effects of *S. divinorum* on humans have been carried out and the results have been conflicting. For example, one author states: "Many who have used salvinorin A find the experience extremely unnerving, frightening and overly intense and most have no desire to repeat the experience."<sup>37</sup> However, another study suggested that this is not the experience of all recreational users of *S. divinorum*.<sup>38</sup> Over eighty percent of users surveyed on a web-based questionnaire about their *S. divinorum* use said that they would probably or definitely use *S. divinorum* again.<sup>39</sup>

In addition, some users have noted that they require increasing doses of salvinorin A in order to achieve the desired effect and the stimulated cerebral KOR may act as a mechanism of tolerance.<sup>40</sup> Therefore, it is difficult to predict with certainty its potential for addiction and abuse.

In studies that have been conducted, there is conflicting information around the addiction liability of *S. divinorum* in both animals and humans. Further studies in this area and on the

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<sup>33</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.

<sup>34</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>35</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>36</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>37</sup> Turner DM. *Salvinorin - The Psychedelic Essence of Salvia Divinorum*. Panther Press, San Francisco, CA 1996.

<sup>38</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62, Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5, and Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs*. 1994 Jul-Sep;26(3):277-83.

<sup>39</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>40</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

KOR mediated decrease of dopamine are also required in order to fully understand the addiction potential of this substance.

While concerns for the potential of abuse were initially considered minimal given that 1 kg of dried leaves only yield 3 to 6 human doses of salvinorin A for oral consumption, it was then discovered that vaporizing and inhaling 200-500 micrograms has profound hallucinogenic effects.<sup>41</sup> Given that only small doses of this substance are now necessary to achieve the desired effects through inhalation, the potential for abuse is much higher. Also, the extraction of salvinorin A from the plant is simple, and with care, approximately 1.5 grams of pure salvinorin A per kilogram of dried leaves (8kg of fresh leaves) can be isolated. This is enough for 2000 oral doses.<sup>42</sup>

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#### 4.2.5 Evidence of Extent of Actual Abuse of the Substance in Canada and Internationally

In Canada, the prevalence of use of *S. divinorum* has recently been documented. Questions about the use of salvia were included in the 2009 Ontario Student Drug Use and Health Survey, the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey.\*

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The results from the 2009 Ontario Student Drug Use and Health Survey were published on November 18, 2009 and indicate that:

- Among all responding students in Ontario, 4.4% reported using *S. divinorum* at least once in the past year. In comparison, 58.2% indicated they had used alcohol, 25.6% indicated they had used cannabis and 5.0% indicated they had used hallucinogens other than LSD and PCP in the past year;
- Males (6.2%) were significantly more likely than females (2.3%) to report using *S. divinorum*;
- There is significant grade variation, with *S. divinorum* use most likely among 11<sup>th</sup> graders (8.6%) and 12<sup>th</sup> graders (8.4%); and

The results of the 2008-2009 Youth Smoking Survey were published on May 31, 2010 and indicate that:

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<sup>41</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>42</sup> Valdés LJ 3rd. Salvia divinorum and the unique diterpene hallucinogen, Salvinorin (divinorin) A. J Psychoactive Drugs. 1994 Jul-Sep;26(3):277-83.

\* It should be noted that in some cases it is not clear if responses indicate the use of *S. divinorum* or salvinorin A given the use of the term "salvia" within the survey question.

- 4.9% of students stated that they had used salvia in the last twelve months. In comparison, 53.0% indicated they had used alcohol, 27.3% indicated they had used cannabis and 6.9% indicated they had used other hallucinogens in the last twelve months;
- 2.6% of students in Grades 7-9 and 7.0% of students in Grades 10-12 had used salvia in the last twelve months; and
- Males (6.6%) were more likely to have used salvia in the past twelve months compared to females (3.2%).

The Canadian Alcohol and Drug Use Monitoring Survey specifically examined salvia for the first time in 2009. An estimated 1.6% of Canadians, aged 15 years and older, reported that they had used salvia in their lifetime, and 0.2% reported using it in the past-year. In comparison, the prevalence of past-year cannabis use among Canadians 15 years of age and older was 10.6%, while 1.2% of respondents reported using cocaine or crack in the past 12 months, 0.9% ecstasy and 0.7% illicit hallucinogens. In conclusion, 'salvia' appears to be a substance that is tried largely by youth with a 7.3% prevalence of lifetime use.

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According to the 2009 Monitoring the Future survey, the annual prevalence of use of *S. divinorum* among 12th graders in the United States is 5.7%. The American Substance Abuse and Mental Health Services Administration's 2006 National Survey on Drug Use and Health found that, of respondents aged 12 or older, 1.8 million had used *S. divinorum* at least once in their lifetime and 756,000 had used the substance in the past year. Among youth aged 12 to 17, males were more likely than females to have used *S. divinorum* in the past year (0.9% vs. 0.3%).

Health Canada's Drug Analysis Services (DAS) has identified salvinorin A in a number of samples seized by law enforcement, ranging from 9 samples in 2006 to 20 samples in 2009. It is, however, difficult to determine how this data reflects the extent of actual abuse of salvinorin A in Canada, given that it is not an illegal substance and would likely only be seized accidentally or during the seizure of other controlled substances.

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The National Forensic Laboratory Information System (NFLIS) and the System to Retrieve Information from Drug Evidence (STRIDE) in the United States are Drug Enforcement Administration (DEA) databases that collect scientifically verified data on analyzed samples in state and local forensic labs as well as samples from DEA labs. While in 2000 no seized samples were found to contain *S. divinorum* or salvinorin A, 70 samples tested positive in 2008. Once again, it is difficult to determine how this data can be used to reflect the actual extent of abuse of *S. divinorum* and salvinorin A in the United States as neither substance is listed in the *Controlled Substances Act*.

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The increase in both the number of enquiries to Health Canada from various municipalities and members of the public and the amount of media interest regarding the availability of *S. divinorum* in Canada may be an indication that the recreational use of *S. divinorum* as a hallucinogen is on the rise. However, it may also reflect an increased awareness of the phenomenon, rather than an increased incidence of use.

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#### 4.2.6 Risk to Personal and Public Health and Safety

The potential for harm to the user and/or other individuals is primarily related to the hallucinogenic properties of the substance. As this substance is typically smoked, there is no risk of infectious disease transmission as is the case when a drug is injected. Users may get up and walk around without apparent awareness of their movements, behaviour or surroundings, and distinction between self and surroundings is often lost. At doses greater than 1mg of salvinorin A, out of body experiences are frequent and loss of consciousness has been reported.<sup>43</sup> There is little information regarding the social behaviours of persons under the influence of *S. divinorum* products, and what risks their activities such as operating a motorized vehicle may pose to the general public. There is also very little data regarding the toxicity, teratogenicity or other long-term effects of *S. divinorum* use.<sup>44</sup>

As far as law enforcement is concerned, the Department has only received a limited number of communications indicating concern with respect to *S. divinorum*. The Royal Canadian Mounted Police (RCMP) has stated that while *S. divinorum* is readily available, it has not become a popular drug in Canada, probably due to its aversive effects such as anxiety and introversion.

A handful of case reports regarding physiological and psychotropic effects of *S. divinorum* use have been published in the scientific/medical literature. For example, an international case report described the perceptions of a 19 year-old man after inhaling *S. divinorum* smoke. The peak psychotropic effects, including prickling of the skin, fever-like hot flashes, muscular tremor, and depersonalization, were reached in less than five minutes after inhalation of an unknown amount of smoke from burning dried leaves.<sup>45</sup> Another report involved a 15-year-old male who presented to psychiatric emergency services with acute onset of paranoia, déjà vu, blunted affect, difficulties in thought processing and slowed speech after smoking *S. divinorum* over an unknown period of time. During his hospitalization all symptoms improved significantly except the feeling of déjà vu. Based on this case presentation, the author suggested that the feelings of déjà vu may be a long-term effect of *S. divinorum* use.<sup>46</sup> However, given that this is the only case report in which déjà vu was associated with the use of *S. divinorum*, more reports are needed to substantiate this finding.

In addition to the above-mentioned reports, in 2006, a case was reported in the U.S. in which a 17-year-old boy committed suicide after smoking *S. divinorum* for an unknown period of time.<sup>47</sup> It should be noted that alcohol and general depression were the main confounders in this case. After this case was reported, the state of Delaware passed a law which classified *S. divinorum* as a Schedule I controlled substance along with other hallucinogenic substances.

Like many drugs of abuse, users are often unaware of the potency and adulterants in the product they purchase. A study by Wolowich *et al.* (2006), showed that the salvinorin A content in five out of five *S. divinorum* products was falsely indicated on the label and 4 out of 5 products

<sup>43</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>44</sup> Grundmann O, Phipps SM, Zadezensky I, Butterweck V. *Salvia divinorum* and Salvinorin A: An Update on Pharmacology and Analytical Methodology. *Planta Med* 2007 Jun;73:1039-1046.

<sup>46</sup> Singh S. (2007) Adolescent salvia substance abuse. *Addiction.* 102, 823-824.

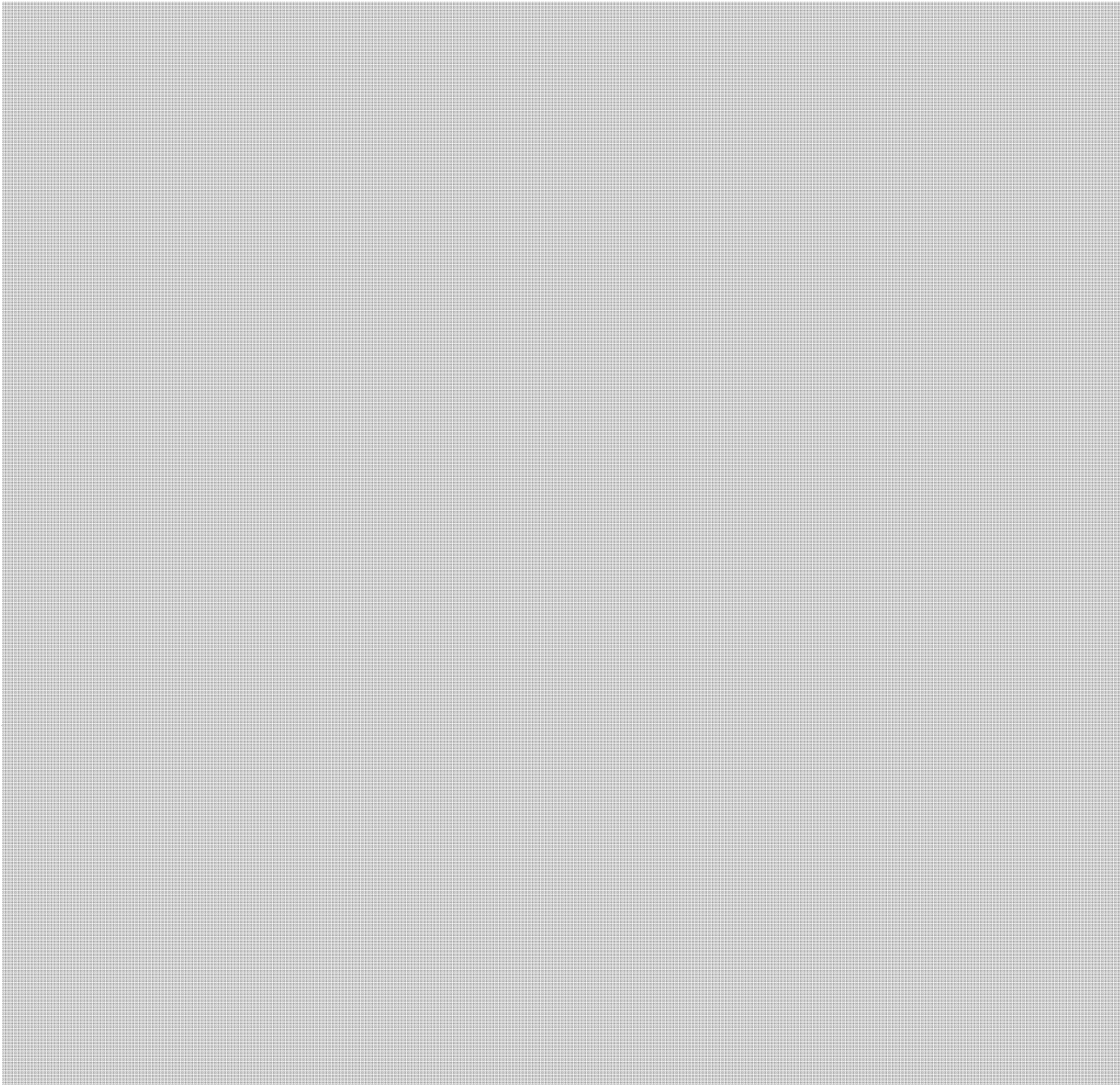
<sup>47</sup> <http://www.kvbc.com/Global/story.asp?S=4893692>

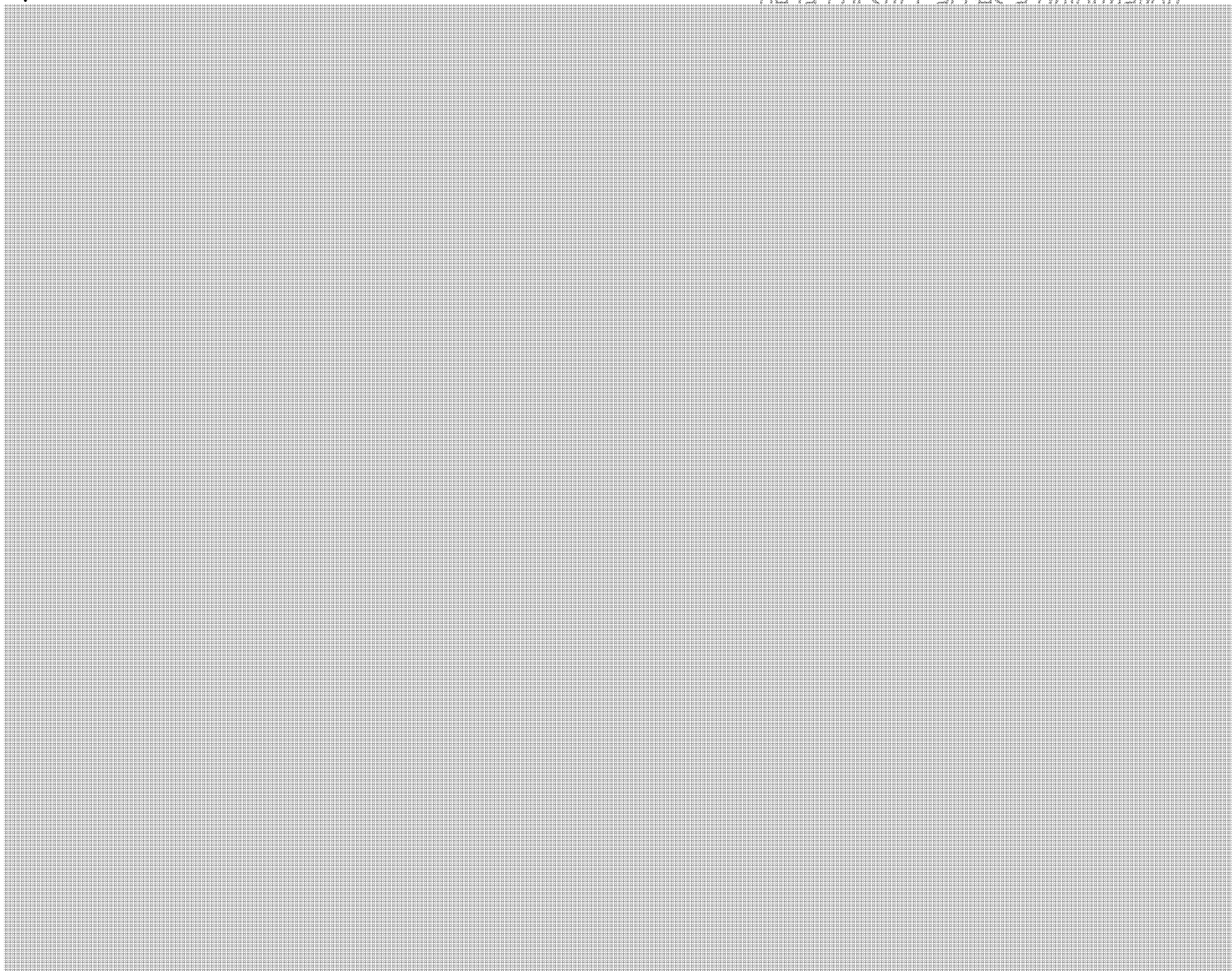
**s.21(1)(a)**

**s.21(1)(b)**

contained unidentified adulterants (i.e. vitamin E, caffeine).<sup>48</sup>

There are also several reports of domestic adverse reactions related to the use of *S. divinorum* that have been received through the Canada Vigilance database. However, this does not reflect true incidence due to under-reporting.





## 7. CONSIDERATIONS

The NHPR are limited in their capacity to control the availability of *S. divinorum* in that *S. divinorum* products are often declared as incense and therefore cannot be considered unapproved natural health products. In addition, compliance and enforcement actions such as voluntary stop-sales, forfeiture, destruction, and administrative seizure, cannot be implemented unless the marketing of the product indicates that it is to be sold for human consumption in order to modify an organic function. Unlicensed natural health products are also permitted to be imported provided they are for personal use only.

**s.21(1)(a)**  
**s.21(1)(b)**

Non-regulatory options for the control of *S. divinorum*, such as the development of an educational campaign to highlight the risks associated with using this plant, were also considered. However, the risks associated with this substance, as well as the confusion concerning its enforcement as a natural health product only when it is sold for use with a health claim, do not make this option viable.

*S. divinorum* meets the criteria for scheduling a substance under the CDSA. While neither the plant nor its main active component salvinorin A are scheduled under any of the UN Drug Control Conventions, a number of countries and American states have taken steps to control the distribution and use of these substances. *S. divinorum* and salvinorin A are pharmacologically similar to other substances included in Schedule III to the CDSA, such as LSD and psilocybin. There are also currently no legitimate therapeutic, commercial or industrial uses for *S. divinorum*.

s.21(1)(a)

s.21(1)(b)

While the addiction potential of *S. divinorum* appears to be low, there is a significant potential for its abuse as a 'legal' hallucinogen. There is very little information with regards to the long-term effects of *S. divinorum* use. There is also evidence of use, particularly by Canadian youth and potential for individual health risks as well as risks to public health and safety.

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In light of a recommendation to include *S. divinorum* under Schedule III to the CDSA, it is also recommended that the main psychoactive ingredient of this plant, salvinorin A, be scheduled. Salvinorin A can easily be extracted from *S. divinorum* and this substance gives the plant its hallucinogenic properties. Therefore the use of salvinorin A poses the same risks as *S. divinorum* and should also be controlled under the CDSA in the same manner as *S. divinorum*.

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## 8. RECOMMENDATIONS

## 9. CONSULTATIONS

The Drug Analysis Services (DAS) was contacted in order to provide any data available regarding the identification of salvinorin A in samples submitted by law enforcement.

The Royal Canadian Mounted Police (RCMP) was contacted in order to establish their views with respect to *S. divinorum* use in Canada. The RCMP advised that *S. divinorum* is readily available and law enforcement agencies have no legal means to prevent its sale.

OCS has received a number of correspondences from Canada Border Services Agency (CBSA) officers concerning a lack of information regarding the status of *S. divinorum* and how the plant should be treated at the border. CBSA officers have also expressed concern regarding the plant's hallucinogenic properties. At present, only shipments of *S. divinorum* that are represented for sale as health products that modify organic functions can be refused for import under the NHPR.

OCS brought *S. divinorum* to the Controlled Substances Scheduling Working Group (CSS-WG) in August 2010 to discuss the possibility of regulatory control of this substance. After assessing the available information against the six criteria listed in the Context section of this Issue Analysis Summary, the CSS-WG recommended that *S. divinorum* be included under Schedule III to the CDSA.

## 10. IMPLEMENTATION AND EVALUATION

**Page(s) 001701 to\à 001701**

**Is(Are) exempted pursuant to section(s)  
est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**



## **Salvia divinorum**

### **Issue**

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff, incense special, and salvia.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs. As of [REDACTED] 2010 Health Canada has not authorized for sale any products containing *S. divinorum*.

Health Canada recommends that you avoid using this plant because very little is known about the effects it may have on your body and/or brain functions. There is also no way to predict how it will affect you with each use.

### **Risks Associated with the Use of *Salvia divinorum***

*S. divinorum* is known to have both physical and mental effects. The effects of *S. divinorum*, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product
- how much is used
- the purity of the product (products that contain *S. divinorum* may be mixed with other substances)
- how it is taken, for example, whether the product is chewed, swallowed or smoked
- the user's mood and expectations

While scientists know which brain receptors are targeted by the active ingredient, salvinorin A, very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or if it can cause permanent damage
- how it interacts with other substances, including other drugs, natural health products and alcohol
- the potential of *S. divinorum* to produce physical dependence and/or addiction

### Minimizing Your Risk

Hallucinogens like *S. divinorum* work by modifying functions in the brain. Health Canada recommends that you avoid using *S. divinorum* because very little is known about the effects it may have on your body and/or brain functions. There is also no way to predict how it will affect you with each use. Just because a drug is plant-based or “natural”, does not mean that it is safe.

Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs, such as marijuana, cocaine, ecstasy, LSD and other substances that distort reality. See the “*Need More Info?*” section below for links to resources that can help you with this.

### Legal Status of *Salvia divinorum*

#### In Canada

Because of their hallucinogenic properties, products containing *S. divinorum* or salvinorin A meet the definition of a Natural Health Product (NHP) in accordance with the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*. It is illegal to sell drugs or NHPs in Canada, unless they have been reviewed and authorized for sale by Health Canada. In the case of NHPs, they need to be labelled with one of the following:

- a Natural Product Number (NPN); or
- an Exemption Number (EN); or
- a Drug Identification Number - Homeopathic Medicine Number (DIN-HM).

As of [REDACTED] 2010 no products containing *S. divinorum* or salvinorin A have been authorized by Health Canada for sale. The sale of unauthorized drugs and NHPs is illegal, and may be subject to compliance and enforcement actions by the Department.

Neither *S. divinorum* nor salvinorin A are currently regulated under the *Controlled Drugs and Substances Act* (CDSA). However, Health Canada has reviewed the available information regarding *S. divinorum*, and plans to issue a Notice of Intent to include *S. divinorum* and salvinorin A in one of the schedules to the CDSA. The purpose of this Notice will be to inform interested parties of Health Canada’s proposal to regulate these substances as controlled substances, as well as to allow the public to provide comments on the proposal.

#### In Other Countries

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Several countries including but not limited to Australia, Belgium, Germany, Italy, Japan, etc., have placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on their sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution. For example, in some states it is illegal for *S. divinorum* to be sold to anyone under the age of 18.

## Background

The leaves of this plant have been used traditionally by the Mazatec people for medicinal and mystical purposes.

Products that claim to contain *S. divinorum* or its main active ingredient, salvinorin A are widely available on the Internet and are sold in various "head shops" and natural food stores. The products are sold in a number of forms, including fresh or dried leaves, liquids or seeds and plant cuttings for growing purposes.

Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, less than 2% of Canadians age 15 and older reported having used *S. divinorum* at least once in their lifetime. Youth, ages 15-24 were much more likely to have used it than adults. The results from the *Canadian 2008-2009 Youth Smoking Survey* show that 5% of 15yr olds have used *S. divinorum* in the past year. For more information on these surveys, see the *Need More Info* section below.

## Health Canada's Role

Health Canada will continue to collect and consider safety information regarding *S. divinorum* and will continue to consult with key stakeholders including health officials in other countries and law enforcement officials here at home. Health Canada will also move forward with the regulation of *S. divinorum* and salvinorin A as controlled substances by issuing a Notice of Intent to schedule these substances under the CDSA. In the interim, Health Canada will continue to monitor the sale of unauthorized health products, including those that contain *S. divinorum* or its main active ingredient salvinorin A, and will take appropriate action when the department becomes aware of any unauthorized health products that may pose a risk to Canadians.

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## Need More Info?

- Complaints about the illegal sale of drugs containing *S. divinorum* can be made to the **Health Products and Food Branch Inspectorate** at: [http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_44\\_consumer\\_consommateur\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_44_consumer_consommateur_cp-pc-eng.php)  
Tel: 1-800-267-9675.

- You can report any adverse reactions to the Canada Vigilance Program by one of the following three ways:  
Report online at the MedEffect™ Canada website at: <http://www.hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>  
Call toll-free at 1-866-234-2345  
Complete a Canada Vigilance Reporting Form and either:  
Fax toll-free to 1-866-678-6789  
Mail to: Canada Vigilance Program  
Health Canada  
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To have postage pre-paid, download the postage paid label from the MedEffect™ Canada website. The Canada Vigilance Reporting Form and the adverse reaction reporting guidelines may also be obtained via this website at : [http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei\\_form-eng.php](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei_form-eng.php)
- For information about the Government of Canada's Anti-Drug Strategy, go to: [www.nationalantidrugstrategy.gc.ca/](http://www.nationalantidrugstrategy.gc.ca/)  
The Prevention section on this site has a number of helpful resources for parents, including:
  - **Tips on Talking to Your Teenager**, at: [www.hc-sc.gc.ca/hc-ps/pubs/adp-adp/talk-aborder/index-eng.php](http://www.hc-sc.gc.ca/hc-ps/pubs/adp-adp/talk-aborder/index-eng.php)
  - **What to Do if Your Teen is Using Drugs**, at: [www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html](http://www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html)
  - Health Canada's **Not4Me** youth drug prevention section at: <http://www.hc-sc.gc.ca/hc-ps/drugs-drogues/youth-jeunes/facts-faits/index-eng.php>
- Information on natural health products and the Natural Health Products Regulations can be found at: [www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php)

For more on the surveys that have collected information about *Salvia divinorum* use in Canada, see:

- **The 2008-2009 Youth Smoking Survey**, at: <http://www.yss.uwaterloo.ca/index.cfm?section=5&page=288>
- **The 2009 Canadian Alcohol and Drug Use Monitoring Survey**, at: <http://www.hc-sc.gc.ca/hc-ps/drugs-drogues/stat/index-eng.php>
- **The 2009 Ontario Student Drug Use and Health Survey**, at: [http://www.camh.net/News\\_events/News\\_releases\\_and\\_media\\_advisories\\_and\\_backgrounders/osduhs2009\\_advisory.html](http://www.camh.net/News_events/News_releases_and_media_advisories_and_backgrounders/osduhs2009_advisory.html)

Additional Resources:

- U.S. Drug Enforcement Administration: **Drugs and Chemicals of Concern: *Salvia divinorum* and Salvinorin A** at: [www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)

- U.S. Department of Health & Human Services, **National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006** at:  
[www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf](http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf)
- For additional articles on health and safety issues go to the **It's Your Health** web section at: [www.healthcanada.gc.ca/iyh](http://www.healthcanada.gc.ca/iyh)

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

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HPFBI : Collin Pinto  
HPFB comms: Elizabeth Keeping, Blossom Leung

DRAFT 14  
November 17, 2010

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### Media Lines *Salvia divinorum*

#### Issue

Since 2006, Health Canada has noted ongoing media interest regarding the availability of *Salvia divinorum* in Canada. Health Canada has also received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum*, particularly given reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada now intends to regulate *S. divinorum* as a controlled substance under the *Controlled Drugs and Substances Act* (CDSA).

#### Key Messages:

*Health Canada has determined the S. divinorum should be regulated as a controlled substance under...*

*this decision stems from the availability of*

Health Canada has studied the available information about *S. divinorum* and has analyzed the options available to manage the risks associated with the availability of this substance in Canada. Health Canada has determined that the risks associated with the use of *S. divinorum* warrant this substance's regulation as a controlled substance under the *Controlled Drugs and Substances Act* (CDSA).

- Health Canada has decided that a Notice of Intent to schedule *S. divinorum* and its main active ingredient, salvinorin A, under the *Controlled Drugs and Substances Act* (CDSA) will be issued. The purpose of this Notice will be to inform stakeholders and other interested parties of Health Canada's proposal to regulate these substances as controlled substances, as well as to allow the public to provide comments on the proposal.
- Health Canada intends to initiate the regulatory process in order to include *S. divinorum* and salvinorin A in one of the schedules to the CDSA in order to mitigate the risks associated with the use and availability of these substances.

#### Supplementary Messages:

- Canadians should not use products containing *S. divinorum* and/or salvinorin A because very little is known about the substance and its potential effects on the brain and/or body, and its impact on physical and mental functions.
- Because of their hallucinogenic properties, products containing *S. divinorum* and/or salvinorin A meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*.
- It is illegal to sell NHPs in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN). The

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<#>It is illegal to sell NHPs in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN). The illegal sale of products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*. ¶

<#>Health Canada will continue to collect and study information about *S. divinorum* as it becomes available, and to consult with law enforcement and health officials domestically and internationally in order to determine the best way to manage the risks associated with its availability in Canada. ¶

DRAFT 14  
November 17, 2010

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### Media Lines *Salvia divinorum*

#### Issue

Since 2006, Health Canada has noted ongoing media interest regarding the availability of *Salvia divinorum* in Canada. Health Canada has also received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum*, particularly given reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada now intends to regulate *S. divinorum* as a controlled substance under the *Controlled Drugs and Substances Act* (CDSA).

#### Key Messages:

- ~~Health Canada has studied the available information about *S. divinorum* and has analyzed the options available to manage the risks associated with the availability of this substance in Canada. Health Canada has determined that the risks associated with the use of *S. divinorum* warrant this substance's regulation as a controlled substance under the *Controlled Drugs and Substances Act* (CDSA).~~ *Health Canada following the receipt of*
- ~~Health Canada has decided that a Notice of Intent to schedule *S. divinorum* and its main active ingredient, salvinorin A, under the *Controlled Drugs and Substances Act* (CDSA) will be issued. The purpose of this Notice will be to inform stakeholders and other interested parties of Health Canada's proposal to regulate these substances as controlled substances, as well as to allow the public to provide comments on the proposal.~~ *with issue*
- ~~Health Canada intends to initiate the regulatory process in order to include *S. divinorum* and salvinorin A in one of the schedules to the CDSA in order to mitigate the risks associated with the use and availability of these substances.~~ *The publication of a Notice of Intent is the first step in*

#### Supplementary Messages:

- Canadians should not use products containing *S. divinorum* and/or salvinorin A because very little is known about the substance and its potential effects on the brain and/or body, and its impact on physical and mental functions.
- Because of their hallucinogenic properties, products containing *S. divinorum* and/or salvinorin A meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*.
- It is illegal to sell NHPs in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN). The

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<#>Health Canada will continue to collect and study information about *S. divinorum* as it becomes available, and to consult with law enforcement and health officials domestically and internationally in order to determine the best way to manage the risks associated with its availability in Canada. ¶

illegal sale of products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*.

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**Current status of *Salvia divinorum* as a controlled substance:**

- In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are currently regulated under the *Controlled Drugs and Substances Act* (CDSA).
- Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and thus, do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.
- Several countries (Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) have placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Although some individual U.S. states have implemented laws restricting its use, sale and/or distribution, *Salvia divinorum* and salvinorin A are not regulated under the federal *Controlled Substances Act* in the United States.

**Questions and Answers:**

**Q1 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why isn't it illegal?**

A1 – Because *S. divinorum* meets the definition of a Natural Health Product (NHP) under the *Natural Health Product Regulations*, it is illegal to manufacture, sell or provide products containing *S. divinorum* and/or salvinorin A without their being authorized by Health Canada prior to sale. Health Canada has reviewed the available information regarding *Salvia divinorum*, including the prevalence of its use in Canada, and plans to issue a Notice of Intent to include *S. divinorum* and salvinorin A in one of the schedules to the *Controlled Drugs and Substances Act* (CDSA). The purpose of this Notice will be to inform stakeholders and other interested parties of Health Canada's proposal to regulate these substances as controlled substances, as well as to allow the public to provide comments on the proposal.

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**Q2 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?**

A2 – The *Natural Health Products Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *Salvia divinorum*.

**Q3 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A3 – *Salvia divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada.



Complaints about the illegal sale of drugs containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

**Q4 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum* as a controlled substance. What does that involve and what stage is it at?**

A4 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada has reviewed the available information regarding *Salvia divinorum*, including the prevalence of its use in Canada, and plans to issue a Notice of Intent to include *S. divinorum* and salvinorin A in one of the schedules to the *Controlled Drugs and Substances Act* (CDSA). The purpose of this Notice will be to inform stakeholders and other interested parties of Health Canada's proposal to regulate these substances as controlled substances, as well as to allow the public to provide comments on the proposal.

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**Q5 – Didn't an internal report from Health Canada's Marketed Health Products Directorate recommend that *Salvia divinorum* be scheduled under the CDSA? Why has that recommendation not been acted upon?**

Deleted: Health Canada is currently reviewing the available information to determine whether regulation of *Salvia divinorum* under the CDSA is warranted.¶

A5 – See A4

**Q6 – What is the significance of the adverse reaction reports that Health Canada has received with respect to the use of *Salvia divinorum*?**

A6 – Health Canada has received four domestic adverse reaction reports related to the use of *Salvia divinorum* as a hallucinogen through the Canada Vigilance database. The number of reports and the nature of reactions reported are, however, not adequate to fully characterize the risk of similar reactions among the general population

***If pressed on whether Health Canada has issued any kind of warning to Canadians about *Salvia divinorum****

A - Health Canada is developing an It's Your Health (IYH) article on *Salvia divinorum* to help inform the general public about the risks associated with the use of this substance.

### **Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

Data from the 2008-2009 Youth Smoking Survey indicates that:

- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;
- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year; and
- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using Salvia in their lifetime (0.2% in the past year); and
- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that:

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;
- 5.4% of students (grades 7-12) ever used *S. divinorum*; and
- the use of *S. divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

**Prepared by:** Cheryl Tremblay and Denis Arsenault, OCS, CSTD

**Input by:** Lisa Mackay IYH/PACCB, Suzanne Desjardins HECSB/ODARS, Hanan Abramovici HECSB/ODARS, Bruna Brands HECSB/ODARS, Jocelyn Kula, HECSB/OCS, Robin Marles HPFB/NHPD, Maggie Graham HPFB/NHPD, Stephanie Collins HPFB/NHPD, Mano Murty HPFB/MHPD, Robert Leitch HPFB/MHPD, Shahid Perwaiz HPFB/MHPD, Collin Pinto, HPFB/HPFBI

**Approved by:**

Robin Marles, Director, Bureau of Clinical Trials, NHPD (pending)  
Lindsay Blaney, Director, Policy and Regulatory Affairs, NHPD (pending)  
Duc Vu, Director, Marketed Biologics, Biotechnology and Natural Health Products  
Bureau, MHPD (pending)  
Kim Dayman-Rutkas, Director, HPFBI (pending)  
Diane Allan, Director, OCS, CSTD, HECS (approved, Sept 29, 2010)

Deleted: pending

Suzanne Desjardins, Director, ODARS, CSTD, HECS approved, Sept 30, 2010

**Deleted:** (pending)

Cathy Sabiston, DG, CSTD, HECS (pending)

Chris Turner, DG, MHPD (pending)

Nancy Richards, DG, NHPD (pending)

Diana Dowthwaite, DG, HPFBI (pending)

Ken Polk, Communications Executive, HPFB (pending)

Jean Tessier, Senior Media Relations, PACCB (pending)

Warren Braun, Director, Strategic Communications, PACCB (pending)

Peter Yendall, Director, Public Affairs, PACCB (pending)

HECS Legal (pending)

HPFB Legal (pending)

Paul Glover, ADM, HECSB (pending)

Meena Ballantyne, ADM, HPFB (pending)

Anne Lamar, ADM, PACCB (pending)

DMO (pending)

MO (pending)

PCO (pending)



**Fw: Salvia products**

Stephanie Chandler to: Jocelyn Kula

2010-11-18 09:21 AM

Cc: Daniel Galarneau, Denis Arsenault, Patricia Rapold, CSTD-OCS-DO

Hi Jocelyn,

After discussing the last draft of the Salvia MLs and IYH with Patricia, I have updated the drafts so that there is consistency between the wording of different paragraph ("HC will issue a Notice of Intent").



IYH Salvia divinatorum\_v19 Nov 18\_SC.doc Salvia Media Lines\_Nov18\_SC.doc

My apologies for any inconvenience caused.

Regards,

Stephanie

----- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2010-11-18 09:15 AM -----

From: Stephanie Chandler/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC, Daniel Galarneau/HC-SC/GC/CA@HWC, CSTD-OCS-DO  
Date: 2010-11-17 03:33 PM  
Subject: Fw: Salvia products

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Hi Jocelyn,

Please see the attached Salvia MLs and IYH for your review. They have been reviewed by Daniel on behalf of Denis.

[attachment "Salvia Media Lines\_Nov17\_SC.doc" deleted by Stephanie Chandler/HC-SC/GC/CA]  
[attachment "IYH Salvia divinatorum\_v19 Nov 16\_SC.doc" deleted by Stephanie Chandler/HC-SC/GC/CA]

Thanks,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

----- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2010-11-17 03:23 PM -----

From: Denis Arsenault/HC-SC/GC/CA  
To: Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2010-11-15 03:14 PM  
Subject: Fw: Salvia products

---

Hi Stephanie,

For action.

Denis

---

Denis Arsenault, A/Manager / Gestionnaire p.i.  
Regulatory Policy Division /  
Division des politiques réglementaires,  
Office of Controlled Substances /  
Bureau des substances contrôlées,  
Health Canada / Santé Canada  
Tel/Tél: (613) 957-6828  
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E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca

----- Forwarded by Denis Arsenault/HC-SC/GC/CA on 2010-11-15 03:13 PM -----

From: Nicole Prentice/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC, Christine Roush/HC-SC/GC/CA@HWC, Paul  
Spendlove/HC-SC/GC/CA@HWC  
Date: 2010-11-15 02:47 PM  
Subject: Salvia products

---

Hi Jocelyn,

Below are the salvia media lines and IYH article. This is not urgent, but if possible can you revise these lines and the IYH article regarding the NOI and possible scheduling by the end of this week so we can move these products along? Cathy would like to get the lines going at the very least so we can limit the amount of media enquiries on salvia in her inbox.

On a side note, I sent these back to HPFB as well so they can correct the wording re: illegal vs. in contravention of etc...

If you have any issues or concerns, please let me know.

Thanks.

[attachment "Salvia Media Lines\_Sept30.doc" deleted by Stephanie Chandler/HC-SC/GC/CA]

[attachment "IYH Salvia divinorum\_v18 clean Oct 1.doc" deleted by Stephanie Chandler/HC-SC/GC/CA]

**Nicole Prentice**

Junior Communications Officer | Agente junior des Communications  
Regulatory Communications and Media Relations Division | Division des communications  
réglementaires et des relations avec les médias  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires  
publiques, de la consultation et des communications  
Health Canada | Santé Canada  
Tel: 613.941.3107  
Fax: 613.948.8085

DRAFT 14  
November 18, 2010

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Deleted: September 16

### Media Lines *Salvia divinorum*

#### Issue

Since 2006, Health Canada has noted ongoing media interest regarding the availability of *Salvia divinorum* in Canada. Health Canada has also received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum*, particularly given reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has now determined that *Salvia divinorum* should be included in one of the schedules to the *Controlled Drugs and Substances Act* (CDSA).

#### Key Messages:

- Health Canada has determined that *S. divinorum* should be regulated as a controlled substance under the *Controlled Drugs and Substances Act* (CDSA). The decision is based on the analysis of the information available about *S. divinorum* as well as an assessment of the possible options to manage the risks associated with the availability of this substance in Canada.
- Health Canada will issue a Notice of Intent to schedule *S. divinorum* and its main active ingredient, salvinorin A, under the *Controlled Drugs and Substances Act* (CDSA). This Notice will inform stakeholders and other interested parties of Health Canada's proposal to regulate these substances as controlled substances, as well as to allow the public to provide comments on the proposal.
- The publication of the Notice of Intent is the first step in the regulatory process to include *S. divinorum* and salvinorin A in one of the schedules to the CDSA in order to mitigate the risks associated with the use and availability of these substances.

#### Supplementary Messages:

- Canadians should not use products containing *S. divinorum* and/or salvinorin A because very little is known about the substance and its potential effects on the brain and/or body, and its impact on physical and mental functions.
- Because of their hallucinogenic properties, products containing *S. divinorum* and/or salvinorin A meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*.
- It is illegal to sell NHPs in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN).

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Deleted: <#>their hallucinogenic properties, products containing *S. divinorum* and/or salvinorin A meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*. ¶

<#>It is illegal to sell NHPs in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN). The illegal sale of products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*. ¶

<#>Health Canada will continue to collect and study information about *S. divinorum* as it becomes available, and to consult with law enforcement and health officials domestically and internationally in order to determine the best way to manage the risks associated with its availability in Canada. ¶

a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN). The illegal sale of products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*.

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**Current status of *Salvia divinorum* as a controlled substance:**

- In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are currently regulated under the *Controlled Drugs and Substances Act* (CDSA).
- Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and thus, do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.
- Several countries (Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) have placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Although some individual U.S. states have implemented laws restricting its use, sale and/or distribution, *Salvia divinorum* and salvinorin A are not regulated under the federal *Controlled Substances Act* in the United States.

**Questions and Answers:**

**Q1 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why isn't it illegal?**

A1 – Because *S. divinorum* meets the definition of a Natural Health Product (NHP) under the *Natural Health Product Regulations*, it is illegal to manufacture, sell or provide products containing *S. divinorum* and/or salvinorin A without their being authorized by Health Canada prior to sale. Health Canada has reviewed the available information regarding *Salvia divinorum*, including the prevalence of its use in Canada, and will issue a Notice of Intent to include *S. divinorum* and salvinorin A in one of the schedules to the *Controlled Drugs and Substances Act* (CDSA). The purpose of this Notice will be to inform stakeholders and other interested parties of Health Canada's proposal to regulate these substances as controlled substances, as well as to allow the public to provide comments on the proposal.

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**Q2 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?**

A2 – The *Natural Health Products Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *Salvia divinorum*.

**Q3 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A3 – *Salvia divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada.

Complaints about the illegal sale of drugs containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

**Q4 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum* as a controlled substance. What does that involve and what stage is it at?**

A4 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada has reviewed the available information regarding *Salvia divinorum*, including the prevalence of its use in Canada, and will issue a Notice of Intent to include *S. divinorum* and salvinorin A in one of the schedules to the *Controlled Drugs and Substances Act* (CDSA). The purpose of this Notice will be to inform stakeholders and other interested parties of Health Canada's proposal to regulate these substances as controlled substances, as well as to allow the public to provide comments on the proposal.

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**Q5 – Didn't an internal report from Health Canada's Marketed Health Products Directorate recommend that *Salvia divinorum* be scheduled under the CDSA? Why has that recommendation not been acted upon?**

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A5 – See A4

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A6 – Health Canada has received four domestic adverse reaction reports related to the use of *Salvia divinorum* as a hallucinogen through the Canada Vigilance database. The number of reports and the nature of reactions reported are, however, not adequate to fully characterize the risk of similar reactions among the general population

***If pressed on whether Health Canada has issued any kind of warning to Canadians about *Salvia divinorum****

A - Health Canada is developing an It's Your Health (IYH) article on *Salvia divinorum* to help inform the general public about the risks associated with the use of this substance.

**Background**



*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

Data from the 2008-2009 Youth Smoking Survey indicates that:

- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;
- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year; and.
- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using Salvia in their lifetime (0.2% in the past year); and
- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that:

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;
- 5.4% of students (grades 7-12) ever used *S. divinorum*; and
- the use of *S. divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

**Prepared by:** Cheryl Tremblay and Denis Arsenault, OCS, CSTD

**Input by:** Lisa Mackay IYH/PACCB, Suzanne Desjardins HECSB/ODARS, Hanan Abramovici HECSB/ODARS, Bruna Brands HECSB/ODARS, Jocelyn Kula, HECSB/OCS, Robin Marles HPFB/NHPD, Maggie Graham HPFB/NHPD, Stephanie Collins HPFB/NHPD, Mano Murty HPFB/MHPD, Robert Leitch HPFB/MHPD, Shahid Perwaiz HPFB/MHPD, Collin Pinto, HPFB/HPFBI

**Approved by:**

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Lindsay Blaney, Director, Policy and Regulatory Affairs, NHPD (pending)  
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Bureau, MHPD (pending)  
Kim Dayman-Rutkas, Director, HPFBI (pending)  
Diane Allan, Director, OCS, CSTD, HECS (approved, Sept 29, 2010)

Deleted: pending

Suzanne Desjardins, Director, ODARS, CSTD, HECS approved, Sept 30, 2010)

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Nancy Richards, DG, NHPD (pending)

Diana Dowthwaite, DG, HPFBI (pending)

Ken Polk, Communications Executive, HPFB (pending)

Jean Tessier, Senior Media Relations, PACCB (pending)

Warren Braun, Director, Strategic Communications, PACCB (pending)

Peter Yendall, Director, Public Affairs, PACCB (pending)

HECS Legal (pending)

HPFB Legal (pending)

Paul Glover, ADM, HECSB (pending)

Meena Ballantyne, ADM, HPFB (pending)

Anne Lamar, ADM, PACCB (pending)

DMO (pending)

MO (pending)

PCO (pending)

## **Salvia divinorum**

### **Issue**

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff, incense special, and salvia.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs. As of [REDACTED] 2010 Health Canada has not authorized for sale any products containing *S. divinorum*.

Health Canada recommends that you avoid using this plant because very little is known about the effects it may have on your body and/or brain functions. There is also no way to predict how it will affect you with each use.

### **Risks Associated with the Use of *Salvia divinorum***

*S. divinorum* is known to have both physical and mental effects. The effects of *S. divinorum*, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product
- how much is used
- the purity of the product (products that contain *S. divinorum* may be mixed with other substances)
- how it is taken, for example, whether the product is chewed, swallowed or smoked
- the user's mood and expectations

While scientists know which brain receptors are targeted by the active ingredient, salvinorin A, very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or if it can cause permanent damage
- how it interacts with other substances, including other drugs, natural health products and alcohol
- the potential of *S. divinorum* to produce physical dependence and/or addiction

### Minimizing Your Risk

Hallucinogens like *S. divinorum* work by modifying functions in the brain. Health Canada recommends that you avoid using *S. divinorum* because very little is known about the effects it may have on your body and/or brain functions. There is also no way to predict how it will affect you with each use. Just because a drug is plant-based or “natural”, does not mean that it is safe.

Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs, such as marijuana, cocaine, ecstasy, LSD and other substances that distort reality. See the “*Need More Info?*” section below for links to resources that can help you with this.

### Legal Status of *Salvia divinorum*

#### In Canada

Because of their hallucinogenic properties, products containing *S. divinorum* or salvinorin A meet the definition of a Natural Health Product (NHP) in accordance with the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*. It is illegal to sell drugs or NHPs in Canada, unless they have been reviewed and authorized for sale by Health Canada. In the case of NHPs, they need to be labelled with one of the following:

- a Natural Product Number (NPN); or
- an Exemption Number (EN); or
- a Drug Identification Number - Homeopathic Medicine Number (DIN-HM).

As of [REDACTED] 2010 no products containing *S. divinorum* or *salvinorin A* have been authorized by Health Canada for sale. The sale of unauthorized drugs and NHPs is illegal, and may be subject to compliance and enforcement actions by the Department.

Neither *S. divinorum* nor salvinorin A are currently regulated under the *Controlled Drugs and Substances Act* (CDSA). However, Health Canada has reviewed the available information regarding *S. divinorum*, and will issue a Notice of Intent to include *S. divinorum* and salvinorin A in one of the schedules to the CDSA. The purpose of this Notice will be to inform interested parties of Health Canada’s proposal to regulate these substances as controlled substances, as well as to allow the public to provide comments on the proposal.

#### In Other Countries

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Several countries including but not limited to Australia, Belgium, Germany, Italy, Japan, etc., have placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on their sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution. For example, in some states it is illegal for *S. divinorum* to be sold to anyone under the age of 18.

## Background

The leaves of this plant have been used traditionally by the Mazatec people for medicinal and mystical purposes.

Products that claim to contain *S. divinorum* or its main active ingredient, salvinorin A are widely available on the Internet and are sold in various "head shops" and natural food stores. The products are sold in a number of forms, including fresh or dried leaves, liquids or seeds and plant cuttings for growing purposes.

Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, less than 2% of Canadians age 15 and older reported having used *S. divinorum* at least once in their lifetime. Youth, ages 15-24 were much more likely to have used it than adults. The results from the *Canadian 2008-2009 Youth Smoking Survey* show that 5% of 15yr olds have used *S. divinorum* in the past year. For more information on these surveys, see the *Need More Info* section below.

## Health Canada's Role

Health Canada will continue to collect and consider safety information regarding *S. divinorum* and will continue to consult with key stakeholders including health officials in other countries and law enforcement officials here at home. Health Canada will also move forward with the regulation of *S. divinorum* and salvinorin A as controlled substances by issuing a Notice of Intent to schedule these substances under the CDSA. In the interim, Health Canada will continue to monitor the sale of unauthorized health products, including those that contain *S. divinorum* or its main active ingredient salvinorin A, and will take appropriate action when the department becomes aware of any unauthorized health products that may pose a risk to Canadians.

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## Need More Info?

- Complaints about the illegal sale of drugs containing *S. divinorum* can be made to the **Health Products and Food Branch Inspectorate** at: [http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_44\\_consumer\\_consommateur\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_44_consumer_consommateur_cp-pc-eng.php)  
Tel: 1-800-267-9675.

- You can report any adverse reactions to the Canada Vigilance Program by one of the following three ways:  
Report online at the MedEffect™ Canada website at: <http://www.hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>  
Call toll-free at 1-866-234-2345  
Complete a Canada Vigilance Reporting Form and either:  
Fax toll-free to 1-866-678-6789  
Mail to: Canada Vigilance Program  
Health Canada  
AL 0701C  
Ottawa, ON K1A 0K9  
To have postage pre-paid, download the postage paid label from the MedEffect™ Canada website. The Canada Vigilance Reporting Form and the adverse reaction reporting guidelines may also be obtained via this website at : [http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei\\_form-eng.php](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei_form-eng.php)
- For information about the Government of Canada's Anti-Drug Strategy, go to: [www.nationalantidrugstrategy.gc.ca/](http://www.nationalantidrugstrategy.gc.ca/)  
The Prevention section on this site has a number of helpful resources for parents, including:
  - **Tips on Talking to Your Teenager**, at: [www.hc-sc.gc.ca/hc-ps/pubs/adp-apd/talk-aborder/index-eng.php](http://www.hc-sc.gc.ca/hc-ps/pubs/adp-apd/talk-aborder/index-eng.php)
  - **What to Do if Your Teen is Using Drugs**, at: [www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html](http://www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html)
  - Health Canada's **Not4Me** youth drug prevention section at: <http://www.hc-sc.gc.ca/hc-ps/drugs-drogues/youth-jeunes/facts-faits/index-eng.php>
- Information on natural health products and the Natural Health Products Regulations can be found at: [www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php)

For more on the surveys that have collected information about *Salvia divinorum* use in Canada, see:

- **The 2008-2009 Youth Smoking Survey**, at: <http://www.yss.uwaterloo.ca/index.cfm?section=5&page=288>
- **The 2009 Canadian Alcohol and Drug Use Monitoring Survey**, at: <http://www.hc-sc.gc.ca/hc-ps/drugs-drogues/stat/index-eng.php>
- **The 2009 Ontario Student Drug Use and Health Survey**, at: [http://www.camh.net/News\\_events/News\\_releases\\_and\\_media\\_advisories\\_and\\_ackgrounders/osduhs2009\\_advisory.html](http://www.camh.net/News_events/News_releases_and_media_advisories_and_ackgrounders/osduhs2009_advisory.html)

Additional Resources:

- U.S. Drug Enforcement Administration: **Drugs and Chemicals of Concern: *Salvia divinorum* and *Salvinorin A*** at: [www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)

- U.S. Department of Health & Human Services, **National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006** at:  
[www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf](http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf)
- For additional articles on health and safety issues go to the **It's Your Health** web section at: [www.healthcanada.gc.ca/iyh](http://www.healthcanada.gc.ca/iyh)

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

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Comments from: HECSB - CSTD (OCS&ODARS) & HPFB – NHPD, MHPD & HPFBI

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HPFBI : Collin Pinto  
HPFB comms: Elizabeth Keeping, Blossom Leung

## Salvia divinorum

### Issue

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff, incense special, and salvia.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs. ~~As of December~~ 2010 Health Canada has not authorized for sale any products containing *S. divinorum*.

Grammar!

no need to be specific  
could say

"At present,  
...."

Health Canada recommends that you avoid using this plant because very little is known about the effects it may have on your body and/or brain functions. There is also no way to predict how it will affect you with each use.

### Risks Associated with the Use of *Salvia divinorum*

*S. divinorum* is known to have both physical and mental effects. The effects of *S. divinorum*, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product
- how much is used
- the purity of the product (products that contain *S. divinorum* may be mixed with other substances)
- how it is taken, for example, whether the product is chewed, swallowed or smoked
- the user's mood and expectations

While scientists know which brain receptors are targeted by the active ingredient, salvinorin A, very little is known about the following:



- how it affects the brain overall, including whether there are any long-term effects or if it can cause permanent damage
- how it interacts with other substances, including other drugs, natural health products and alcohol
- the potential of *S. divinorum* to produce physical dependence and/or addiction

### Minimizing Your Risk

Hallucinogens like *S. divinorum* work by modifying functions in the brain. Health Canada recommends that you avoid using *S. divinorum* because very little is known about the effects it may have on your body and/or brain functions. There is also no way to predict how it will affect you with each use. Just because a drug is plant-based or “natural”, does not mean that it is safe.

Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs, such as marijuana, cocaine, ecstasy, LSD and other substances that distort reality. See the “Need More Info?” section below for links to resources that can help you with this.

### Legal Status of *Salvia divinorum*

#### In Canada

Because of their hallucinogenic properties, products containing *S. divinorum* or salvinorin A meet the definition of a Natural Health Product (NHP) in accordance with the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*. It is illegal to sell drugs or NHPs in Canada, unless they have been reviewed and authorized for sale by Health Canada. In the case of NHPs, they need to be labelled with one of the following:

- a Natural Product Number (NPN); or
- an Exemption Number (EN); or
- a Drug Identification Number - Homeopathic Medicine Number (DIN-HM).

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At present,

~~As of DATE 2010 no products containing *S. divinorum* or salvinorin A have been authorized by Health Canada for sale. The sale of unauthorized drugs and NHPs is illegal, and may be subject to compliance and enforcement actions by the Department.~~

Grammar!

and has recently issued a

While

~~Neither *S. divinorum* nor salvinorin A are currently regulated under the *Controlled Drugs and Substances Act* (CDSA). However, Health Canada has reviewed the available information regarding *S. divinorum*, and will issue a Notice of Intent to include *S. divinorum* and salvinorin A in one of the schedules to the CDSA. The purpose of this Notice will be to inform interested parties of Health Canada's proposal to regulate these substances as controlled substances, as well as to allow the public to provide comments on the proposal.~~

as controlled

that it intends to

informing

under the CDSA.

#### In Other Countries

Deleted: Health Canada is currently considering the available information to determine whether regulation as a controlled substance is warranted.

and a salvinorin A (with circled A) its active ingredient

Several countries including but not limited to Australia, Belgium, Germany, Italy, Japan, etc., have placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on their sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution. For example, in some states it is illegal for *S. divinorum* to be sold to anyone under the age of 18.

### Background

The leaves of this plant have been used traditionally by the Mazatec people for medicinal and mystical purposes.

Products that claim to contain *S. divinorum* or its main active ingredient, salvinorin A are widely available on the Internet and are sold in various "head shops" and natural food stores. The products are sold in a number of forms, including fresh or dried leaves, liquids or seeds and plant cuttings for growing purposes.

Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, less than 2% of Canadians age 15 and older reported having used *S. divinorum* at least once in their lifetime. Youth, ages 15-24 were much more likely to have used it than adults. The results from the *Canadian 2008-2009 Youth Smoking Survey* show that 5% of 15yr olds have used *S. divinorum* in the past year. For more information on these surveys, see the *Need More Info* section below.

### Health Canada's Role

Health Canada will continue to collect and consider safety information regarding *S. divinorum* and will continue to consult with key stakeholders including health officials in other countries and law enforcement officials here at home. ~~Health Canada will move forward with the regulation of *S. divinorum* and salvinorin A as controlled substances by issuing a Notice of Intent to schedule these substances under the CDSA. In the interim, Health Canada will continue to monitor the sale of unauthorized health products, including those that contain *S. divinorum* or its main active ingredient salvinorin A, and will take appropriate action when the Department becomes aware of any unauthorized health products that may pose a risk to Canadians.~~

### Need More Info?

- Complaints about the illegal sale of drugs containing *S. divinorum* can be made to the **Health Products and Food Branch Inspectorate** at: [http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_44\\_consumer\\_consommateur\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_44_consumer_consommateur_cp-pc-eng.php)  
Tel: 1-800-267-9675.

development of a regulatory proposal seeking to add Salvia divinorin A to Schedule III of the CDSA

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In

will also continue to consult with health officials and law enforcement officials in Canada and in other countries

on countries

to and to the Schedule of Part J of the FDC

- You can report any adverse reactions to the Canada Vigilance Program by one of the following three ways:  
Report online at the MedEffect™ Canada website at: <http://www.hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>  
Call toll-free at 1-866-234-2345  
Complete a Canada Vigilance Reporting Form and either:  
Fax toll-free to 1-866-678-6789  
Mail to: Canada Vigilance Program  
Health Canada  
AL 0701C  
Ottawa, ON K1A 0K9  
To have postage pre-paid, download the postage paid label from the MedEffect™ Canada website. The Canada Vigilance Reporting Form and the adverse reaction reporting guidelines may also be obtained via this website at : [http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei\\_form-eng.php](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei_form-eng.php)
- For information about the Government of Canada's Anti-Drug Strategy, go to: [www.nationalantidrugstrategy.gc.ca/](http://www.nationalantidrugstrategy.gc.ca/)  
The Prevention section on this site has a number of helpful resources for parents, including:
  - **Tips on Talking to Your Teenager**, at: [www.hc-sc.gc.ca/hc-ps/pubs/adp-adpd/talk-aborder/index-eng.php](http://www.hc-sc.gc.ca/hc-ps/pubs/adp-adpd/talk-aborder/index-eng.php)
  - **What to Do if Your Teen is Using Drugs**, at: [www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html](http://www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html)
  - Health Canada's **Not4Me** youth drug prevention section at: <http://www.hc-sc.gc.ca/hc-ps/drugs-drogues/youth-jeunes/facts-faits/index-eng.php>
- Information on natural health products and the Natural Health Products Regulations can be found at: [www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php)

For more on the surveys that have collected information about *Salvia divinorum* use in Canada, see:

- **The 2008-2009 Youth Smoking Survey**, at: <http://www.yss.uwaterloo.ca/index.cfm?section=5&page=288>
- **The 2009 Canadian Alcohol and Drug Use Monitoring Survey**, at: <http://www.hc-sc.gc.ca/hc-ps/drugs-drogues/stat/index-eng.php>
- **The 2009 Ontario Student Drug Use and Health Survey**, at: [http://www.camh.net/News\\_events/News\\_releases\\_and\\_media\\_advisories\\_and\\_backgrounders/osduhs2009\\_advisory.html](http://www.camh.net/News_events/News_releases_and_media_advisories_and_backgrounders/osduhs2009_advisory.html)

**Additional Resources:**

- U.S. Drug Enforcement Administration: **Drugs and Chemicals of Concern: Salvia divinorum and Salvinorin A** at: [www.dea.diversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.dea.diversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)

← should we include a link to CDSA or laws site.

- U.S. Department of Health & Human Services, **National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006** at:  
[www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf](http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf)
- For additional articles on health and safety issues go to the *It's Your Health* web section at: [www.healthcanada.gc.ca/iyh](http://www.healthcanada.gc.ca/iyh)

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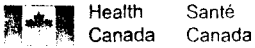
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HPFB comms: Elizabeth Keeping, Blossom Leung



HECS, CSTD, Office of Controlled Substances

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FOR SIGNATURE

Name / Nom	Date	Initial
Stephanie / Denis	Nov 26	

Remarks / Remarques

Needs a bit of a rewrite due to shift in approach, i.e.

Step 1: NOI + media lines to support  
Step 2: (when NOI posted) release of IYH

Ergo language in two docs has to be different.

Would suggest that next package focus on revised lines + draft NOI as two should move together

IYH can go later.

Happy to discuss  
JK

DRAFT 14  
November 18, 2010

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Media Lines  
Salvia divinorum

Issue

~~Since 2006, Health Canada has noted ongoing media interest regarding the availability of Salvia divinorum in Canada. Health Canada has also received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of Salvia divinorum, particularly given reports from scientific and media sources suggesting that Salvia divinorum is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has now determined that Salvia divinorum should be included in one of the Schedules to the Controlled Drugs and Substances Act (CDSA).~~

Further to

and Salvinorin A?

Key Messages:

- Health Canada has determined that *S. divinorum* should be regulated as a controlled substance under the *Controlled Drugs and Substances Act* (CDSA). The decision is based on the analysis of the information available about *S. divinorum* as well as an assessment of the possible options to manage the risks associated with the availability of this substance in Canada.
- Health Canada will issue a Notice of Intent to schedule *S. divinorum* and its main active ingredient, salvinorin A, under the *Controlled Drugs and Substances Act* (CDSA). This Notice will inform stakeholders and other interested parties of Health Canada's proposal to regulate these substances as controlled substances, as well as to allow the public to provide comments on the proposal.
- The publication of the Notice of Intent is the first step in the regulatory process to include *S. divinorum* and salvinorin A in one of the Schedules to the CDSA in order to mitigate the risks associated with the use and availability of these substances.

stating that it intends to add

to Schedule III to the CDSA

inclusion provide

and with the opp to comment on

Supplementary Messages:

- Canadians should not use products containing *S. divinorum* and/or salvinorin A because very little is known about the substance and its potential effects on the brain and/or body, and its impact on physical and mental functions.
- Because of their hallucinogenic properties, products containing *S. divinorum* and/or salvinorin A meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*.
- It is illegal to sell NHPs in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN).

Reorder as shown

might state

and propose self-identify for future consultations.

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<#>Because of

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Deleted: <#>their hallucinogenic properties, products containing *S. divinorum* and/or salvinorin A meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*. ¶

<#>It is illegal to sell NHPs in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN). The illegal sale of products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*. ¶

<#>Health Canada will continue to collect and study information about *S. divinorum* as it becomes available, and to consult with law enforcement and health officials domestically and internationally in order to determine the best way to manage the risks associated with its availability in Canada. ¶

a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN). The illegal sale of products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*.

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~~Current status of *Salvia divinorum* as a controlled substance:~~

- ~~In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are currently regulated under the *Controlled Drugs and Substances Act* (CDSA).~~
- Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and thus, do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.
- Several countries (Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) <sup>who have also</sup> have placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. ~~Although some individual U.S. states have implemented laws restricting its use, sale and/or distribution, *Salvia divinorum* and salvinorin A are not regulated under the federal *Controlled Substances Act* in the United States.~~

placement?

The markets include Salvin-D and Salvinorin A in Schedule III to the CDSA is consistent with actions taken by ...

Questions and Answers:

It is also consistent with the fact that

**Q1 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why isn't it illegal?**

A1 – Because *S. divinorum* meets the definition of a Natural Health Product (NHP) under the Natural Health Product Regulations, it is illegal to manufacture, sell or provide products containing *S. divinorum* and/or salvinorin A without their being authorized by Health Canada prior to sale. Health Canada has reviewed the available information regarding *Salvia divinorum*, including the prevalence of its use in Canada, and will issue a Notice of Intent to include *S. divinorum* and salvinorin A in one of the schedules to the Controlled Drugs and Substances Act (CDSA). The purpose of this Notice will be to inform stakeholders and other interested parties of Health Canada's proposal to regulate these substances as controlled substances, as well as to allow the public to provide comments on the proposal.

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does not really fit with Q

**Q2 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?**

A2 – The Natural Health Products Regulations apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *Salvia divinorum*. When Salvin-D and Sal A are included in Schedule III to the CDSA, it will be illegal to possess, import, export, distribute etc them in any form.

**Q3 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A3 – ~~*Salvia divinorum* products that are not in compliance with the Natural Health Products Regulations may be subject to compliance and enforcement action by Health Canada.~~

needs to be post scheduling 1st

When Salvin D and Sal A are included in Schedule III to the CDSA, law enforcement will be able to take appropriate action in response to suspected illegal activity. In the interim,

Complaints about the illegal sale of drugs containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

**Q4 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum* as a controlled substance. What does that involve and what stage is it at?**

A4 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

*recently concluded its assessment of Salv D and Salvia A against the above mentioned factors and has decided*

~~Health Canada has reviewed the available information regarding *Salvia divinorum*, including the prevalence of its use in Canada, and will issue a Notice of Intent to include *S. divinorum* and salvinorin A in one of the schedules to the *Controlled Drugs and Substances Act* (CDSA). The purpose of this Notice will be to inform stakeholders and other interested parties of Health Canada's proposal to regulate these substances as controlled substances, as well as to allow the public to provide comments on the proposal.~~

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*intends to include both substances in Sched III to the*

**Q5 – Didn't an internal report from Health Canada's Marketed Health Products Directorate recommend that *Salvia divinorum* be scheduled under the CDSA? Why has that recommendation not been acted upon?**

A5 – See A4

*remove no longer relevant CDSA*

**Deleted:** Health Canada is currently reviewing the available information to determine whether regulation of *Salvia divinorum* under the CDSA is warranted.¶

**Q6 – What is the significance of the adverse reaction reports that Health Canada has received with respect to the use of *Salvia divinorum*?**

A6 – Health Canada has received four domestic adverse reaction reports related to the use of *Salvia divinorum* as a hallucinogen through the Canada Vigilance database. The number of reports and the nature of reactions reported are, however, not adequate to fully characterize the risk of similar reactions among the general population

***If pressed on whether Health Canada has issued any kind of warning to Canadians about *Salvia divinorum****

A - Health Canada is developing an It's Your Health (IYH) article on *Salvia divinorum* to help inform the general public about the risks associated with the use of this substance.

**Background**



*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

Data from the 2008-2009 Youth Smoking Survey indicates that:

- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;
- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year; and
- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using Salvia in their lifetime (0.2% in the past year); and
- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that:

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;
- 5.4% of students (grades 7-12) ever used *S. divinorum*; and
- the use of *S. divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

*Stephanie Chandler*

**Prepared by:** ~~Cheryl Tremblay~~ and Denis Arsenault, OCS, CSTD

**Input by:** Lisa Mackay IYH/PACCB, Suzanne Desjardins HECSB/ODARS, Hanan Abramovici HECSB/ODARS, Bruna Brands HECSB/ODARS, Jocelyn Kula, HECSB/OCS, Robin Marles HPFB/NHPD, Maggie Graham HPFB/NHPD, Stephanie Collins HPFB/NHPD, Mano Murty HPFB/MHPD, Robert Leitch HPFB/MHPD, Shahid Perwaiz HPFB/MHPD, Collin Pinto, HPFB/HPFBI

**Approved by:**

Robin Marles, Director, Bureau of Clinical Trials, NHPD (pending)  
Lindsay Blaney, Director, Policy and Regulatory Affairs, NHPD (pending)  
Duc Vu, Director, Marketed Biologics, Biotechnology and Natural Health Products  
Bureau, MHPD (pending)  
Kim Dayman-Rutkas, Director, HPFBI (pending)  
Diane Allan, Director, OCS, CSTD, HECS (approved, Sept 29, 2010)

Deleted: pending

Suzanne Desjardins, Director, ODARS, CSTD, HECS approved, Sept 30, 2010)

Deleted: (pending)

Cathy Sabiston, DG, CSTD, HECS (pending)

Chris Turner, DG, MHPD (pending)

Nancy Richards, DG, NHPD (pending)

Diana Dowthwaite, DG, HPFBI (pending)

Ken Polk, Communications Executive, HPFB (pending)

Jean Tessier, Senior Media Relations, PACCB (pending)

Warren Braun, Director, Strategic Communications, PACCB (pending)

Peter Yendall, Director, Public Affairs, PACCB (pending)

HECS Legal (pending)

HPFB Legal (pending)

Paul Glover, ADM, HECSB (pending)

Meena Ballantyne, ADM, HPFB (pending)

Anne Lamar, ADM, PACCB (pending)

DMO (pending)

MO (pending)

PCO (pending)

DRAFT

DEPARTMENT OF HEALTH

CONTROLLED DRUGS AND SUBSTANCES ACT

*Notice to interested parties - Proposal regarding the addition of substances to the schedules to the Controlled Drugs and Substances Act*

This notice provides interested stakeholders with the opportunity to provide preliminary comments on Health Canada's proposal to add the plant *Salvia divinorum* (*S. divinorum*) and its active ingredient salvinorin A to the schedules to the *Controlled Drugs and Substances Act* (CDSA), and to identify themselves for inclusion in any future consultation.

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are <sup>usually</sup> chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant. Neither *S. divinorum* nor salvinorin A are currently included in any of the schedules to the *Controlled Drugs and Substances Act*.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs. However, neither of these substances have been approved as natural health products under the *Natural Health Products Regulations*. It is illegal to sell drugs or natural health products in Canada, unless they have been reviewed and authorized for sale by Health Canada. (Health Canada has also noticed an increase in public interest and media attention surrounding these substances.)

*S. divinorum* and salvinorin A are pharmacologically similar to other substances included in schedules to the CDSA, such as LSD and psilocybin. Very little is known about the long-term effects of the use of *S. divinorum* and salvinorin A. There is also evidence of abuse of these substances, particularly by Canadian youth. Health Canada is thus concerned that these substances pose a risk to the health and safety of Canadians and is therefore considering regulating them as controlled substances.

Although these substances are not currently included in any of the United Nations Drug Control Conventions, a number of countries have chosen to regulate one or both of these substances as controlled substances. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden have all placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. Although some individual American states have implemented laws restricting its use, sale and/or distribution, *S. divinorum* and salvinorin A are not regulated under the federal *Controlled Substances Act* in the United States.

Placing these substances within the scope of the CDSA may prohibit any or all of the following activities with these substances unless authorized by regulation: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production ~~or~~ (cultivation).

As this action is not intended to interfere with the use and availability of *S. divinorum* and/or salvinorin A for a legitimate medical or industrial purpose, Health Canada is seeking information from stakeholders on whether there are any legitimate industrial or medical uses for these aforementioned substances in Canada. Information received in response to this notice will be instrumental in determining appropriate scheduling under the CDSA.

The publication of this notice begins a 30-day comment period. There will be additional opportunities to provide comments following prepublication of a proposed regulatory amendment in *Canada Gazette*, Part I. This is expected to take place in 2011.

If you are interested in this process or have comments on this proposal, please contact Stephanie Chandler, Regulatory Policy Division, Office of Controlled Substances, Address Locator: 3503D, 123 Slater St., Ottawa, Ontario, Canada, K1A 1B9, by fax at (613) 946-4224 or by email at [OCS\\_Policy\\_and\\_Regulatory\\_Affairs@hc-sc.gc.ca](mailto:OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca).

Cathy Sabiston  
Director General  
Controlled Substances and Tobacco Directorate

Date \_\_\_\_\_

DRAFT V.1

DEPARTMENT OF HEALTH

CONTROLLED DRUGS AND SUBSTANCES ACT

Notice to interested parties - Proposal regarding the addition of <sup>Salvia divinorum & Salvinorin A</sup> substances to the schedules to the Controlled Drugs and Substances Act

This notice provides interested stakeholders with the opportunity to provide preliminary comments on Health Canada's proposal to add the plant *Salvia divinorum* (*S. divinorum*) and its active ingredient salvinorin A to the schedules to the *Controlled Drugs and Substances Act* (CDSA), and to identify themselves for inclusion in any future consultation.

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are generally chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant. Neither *S. divinorum* nor salvinorin A are currently included in any of the schedules to the CDSA.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs. However, neither of these substances have been approved as natural health products under the *Natural Health Products Regulations*. It is illegal to sell drugs or natural health products in Canada, unless they have been reviewed and authorized for sale by Health Canada. Health Canada has also noticed an increase in public interest and media attention surrounding these substances.

*S. divinorum* and salvinorin A are pharmacologically similar to other substances included in schedules to the CDSA, such as LSD and psilocybin. Very little is known about the long-term effects of the use of *S. divinorum* and salvinorin A. There is also evidence of abuse of these substances, particularly by Canadian youth. Health Canada is thus concerned that these substances pose a risk to the health and safety of Canadians and is therefore considering regulating them as controlled substances.

Although these substances are not currently included in any of the United Nations Drug Control Conventions, a number of countries have chosen to regulate one or both of these substances as controlled substances. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden have all placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. Although some individual American states have implemented laws restricting its use, sale and/or distribution, *S. divinorum* and salvinorin A are not regulated under the federal *Controlled Substances Act* in the United States.

Placing these substances within the scope of the CDSA may prohibit any or all of the following activities with these substances unless authorized by regulation: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of

exportation, and production (or cultivation).

As this action is not intended to interfere with the use and availability of *S. divinorum* and/or salvinorin A for a legitimate medical or industrial purpose, Health Canada is seeking information from stakeholders on whether there are any legitimate industrial or medical uses for these aforementioned substances in Canada. Information received in response to this notice will be instrumental in determining appropriate scheduling under the CDSA.

The publication of this notice begins a 30-day comment period. There will be additional opportunities to provide comments following prepublication of a proposed regulatory amendment in *Canada Gazette*, Part I. This is expected to take place in 2011.

If you are interested in this process or have comments on this proposal, please contact Stephanie Chandler, Regulatory Policy Division, Office of Controlled Substances, Address Locator: 3503D, 123 Slater St., Ottawa, Ontario, Canada, K1A 1B9, by fax at (613) 946-4224 or by email at [OCS\\_Policy\\_and\\_Regulatory\\_Affairs@hc-sc.gc.ca](mailto:OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca).

Cathy A. Sabiston  
Director General  
Controlled Substances and Tobacco Directorate

Date \_\_\_\_\_

Hello Stephanie,

DEPARTMENT OF HEALTH  
CONTROLLED DRUGS AND SUBSTANCE

Notice to interested parties - Proposal regarding A to the schedules to the Controlled Drugs and

This notice provides interested stakeholders with comments on Health Canada's proposal to add active ingredient salvinorin A to the schedules (CDSA), and to identify themselves for inclusion

*Salvia divinorum* is a species of sage belonging to the mint family. It is often chewed or smoked to obtain psychotropic effects which include hallucinations, dysphoria, out-of-body experiences, and memory loss. The effects, which vary from person to person, can be unpleasant. Neither *S. divinorum* nor salvinorin A are currently listed in the CDSA.

- publish on website.

The list of stakeholders is basically derived from best guess/estimate for this NOI. For instance, NHP shops, plant/flower shops, plant breeders?, etc. The NOI also serves to have stakeholders come up and identify themselves.

I think the NOI is self explanatory at this point. It will simply be a matter of getting approval from Jocelyn.

read catalogues. Hope this helps.

we can discuss

Daniel

Hi Daniel,

Here is the draft NOI for Salvia (though it should be noted that Jocelyn has not approved the IAS yet).

I'm also wondering how to go about creating a list of stakeholders to contact regarding the NOI. Elizabeth has one for BZP, but a lot of the contacts would not be applicable for Salvia. Can we discuss?

Thanks,  
Stephanie

Health Canada has also noticed an increase in public substances.

Salvia is very similar to other substances included in the bin. Very little is known about the long-term effects of salvinorin A. There is also evidence of abuse of these substances. Health Canada is thus concerned that these substances are being used by Canadians and is therefore considering

Salvia is included in any of the United Nations Drug Control Conventions. It is proposed to regulate one or both of these substances as controlled substances. Finland, Germany, Italy, Japan, South Korea, and the United States are on the import and/or sale of *S. divinorum*. Some American states have implemented laws regulating *S. divinorum* and salvinorin A are not regulated under the Controlled Substances Act in the United States.

The CDSA may prohibit any or all of the following activities by regulation: possession, trafficking, importation, exportation, possession for the purpose of

**DRAFT V.1**

DEPARTMENT OF HEALTH

CONTROLLED DRUGS AND SUBSTANCES ACT

*Notice to interested parties - Proposal regarding the addition of Salvia divinorum and salvinorin A to the schedules to the Controlled Drugs and Substances Act*

This notice provides interested stakeholders with the opportunity to provide preliminary comments on Health Canada's proposal to add the plant *Salvia divinorum* (*S. divinorum*) and its active ingredient salvinorin A to the schedules to the *Controlled Drugs and Substances Act* (CDSA), and to identify themselves for inclusion in any future consultation.

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are generally chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant. Neither *S. divinorum* nor salvinorin A are currently included in any of the schedules to the CDSA.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs. However, neither of these substances have been approved as natural health products under the *Natural Health Products Regulations*. It is illegal to sell drugs or natural health products in Canada, unless they have been reviewed and authorized for sale by Health Canada. Health Canada has also noticed an increase in public interest and media attention surrounding these substances.

*S. divinorum* and salvinorin A are pharmacologically similar to other substances included in schedules to the CDSA, such as LSD and psilocybin. Very little is known about the long-term effects of the use of *S. divinorum* and salvinorin A. There is also evidence of abuse of these substances, particularly by Canadian youth. Health Canada is thus concerned that these substances pose a risk to the health and safety of Canadians and is therefore considering regulating them as controlled substances.

Although these substances are not currently included in any of the United Nations Drug Control Conventions, a number of countries have chosen to regulate one or both of these substances as controlled substances. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden have all placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. Although some individual American states have implemented laws restricting its use, sale and/or distribution, *S. divinorum* and salvinorin A are not regulated under the federal *Controlled Substances Act* in the United States.

Placing these substances within the scope of the CDSA may prohibit any or all of the following activities with these substances unless authorized by regulation: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of



exportation, and production (or cultivation).

As this action is not intended to interfere with the use and availability of *S. divinorum* and/or salvinorin A for a legitimate medical or industrial purpose, Health Canada is seeking information from stakeholders on whether there are any legitimate industrial or medical uses for these aforementioned substances in Canada. Information received in response to this notice will be instrumental in determining appropriate scheduling under the CDSA.

The publication of this notice begins a 30-day comment period. There will be additional opportunities to provide comments following republication of a proposed regulatory amendment in *Canada Gazette*, Part I. This is expected to take place in 2011.

If you are interested in this process or have comments on this proposal, please contact Stephanie Chandler, Regulatory Policy Division, Office of Controlled Substances, Address Locator: 3503D, 123 Slater St., Ottawa, Ontario, Canada, K1A 1B9, by fax at (613) 946-4224 or by email at [OCS\\_Policy\\_and\\_Regulatory\\_Affairs@hc-sc.gc.ca](mailto:OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca).

Cathy A. Sabiston  
Director General  
Controlled Substances and Tobacco Directorate

Date \_\_\_\_\_

DRAFT V.1

DEPARTMENT OF HEALTH

CONTROLLED DRUGS AND SUBSTANCES ACT

Notice to interested parties - Proposed A to the schedules to the Controlled Substances Act  
Schedule III

This notice provides interested stakeholders with an opportunity to provide comments on Health Canada's proposed active ingredient salvinorin A to the CDSA, and to identify themselves.

*Salvia divinorum* is a species of sage that is often chewed or smoked to obtain psychotropic effects. These effects include hallucinations, dysphoria, outbursts of anger, and memory loss. The effects, which vary in intensity, are often unpleasant. Neither *S. divinorum* nor salvinorin A are listed in the CDSA.

Recently there have been reports suggesting that *Salvia divinorum* is being used for its ability to produce hallucinations. *S. divinorum* has been approved as a "legal" alternative to marijuana. It has been approved as a natural health product. It is illegal to sell drugs or natural health products that are not authorized for sale by Health Canada. Health Canada is currently receiving interest and media attention surrounding *S. divinorum*.

*S. divinorum* and salvinorin A are pharmacologically active substances listed in the schedules to the CDSA, such as LSD and marijuana. The effects of the use of *S. divinorum* and salvinorin A are similar to those of other controlled substances, particularly by Canadian youth. The use of these substances pose a risk to the health and safety of Canadians. Health Canada is currently regulating them as controlled substances.

Although these substances are not currently included in any of the United Nations Drug Control Conventions, a number of countries have chosen to regulate one or both of these substances as controlled substances. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden have all placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. Although some individual American states have implemented laws restricting its use, sale and/or distribution, *S. divinorum* and salvinorin A are not regulated under the federal *Controlled Substances Act* in the United States.

Placing these substances within the scope of the CDSA may prohibit any or all of the following activities with these substances unless authorized by regulation: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of

NOI PROCESS  
-> approvals & timelines  
- approved up to level of scheduling  
-> DG  
- DG decides if it's an ADM issue. (maybe)  
- in MFCS -> check for BZP  
-> DG  
- doctor's, nurses  
- hospitals? Safe Environments (SEEP)

Step  
in  
militarize  
-> divinorum  
-> salvinorin A?  
necessary?

exportation, and production (or cultivation).

As this action is not intended to interfere with the use and availability of *S. divinorum* and/or salvinorin A for a legitimate medical or industrial purpose, Health Canada is seeking information from stakeholders on whether there are any legitimate industrial or medical uses for these aforementioned substances in Canada. Information received in response to this notice will be instrumental in determining appropriate scheduling under the CDSA. ~~It is expected to take place in 2011.~~ *scrutinise*

The publication of this notice begins a 30-day comment period. There will be additional opportunities to provide comments following prepublication of a proposed regulatory amendment in *Canada Gazette*, Part I. ~~This is expected to take place in 2011.~~ *necessaire?*

If you are interested in this process or have comments on this proposal, please contact Stephanie Chandler, Regulatory Policy Division, Office of Controlled Substances, Address Locator: 3503D, 123 Slater St., Ottawa, Ontario, Canada, K1A 1B9, by fax at (613) 946-4224 or by email at [OCS\\_Policy\\_and\\_Regulatory\\_Affairs@hc-sc.gc.ca](mailto:OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca).

Cathy A. Sabiston  
Director General  
Controlled Substances and Tobacco Directorate

Date \_\_\_\_\_



Re: PCO request - response DUE 10am on Tues. Nov 23 - citizen engagement/consultation 

Angela Doyle to: Stephanie Chandler  
Cc: Daniel Galarneau

2010-11-22 03:06 PM

Thank you Stephanie,  
Angela

Stephanie Chandler Hi Angela, As requested, please see below.

2010-11-22 02:56:02 PM

From: Stephanie Chandler/HC-SC/GC/CA  
To: Angela Doyle/HC-SC/GC/CA@HWC  
Cc: Daniel Galarneau/HC-SC/GC/CA@HWC  
Date: 2010-11-22 02:56 PM  
Subject: Re: PCO request - response DUE 10am on Tues. Nov 23 - citizen engagement/consultation

Hi Angela,

As requested, please see below.

Stephanie

-----  
- Branch/DG:  
HECSB

- Title/Titre:  
Notice of Intent to Schedule *Salvia divinorum* and salvinorin A under the *Controlled Drugs and Substances Act*

- Purpose and Outcome / Objectif et résultat & Hyperlink/Hyperlien  
When published in Canada Gazette, the Notice of Intent will inform stakeholders and other interested parties of Health Canada's proposal to regulate *Salvia divinorum* and salvinorin A as controlled substances. It will also allow the public to provide comments on the proposal. These comments will be considered when determining the appropriate scheduling of these substances.

- Timeframe / Échéance  
Estimated time frame for publication in Canada Gazette is Winter 2011

- Type of Stakeholders / Type d'intervenants  
Potential stakeholders include law enforcement agencies, medical practitioners and naturopathic practitioners, sellers and importers of *Salvia divinorum* (to be identified by HPFB and HPFBI), and other interested parties within the general public

- Lead Contact / Contact principal:  
Stephanie Chandler, 613-946-0124

Angela Doyle Good morning all: We received a request from P...

2010-11-22 11:36:41 AM

From: Angela Doyle/HC-SC/GC/CA  
To: Amal Helal/HC-SC/GC/CA@HWC, Daniel Galarneau/HC-SC/GC/CA@HWC, Hong Zhang/HC-SC/GC/CA@HWC, Nathan J Isotalo/HC-SC/GC/CA@HWC, Richard J Robert/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC, Tiana Branch/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC  
Cc: Catherine McNicol/HC-SC/GC/CA@HWC, Isabel Shanahan/HC-SC/GC/CA@HWC, Salha Jumba/HC-SC/GC/CA@HWC  
Date: 2010-11-22 11:36 AM  
Subject: PCO request - response DUE 10am on Tues. Nov 23 - citizen engagement/consultation

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Good morning all:

We received a request from PCO, for which I am coordinating the preparation of a response for PRAD. Please provide your response to this e-mail by **10:00AM Tuesday, November 23**.

**Request:** For each of your projects that have/will require citizen engagement and/or consultation activities from **November 4, 2010 onward**, please complete and e-mail me the following information:

- Branch/DG (assumed HECSB)
- Title/Titre
- Purpose and Outcome / Objectif et résultat & Hyperlink/Hyperlien
- Timeframe / Échéance
- Type of Stakeholders / Type d'intervenants
- Lead Contact / Contact principal

Only projects led by HECSB should be included, i.e., if you are involved in a project led by another Branch, you should not include the details of that project.

Also, the PCO definitions of citizen engagement and consultation are enclosed for your reference.

[attachment "Q-555-instructions.pdf" deleted by Stephanie Chandler/HC-SC/GC/CA]

**Citizen engagement activities** include in-person events & values-based dialogues with individual citizens early on in policy/program development.

**Citizen consultation activities** include online &/or in-person or targeted emails to individual citizens and/or stakeholder groups & organizations.

- Do NOT include Canada Gazette Part I consultations.
- Do NOT include advisory bodies-- Someone else is adding this information

Thank you and please let me know if you have questions and I will try to have them addressed.

Sincerely,  
Angela

DRAFT V.2

DEPARTMENT OF HEALTH

CONTROLLED DRUGS AND SUBSTANCES ACT

*Notice to interested parties - Proposal regarding the addition of Salvia divinorum and salvinorin A to Schedule III to the Controlled Drugs and Substances Act*

This notice provides interested stakeholders with the opportunity to provide preliminary comments on Health Canada's proposal to add the plant *Salvia divinorum* (*S. divinorum*) and its active ingredient salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA), and to identify themselves for inclusion in any future consultation.

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are generally chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant. Neither *S. divinorum* nor salvinorin A are currently included in any of the Schedules to the CDSA.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs. *S. divinorum* and salvinorin A are pharmacologically similar to other substances included in Schedule III to the CDSA, such as LSD and psilocybin. Health Canada is thus concerned that *S. divinorum* and salvinorin A pose a risk to the health and safety of Canadians and is therefore considering regulating them as controlled substances.

While Although <sup>these</sup> these substances are not currently included in any of the United Nations Drug Control Conventions, a number of countries have chosen to regulate one or both as controlled substances. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden have all placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. Although some individual American states have implemented laws restricting its use, sale and/or distribution, *S. divinorum* and salvinorin A are not regulated under the federal *Controlled Substances Act* in the United States.

Placing these substances within Schedule III to the CDSA would prohibit the following activities with these substances unless authorized by regulation: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation).

As this action is not intended to interfere with the use and availability of *S. divinorum* and/or salvinorin A for a legitimate medical, scientific or industrial purpose, Health Canada is seeking information from stakeholders on whether there are any legitimate industrial or medical uses for these aforementioned substances in Canada. Information received in response to this notice will be instrumental in determining appropriate scheduling under the CDSA.

001747

such


The publication of this notice begins a 30-day comment period. There will be additional opportunities to provide comments following prepublication of a ~~proposed regulatory amendment~~ in *Canada Gazette*, Part I. *the scheduling proposal*

If you are interested in this process or have comments on this proposal, please contact Stephanie Chandler, Regulatory Policy Division, Office of Controlled Substances, Address Locator: 3503D, 123 Slater St., Ottawa, Ontario, Canada, K1A 1B9, by fax at (613) 946-4224 or by email at [OCS\\_Policy\\_and\\_Regulatory\\_Affairs@hc-sc.gc.ca](mailto:OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca).

Cathy A. Sabiston  
Director General  
Controlled Substances and Tobacco Directorate

Date \_\_\_\_\_



**Re: salvia/naturopathic practitioners - question**   
Angela Doyle to: Stephanie Chandler  
Cc: Denis Arsenault, Daniel Galarneau

2010-11-23 12:59 PM

Thanks and I will assume we can leave it in unless I hear differently from Daniel or Denis.

Angela

Stephanie Chandler Hi Angela, While we have yet to develop the a... 2010-11-23 12:56:21 PM

From: Stephanie Chandler/HC-SC/GC/CA  
To: Angela Doyle/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC, Daniel Galarneau/HC-SC/GC/CA@HWC  
Date: 2010-11-23 12:56 PM  
Subject: Re: salvia/naturopathic practitioners - question

Hi Angela,

While we have yet to develop the actual list of stakeholders that will be used for the salvia NOI, medical practitioners (i.e. those working in hospital ERs who may see salvia cases come in, or those who have been approached by concerned parents(?)) might be interested in knowing it will be scheduled. I have included naturopathic practitioners as salvia was traditionally used as a healing plant in South America (Mexico). I realise its highly unlikely that Canadian naturopaths would use this plant, but I was thinking along the lines of being too inclusive rather than leaving someone out... (We are also waiting on NHPD to provide their list of stakeholders.)

If Denis or Daniel have other thoughts, I'm open to excluding these parties or including others who they think might be more appropriate?

Stephanie

Angela Doyle Stephanie: Can you confirm that medical practit... 2010-11-23 12:29:01 PM

From: Angela Doyle/HC-SC/GC/CA  
To: Stephanie Chandler/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2010-11-23 12:29 PM  
Subject: salvia/naturopathic practitioners - question

Stephanie: Can you confirm that medical practitioners and naturopathic practitioners may be a type of stakeholder re: salvia initiative?

Thanks!  
Ange



# Issue Analysis Summary

DRAFT

## Scheduling *Salvia Divinorum* under the CDSA

Regulatory Policy Division  
Office of Controlled Substances  
Controlled Substances and Tobacco and Directorate

November 26, 2010

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7. CONSIDERATIONS
8. RECOMMENDATION(S)
9. CONSULTATIONS
10. IMPLEMENTATION AND EVALUATION

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### 1. APPROVALS

This Issue Analysis Summary is approved.

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Jocelyn Kula, A/Director  
Office of Controlled Substances  
Controlled Substances and Tobacco Directorate

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[DD/MM/2010]

### 2. ISSUE

Health Canada has received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum* (*S. divinorum*) under the *Controlled Drugs and Substances Act* (CDSA). These requests are further to reports from scientific and media sources suggesting that *S. divinorum* is being used by youth specifically for its hallucinogenic properties. Health Canada has also noted an ongoing media interest regarding the availability of *S. divinorum* in Canada.

### 3. PURPOSE

To assess *S. divinorum* against the criteria for the addition of a substance to one of the Schedules to the CDSA, and determine whether this substance should be regulated as a controlled substance in Canada.

### 4. CONTEXT

*S. divinorum* is a species of sage which belongs to the mint family, and which is found in the form of dried leaves, extracts and plant cuttings. Also called "diviner's sage", the plant is known to induce illusions and hallucinations when chewed or smoked. Salvinorin A, the psychoactive ingredient in *S. divinorum* is a neoclerodane diterpene which is found primarily in the leaves, and to a lesser extent in the stem of the plant.<sup>1</sup>

*S. divinorum* is widely touted as a "legal" hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs among adolescents and young adults.<sup>2</sup> While very little is known about how and where *S. divinorum* is sold in Canada, it is suspected that it is mainly purchased over the Internet and/or bought at head shops or alternative life style stores, etc. *S. divinorum* cuttings are also available from a number of garden supply companies.

*S. divinorum* is a substance not currently scheduled under the CDSA. It can be imported and sold legally in Canada to anyone of any age, anywhere in Canada provided it is not sold as a health product or marketed as a hallucinogen. In addition, the *S. divinorum* sold in Canada is currently not subject to any specific quality or safety standards.

The use of *S. divinorum* as a psychotropic agent first came to Health Canada's attention in 2002. In 2004, Health Canada received four adverse drug reaction (ADR) reports associated with the use of *S. divinorum* as a hallucinogen, with three being considered non-serious (requiring no medical attention) and the fourth being considered serious (medical intervention was required). The serious ADR report involved the concomitant use of alcohol in a person diagnosed with Attention Deficit Disorder.

Further to the receipt of the aforementioned ADRs, the Marketed Health Products Directorate (MHPD) and the Natural Health Products Directorate (NHPD) of the Health Products and Food Branch (HPFB) prepared an issue analysis summary (IAS) in November 2005, which recommended that *S. divinorum* and its active ingredient salvinorin A be regulated as controlled substances. This recommendation was maintained when the IAS was updated in November

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<sup>1</sup> U.S. Department of Justice Drug Enforcement Administration. 2002. Drugs and Chemicals of Concern: Salvia Divinorum (salvinorin A, divinorin A) URL:

[http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm) Nov 2008

<sup>2</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.

2006.

Later, in December 2005, MHPD and NHPD prepared a Signal Assessment (SA) (updated in June 2007) that eventually led to the preparation of a Health Risk Assessment (HRA), which concluded that *S. divinorum* or salvinorin A-containing health products would constitute a Type II Health Risk according to the Health Hazard Classification of the Recall Policy of the Health Products and Food Branch Inspectorate (HBFBI). Such a risk is defined as “a situation in which the use of, or exposure to, a product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote”.

Further to a discussion with the Assistant Deputy Minister (ADM) of the Healthy Environments and Consumer Safety Branch (HECSB) in April 2007, the (then) Drug Strategy and Controlled Substances Directorate (DSCSD) (now the Controlled Substances and Tobacco Directorate, CSTD) organized a meeting with MHPD, NHPD and HPFBI to discuss *S. divinorum*. HPFBI was to determine appropriate compliance activities regarding *S. divinorum* and consult with the Canada Border Services Agency (CBSA) regarding the movement of products containing *S. divinorum* into and out of Canada.

On September 13, 2007, a further meeting between DSCSD, MHPD, NHPD and HPFBI led to the conclusion that DSCSD would conduct a scheduling assessment of *S. divinorum* in order to explore the possibility of scheduling this substance under the CDSA.

In September 2008, the Director Generals of DSCSD, MHPD, TPD and the HPFBI agreed that media lines and an “It’s Your Health” article on *S. divinorum* would be prepared.

#### **4.1 Relevant Legislative Frameworks in Canada**

##### **4.1.1 Food and Drug Regulations (under the Food and Drugs Act)**

The *Food and Drug Regulations* (F&DR) serve to ensure the safety, efficacy, and quality of health products offered for sale in Canada, including drugs and medical devices. Prior to being given market authorization, a manufacturer must present substantive scientific evidence that their product is safe, efficacious and of high quality. For drugs, Health Canada reviews this information carefully and, if the review is satisfactory, a Notice of Compliance (NOC) is issued and appropriate Drug Identification Numbers (DINs) are assigned.

A “drug” is defined under the F&DR as any substance or mixture of substances manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
- (b) restoration, correction or modification of organic functions in human beings or animals, or

(c) disinfection in premises in which food is manufactured, prepared or kept;

As no products containing *S. divinorum* or its extracts have been reviewed and approved by Health Canada as of October 2010, it is illegal to market *S. divinorum* when it is represented as a drug.

#### **4.1.2 Natural Health Products Regulations (under the Food and Drugs Act)**

The *Natural Health Products Regulations* (NHPR) aim to provide Canadians with ready access to natural health products (NHPs) that are safe, effective, and of high quality, while respecting freedom of choice and philosophical and cultural diversity. The NHPR require that all licensed products display a Natural Product Number (NPN), or, in the case of a homeopathic medicine, a Drug Identification Number - Homeopathic Medicine (DIN-HM), on their labels. These numbers are issued once a product is authorized for sale in Canada. A product licence may be obtained pursuant to an application in which the applicant attests to all of the conditions set out in a natural health product monograph prepared and published by the Natural Health Products Directorate. Alternatively, an applicant may submit a product license application that provides evidence of quality, safety and efficacy that is assessed as being sufficient and approved by NHPD by the full submission route. The NHPR also require that all manufacturers, packagers, labelers, and importers have a site license issued on the basis of sufficient evidence of procedures respecting distribution records, product recalls, product handling, storage and delivery, and all other aspects of Good Manufacturing Practices as set out in the NHPR.

The definition of an NHP under the NHPR has both a function and substance component. The function component refers to those substances that are manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
- (b) restoring or correcting organic functions in humans; or
- (c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

The substance component refers to the requirement that all of the medicinal ingredients of an NHP must be substances set out in Schedule 1 (a list of included substances) to the NHPR, a traditional medicine or a homeopathic medicine, and none of the ingredients can be substances set out in Schedule 2, a list of excluded substances which includes any substance listed on Schedules I to V of the CDSA. Section 2(2) of the NHPR excludes those substances (except homeopathic medicines) whose sale is required to be pursuant to a prescription as per Section C.01.043 of the F&DR.

As per section 93(1)(b)(vi) of the NHPR, every natural health product must be labeled with its

authorized recommended use or purpose. In the case of *S. divinorum*, it is generally marketed for its hallucinogenic properties which are considered a modification of an organic function. Therefore products that contain *S. divinorum* and are manufactured, sold or represented for use as a hallucinogen meet the definition of an NHP.

As of October 2010, no products containing *S. divinorum* have been authorized by Health Canada. Therefore no NPNs or DIN-HMs have been issued for such products. Therefore sales of *S. divinorum* are illegal under the NHPR if the product is represented for use as a hallucinogen or if other health claims are made.

#### **4.1.3 Controlled Drugs and Substances Act and its Regulations**

The CDSA provides a legislative framework for the control of substances that can alter mental processes and that may produce harm to the health of an individual or to society when diverted or misused. Except as authorized under its regulations, activities such as possession, possession for the purposes of trafficking, trafficking, importation, exportation, possession for the purposes of exportation and production of controlled substances are prohibited under the CDSA.

The substances regulated under the CDSA are grouped into eight Schedules, and each Schedule is associated with particular offences and penalties as described in Part I of the CDSA.

In determining whether a substance should be regulated as a controlled substance, and into which Schedule of the CDSA it should be placed, Health Canada considers the following factors:

- International requirements and trends in control and/or scheduling;
- Chemical and/or pharmacological similarity to substances listed in the Schedules to the CDSA;
- Legitimate use of the substance, including therapeutic, scientific, or industrial uses;
- Potential for abuse and/or addiction liability;
- Evidence of extent of actual abuse of the substance in Canada and internationally; and
- Risk to personal and public health and safety.

#### **4.2 Assessment of *S. Divinorum* for Scheduling Purposes**

##### **4.2.1 International Requirements and Trends in Control and/or Scheduling**

At the present time, neither *S. divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and therefore do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

##### ***Australia***

In June 2002, Australia became the first country to prohibit the sale, supply, possession and use of *S. divinorum* and salvinorin A. Both *S. divinorum* and salvinorin A are listed in Schedule 9 of

Australia's *Standard for the Uniform Scheduling of Drugs and Poisons* on the basis of "high potential for abuse and risk to public health and safety."<sup>3</sup> Schedule 9 is Australia's most restrictive drug schedule, and includes "substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities."<sup>4</sup>

### **Belgium**

A decree was passed in Belgium on October 22, 2006 which added *S. divinorum* to the list of controlled substances. This list includes substances such as psilocybin mushrooms, khat and peyote cactus.<sup>5</sup>

### **Denmark**

In 2003, Denmark added *S. divinorum* and salvinorin A to their list of "category B" controlled substances, a category which also includes psilocybin mushrooms, cocaine, amphetamine, and several others substances that are only legal for medicinal and scientific purposes. Illegal possession carries a penalty of up to two years in prison.

### **Germany**

*S. divinorum* (plant and plant parts) was added to Appendix I of the *Narcotics Act* in Germany on March 1, 2008, making it illegal to produce, traffic, or possess. The law does not specifically mention salvinorin A.

### **Italy**

On June 25, 2004, the Italian Ministry of Health issued an ordinance prohibiting the sale of *S. divinorum* and its active constituent salvinorin A. On January 11, 2005, the Ministry of Health made possession of *S. divinorum* and salvinorin A illegal by placing them in "*Tabella I*" of the *Tabella Sostanze Stupefacenti o Psicotrope*.

### **Japan**

On November 9, 2006, the Japanese government added a group of thirty-three drugs to its list of controlled substances, including salvinorin A. The drugs are banned under a revised pharmaceutical law, under which persons involved in their illegal import, production, and sale, i.e. beyond medical treatment or research purposes, will be subject to up to five years

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<sup>3</sup> <http://www.tga.gov.au/ndpsc/record/rr200111.pdf>

<sup>4</sup> [http://www.cognitiveliberty.org/news/salvia\\_australia.htm](http://www.cognitiveliberty.org/news/salvia_australia.htm)

<sup>5</sup>

imprisonment or a fine of up to five million yen.

### ***Spain***

On January 28, 2004, the Spanish Ministry of Health and Consumption issued an order prohibiting the sale of *S. divinorum*. The regulation went into effect on May 6, 2004 and only prohibits activities related to commerce. Possession and/or use are not considered to be criminal offences.

### ***Other Countries***

It is illegal to possess or sell *S. divinorum* in Croatia, Latvia, Lithuania, Poland, Romania, South Korea and Sweden. In Russia it is illegal to grow or sell *S. divinorum*, but it is legal to possess it. In Estonia, Finland, Iceland and Norway, *S. divinorum* is treated as a medicinal herb and it is illegal to import it without a relevant prescription from a doctor.

### ***United States of America***

*S. divinorum* and salvinorin A are not included in the Schedules to the United States *Controlled Substances Act*. Although both *S. divinorum* and salvinorin A have been added to a list of chemicals "of concern", this has no legal implications. According to the National Institute for Drug Abuse, the Drug Enforcement Administration is considering classifying *S. divinorum* and/or salvinorin A as Schedule I drugs. This Schedule includes substances such as LSD and marihuana.

At the state level, some state legislatures have implemented laws restricting the use, sale and/or distribution of *S. divinorum* and/or salvinorin A. As of July 2010, a number of states have placed regulatory controls on *S. divinorum* and/or salvinorin A including Delaware, Georgia, Florida, Hawaii, Illinois, Kansas, Kentucky, Maryland, Mississippi, Missouri, Nebraska, North Dakota, Ohio, Oklahoma, South Dakota, Wisconsin, Virginia, California, Louisiana, Maine, North Carolina, and Tennessee. By way of example, additional details regarding the regulation of *S. divinorum* in these last five states are provided below.

#### ***California***

As of January 1, 2009, the sale or distribution of *S. divinorum* or salvinorin A, or any substance or material containing *S. divinorum* or salvinorin A, to any person under 18 years of age is a misdemeanor punishable by imprisonment in a county jail for not more than six months, a fine of no more than \$1,000, or both.

#### ***Louisiana***

In 2005, Louisiana passed a bill which prohibits the possession, production, manufacture and distribution of a material, compound, mixture, or preparation intended for human

consumption and that contains a hallucinogenic plant. A "hallucinogenic plant" is defined as "any part or portion" of a plant on a list of forty plants, which includes *S. divinorum*.

### ***Maine***

In Maine, *S. divinorum* and salvinorin A are regulated in the same way as tobacco products; adults eighteen years of age or over can legally purchase and use the material, but selling or providing *S. divinorum* or salvinorin A to anyone under the age of eighteen is a criminal offence. Possession by a minor is a civil violation, punishable by a fine, community service, or both.

### ***North Carolina***

On December 1, 2009, the North Carolina State Legislature brought a new law into force which made *S. divinorum* and salvinorin A illegal. The only legal *S. divinorum* activities are the growing for aesthetic, landscaping, or decorative purposes or university-affiliated medical or pharmacological research.

### ***Tennessee***

On July 1, 2006, Tennessee classified the deliberate production, manufacture, distribution, or possession of the active chemical ingredient in the hallucinogenic plant *S. divinorum* as a Class A misdemeanor. It is not, however, a criminal offence to possess, plant, cultivate, grow, or harvest *S. divinorum* for aesthetic, landscaping, or decorative purposes. The law also does not apply to any dosage that is legally obtainable from a retail establishment without a prescription when (and if) it is recognized by the Food and Drug Administration as a homeopathic drug.

#### **4.2.2 Chemical and/or Pharmacological Similarity to Substances Listed in the Schedules to the CDSA**

The psychoactive ingredient in *S. divinorum* is the neoclerodane diterpene salvinorin A.<sup>6</sup> As a diterpene, salvinorin A is part of a family of substances that contain terpenoids. Another plant which contains psychotropic terpenoids is *Artemisia absinthium* (wormwood).<sup>7</sup> Salvinorin A is a hallucinogen with a distinct structure and it does not interact with the serotonin type-2A receptor or any other molecular target of classical hallucinogens.<sup>8</sup> Instead, the available research suggests that the psychotropic effects of salvinorin A are mediated by its agonistic actions at the  $\kappa$ -opioid

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<sup>6</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage *Salvia divinorum*. *Life Sci.* 2005 Dec 22;78(5):527-31.

<sup>7</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.



(KOR) receptor.<sup>9</sup> Its mechanism of action is therefore unique.<sup>10</sup>

The psychoactive effects of *S. divinorum* vary in onset and duration and include perceptual distortions such as the sensation of becoming an object, having visions of various two-dimensional surfaces, films and membranes, revisiting places of the past (particularly childhood), perceived loss of the body and/or identity, various sensations of motion (being pulled or twisted by a force of some kind), uncontrollable hysterical laughter, and overlapping realities (perceptions of being in more than one place).<sup>11</sup> Laughter, happiness, a sense of well-being and dissociative effects were deemed the most positive aspects of *S. divinorum* by users, second only to the "trip" that the drug elicits.<sup>12</sup> Depersonalization, speaking gibberish, widening of consciousness and subjective illusions of rapid movement, flying or hovering have also been reported.<sup>13</sup>

The psychotomimetic effects of *S. divinorum* closely resemble the schizoid symptoms induced by lysergic acid diethylamide (LSD) or phencyclidine (PCP).<sup>14</sup> Yet, it is said to have only a weak influence on the prevailing mood of the user which differentiates it from other hallucinogens such as LSD and psilocybin.<sup>15</sup> Its strong dissociative effects are often compared to those of ketamine.<sup>16</sup> Users have reported that the psychedelic effects of *S. divinorum* were most similar to those caused by psilocybin mushrooms.<sup>17</sup> However, users familiar with the effects of other hallucinogens agree that despite certain similarities to classical hallucinogens, the visions and overall experience are quite unique.<sup>18</sup>

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<sup>9</sup> Roth BL, Baner K, Westkaemper R, Siebert D, Rice KC, Steinberg S, Ernsberger P, Rothman RB. Salvinorin A: a potent naturally occurring nonnitrogenous kappa opioid selective agonist. *Proc Natl Acad Sci U S A*. 2002 Sep 3;99(18):11934-9.

<sup>10</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>11</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>12</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>13</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5 and Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>14</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>15</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>16</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

<sup>17</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>18</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6 and González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

*S. divinorum* causes an unusually high degree of sedation, weakness and fatigue, and the increased de-realization is not commonly reported for classical psychedelics.<sup>19</sup> The combination of these effects seems to correlate with that of other KOR agonists such as pentazocine.<sup>20</sup>

The onset and intensity of the effects of *S. divinorum* appear to be related to the route of administration. Traditional uses generally produce mild effects because the leaves are rolled and chewed or crushed and prepared as a foamy infusion whereby the salvinorin A is degraded in the gastrointestinal system before being absorbed into the bloodstream. Hence, the level of effect relates quite closely to the length of time the material spends in the mouth, with the onset of effect generally taking 5-10 minutes. The effects build over the next hour and last for another hour before they begin to subside.<sup>21</sup>

Routes of administration that avoid the hepatic first-pass effect (i.e. inhalation, intravenous, intramuscular and sublingual use) provide the quickest and most intense effect.<sup>22</sup> Salvinorin A can be isolated from the plant to make a powder which can be vaporized and inhaled. The effects felt from vaporizing salvinorin A are experienced in about 30 seconds, last for about 5-10 minutes, and then subside over the next 30 minutes.<sup>23</sup>

Smoking the dried leaves or a concentrated extract using a pipe or bong is by far the most popular method of administration.<sup>24</sup> Dried leaves may also be fortified with a concentrated extract of salvinorin A. A concentrated extract can also be used sublingually. Neither *S. divinorum* nor salvinorin A can be injected because the powder is insoluble in water.<sup>25</sup>

#### 4.2.3 Legitimate Use of the Substance (Therapeutic, Scientific, Industrial)

*S. divinorum* has traditionally been used for spiritual and medicinal purposes by the Mazatec Indians in Oaxaca, Mexico.<sup>26</sup> For medicinal purposes (gastrointestinal problems, headaches,

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<sup>19</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>20</sup> Arasteh K, Poudevida S, Farre M, Roset PN, Cami J. Response patterns of the Spanish version of the 49-item short form of the Addiction Research Center Inventory after the use of sedatives, stimulants, and opioids. *Drug Alcohol Depend.* 1999 Jun 1;55(1-2):117-25.

<sup>21</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>22</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.

<sup>23</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>24</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62 and Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>25</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs.* 1994 Jul-Sep;26(3):277-83.

<sup>26</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

rheumatism, anemia and swelling of the stomach) an infusion of the leaves or the leaves themselves are ingested.<sup>27</sup> However, its main use in Mexico today is believed to be for its psychedelic properties in the aid of producing “mystical” or hallucinogenic experiences as part of spiritual rituals.<sup>28</sup>

Although selective KOR agonists have been shown to produce analgesic effects, adverse effects such as psychotomimesis, dysphoria and diuresis have been observed in studies investigating their therapeutic use.<sup>29</sup> In addition, while it has been speculated that KOR agonists may be useful in the treatment of certain psychiatric disorders including Alzheimer’s disease, schizophrenia, dementia and bipolar disorder, there has been no clinical research to support these hypotheses.<sup>30</sup> There are presently no recognized medical uses for *S. divinorum* in Canada.

Similarly, there are no known industrial or commercial uses for *S. divinorum* in Canada. Most websites offering *S. divinorum* cuttings and seeds for sale appear to do so in the context of growing the plant for “recreational” purposes, rather than out of horticultural interest or for its esthetic appeal. However, it should be acknowledged that this does not preclude the possibility of a person growing this plant for purely decorative purposes. *S. divinorum* is also marketed as incense. However, there is no evidence that *S. divinorum* has any fragrant properties that would legitimize such a use. Therefore it is believed that the marketing of this plant as an incense is a means to avoid compliance and enforcement actions by Health Canada.

#### **4.2.4 Potential for Abuse and/or Addiction Liability**

Salvinorin A is a potent, KOR-selective agonist and in contrast to the euphoria produced by MOR agonists such as morphine, KOR agonists are negatively reinforcing and aversive.<sup>31</sup> In addition, KOR agonists have analgesic properties, but are not associated with respiratory depression like MOR agonists.<sup>32</sup> Finally, while MOR agonists increase the release of dopamine, the activation of KOR decreases dopamine release in the nucleus accumbens.<sup>33</sup> In the case of

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<sup>27</sup> Munro, T. The Chemistry of *Salvia divinorum*. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

<sup>28</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage *Salvia divinorum*. *Life Sci.* 2005 Dec 22;78(5):527-31.

<sup>29</sup> Barker RL, Fawcett J, Barkin SJ. 2002. Chronic pain management with a focus on the role of newer antidepressants and centrally acting agents. In: *Pain Management: A Practical Guide for Clinicians*, 6th edition, Weiner RS ed. CRC Press, Boca Raton, FL. pp. 415-34 and Tidgewell et al., 2004. A facile method for the preparation of deuterium labelled salvinorin A: *Biorganic & Medicinal Chemistry Letters*, 14: 5099-5102.

<sup>30</sup> Sheffler DJ & Roth BL. Salvinorin A: the ‘magic mint’ hallucinogen finds a molecular target in the kappa opioid receptor. *Trends Pharmacol Sci.* 2003 Mar;24(3):107-109.

<sup>31</sup> Killinger BA, Peet MM, Baker LE. Salvinorin A fails to substitute for the discriminative stimulus effects of LSD or ketamine in Sprague–Dawley rats. *Pharmacology, Biochemistry & Behaviour.* 2010 May 96; 260-265.

<sup>32</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman’s The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.

<sup>33</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman’s The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.

MOR agonists, the increase of dopamine acts as a positive reinforcer. This action motivates the user to use the drug again, which could lead to drug abuse and/or addiction. For KOR agonists, this is not the case.

The aversive effects of KOR agonists suggest that the risk of addiction to *S. divinorum* is negligible. Users have reported the negative effects of *S. divinorum* as: the short duration of action, lack of control over the experience, persisting negative effects (most often anxiety),<sup>34</sup> sweating, chills, increased diuresis, impaired vigilance,<sup>35</sup> and negative after-effects including tiredness, feeling head heavy, dizziness, physical exhaustion, and some degree of malaise or 'hangover' as they 'comedown' from the drug.<sup>36</sup> Despite these reports, very few controlled scientific studies of the physical and psychotropic effects of *S. divinorum* on humans have been carried out and the results have been conflicting. For example, one author states: "Many who have used salvinorin A find the experience extremely unnerving, frightening and overly intense and most have no desire to repeat the experience."<sup>37</sup> However, another study suggested that this is not the experience of all recreational users of *S. divinorum*.<sup>38</sup> Over eighty percent of users surveyed on a web-based questionnaire about their *S. divinorum* use said that they would probably or definitely use *S. divinorum* again.<sup>39</sup>

In addition, some users have noted that they require increasing doses of salvinorin A in order to achieve the desired effect and the stimulated cerebral KOR may act as a mechanism of tolerance.<sup>40</sup> Therefore, it is difficult to predict with certainty its potential for addiction and abuse. In studies that have been conducted, there is conflicting information around the addiction liability of *S. divinorum* in both animals and humans. Further studies in this area and on the KOR mediated decrease of dopamine are also required in order to fully understand the addiction potential of this substance.

While concerns for the potential of abuse were initially considered minimal given that 1 kg of

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<sup>34</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>35</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>36</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>37</sup> Turner DM. *Salvinorin - The Psychedelic Essence of Salvia Divinorum*. Panther Press, San Francisco, CA 1996.

<sup>38</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62, Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5, and Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs*. 1994 Jul-Sep;26(3):277-83.

<sup>39</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>40</sup> Bucheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

dried leaves only yield 3 to 6 human doses of salvinorin A for oral consumption, it was then discovered that vaporizing and inhaling 200-500 micrograms has profound hallucinogenic effects.<sup>41</sup> Given that only small doses of this substance are now necessary to achieve the desired effects through inhalation, the potential for abuse is much higher. Also, the extraction of salvinorin A from the plant is simple, and with care, approximately 1.5 grams of pure salvinorin A per kilogram of dried leaves (8kg of fresh leaves) can be isolated. This is enough for 2000 oral doses.<sup>42</sup>

#### 4.2.5 Evidence of Extent of Actual Abuse of the Substance in Canada and Internationally

In Canada, the prevalence of use of *S. divinorum* has recently been documented. Questions about the use of salvia were included in the 2009 Ontario Student Drug Use and Health Survey, the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey.\*

The results from the 2009 Ontario Student Drug Use and Health Survey were published on November 18, 2009 and indicate that:

- Among all responding students in Ontario, 4.4% reported using *S. divinorum* at least once in the past year. In comparison, 58.2% indicated they had used alcohol, 25.6% indicated they had used cannabis and 5.0% indicated they had used hallucinogens other than LSD and PCP in the past year;
- Males (6.2%) were significantly more likely than females (2.3%) to report using *S. divinorum*;
- There is significant grade variation, with *S. divinorum* use most likely among 11<sup>th</sup> graders (8.6%) and 12<sup>th</sup> graders (8.4%); and

The results of the 2008-2009 Youth Smoking Survey were published on May 31, 2010 and indicate that:

- 4.9% of students stated that they had used salvia in the last twelve months. In comparison, 53.0% indicated they had used alcohol, 27.3% indicated they had used cannabis and 6.9% indicated they had used other hallucinogens in the last twelve months;
- 2.6% of students in Grades 7-9 and 7.0% of students in Grades 10-12 had used salvia in the last twelve months; and

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<sup>41</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>42</sup> Valdès LJ 3rd. Salvia divinorum and the unique diterpene hallucinogen, Salvinorin (divinorin) A. J Psychoactive Drugs. 1994 Jul-Sep;26(3):277-83.

\* It should be noted that in some cases it is not clear if responses indicate the use of *S. divinorum* or salvinorin A given the use of the term "salvia" within the survey question.

- Males (6.6%) were more likely to have used salvia in the past twelve months compared to females (3.2%).

The Canadian Alcohol and Drug Use Monitoring Survey specifically examined salvia for the first time in 2009. An estimated 1.6% of Canadians, aged 15 years and older, reported that they had used salvia in their lifetime, and 0.2% reported using it in the past-year. In comparison, the prevalence of past-year cannabis use among Canadians 15 years of age and older was 10.6%, while 1.2% of respondents reported using cocaine or crack in the past 12 months, 0.9% ecstasy and 0.7% illicit hallucinogens. In conclusion, 'salvia' appears to be a substance that is tried largely by youth with a 7.3% prevalence of lifetime use.

According to the 2009 Monitoring the Future survey, the annual prevalence of use of *S. divinorum* among 12th graders in the United States is 5.7%. The American Substance Abuse and Mental Health Services Administration's 2006 National Survey on Drug Use and Health found that, of respondents aged 12 or older, 1.8 million had used *S. divinorum* at least once in their lifetime and 756,000 had used the substance in the past year. Among youth aged 12 to 17, males were more likely than females to have used *S. divinorum* in the past year (0.9% vs. 0.3%).

Health Canada's Drug Analysis Services (DAS) has identified salvinorin A in a number of samples seized by law enforcement, ranging from 9 samples in 2006 to 20 samples in 2009. It is, however, difficult to determine how this data reflects the extent of actual abuse of salvinorin A in Canada, given that it is not an illegal substance and would likely only be seized accidentally or during the seizure of other controlled substances.

The National Forensic Laboratory Information System (NFLIS) and the System to Retrieve Information from Drug Evidence (STRIDE) in the United States are Drug Enforcement Administration (DEA) databases that collect scientifically verified data on analyzed samples in state and local forensic labs as well as samples from DEA labs. While in 2000 no seized samples were found to contain *S. divinorum* or salvinorin A, 70 samples tested positive in 2008. Once again, it is difficult to determine how this data can be used to reflect the actual extent of abuse of *S. divinorum* and salvinorin A in the United States as neither substance is listed in the *Controlled Substances Act*.

The increase in both the number of enquiries to Health Canada from various municipalities and members of the public and the amount of media interest regarding the availability of *S. divinorum* in Canada may be an indication that the recreational use of *S. divinorum* as a hallucinogen is on the rise. However, it may also reflect an increased awareness of the phenomenon, rather than an increased incidence of use.

#### **4.2.6 Risk to Personal and Public Health and Safety**

The potential for harm to the user and/or other individuals is primarily related to the hallucinogenic properties of the substance. As this substance is typically smoked, there is no risk of infectious disease transmission as is the case when a drug is injected. Users may get up and walk around without apparent awareness of their movements, behaviour or surroundings, and distinction between self and surroundings is often lost. At doses greater than 1mg of salvinorin

A, out of body experiences are frequent and loss of consciousness has been reported.<sup>43</sup> There is little information regarding the social behaviours of persons under the influence of *S. divinorum* products, and what risks their activities such as operating a motorized vehicle may pose to the general public. There is also very little data regarding the toxicity, teratogenicity or other long-term effects of *S. divinorum* use.<sup>44</sup>

As far as law enforcement is concerned, the Department has only received a limited number of communications indicating concern with respect to *S. divinorum*. The Royal Canadian Mounted Police (RCMP) has stated that while *S. divinorum* is readily available, it has not become a popular drug in Canada, probably due to its aversive effects such as anxiety and introversion.

A handful of case reports regarding physiological and psychotropic effects of *S. divinorum* use have been published in the scientific/medical literature. For example, an international case report described the perceptions of a 19 year-old man after inhaling *S. divinorum* smoke. The peak psychotropic effects, including prickling of the skin, fever-like hot flashes, muscular tremor, and depersonalization, were reached in less than five minutes after inhalation of an unknown amount of smoke from burning dried leaves.<sup>45</sup> Another report involved a 15-year-old male who presented to psychiatric emergency services with acute onset of paranoia, déjà vu, blunted affect, difficulties in thought processing and slowed speech after smoking *S. divinorum* over an unknown period of time. During his hospitalization all symptoms improved significantly except the feeling of déjà vu. Based on this case presentation, the author suggested that the feelings of déjà vu may be a long-term effect of *S. divinorum* use.<sup>46</sup> However, given that this is the only case report in which déjà vu was associated with the use of *S. divinorum*, more reports are needed to substantiate this finding.

In addition to the above-mentioned reports, in 2006, a case was reported in the U.S. in which a 17-year-old boy committed suicide after smoking *S. divinorum* for an unknown period of time.<sup>47</sup> It should be noted that alcohol and general depression were the main confounders in this case. After this case was reported, the state of Delaware passed a law which classified *S. divinorum* as a Schedule I controlled substance along with other hallucinogenic substances.

Like many drugs of abuse, users are often unaware of the potency and adulterants in the product they purchase. A study by Wolowich *et al.* (2006), showed that the salvinorin A content in five out of five *S. divinorum* products was falsely indicated on the label and 4 out of 5 products contained unidentified adulterants (i.e. vitamin E, caffeine).<sup>48</sup>

There are also several reports of domestic adverse reactions related to the use of *S. divinorum* that have been received through the Canada Vigilance database. However, this does not reflect

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<sup>43</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>44</sup> Grundmann O, Phipps SM, Zadezensky I, Butterweck V. *Salvia divinorum* and Salvinorin A: An Update on Pharmacology and Analytical Methodology. Planta Med 2007 Jun;73:1039-1046.

<sup>46</sup> Singh S. (2007) Adolescent salvia substance abuse. Addiction. 102, 823-824.

<sup>47</sup> <http://www.kvbc.com/Global/story.asp?S=4893692>

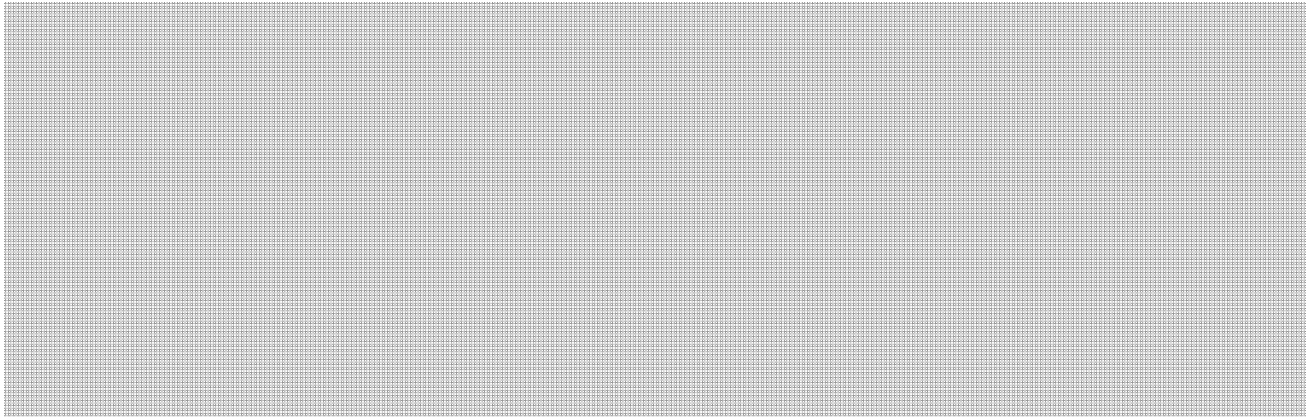
<sup>48</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. Pharmacotherapy. 2006 Sep;26(9):1268-72.

**s.21(1)(a)**

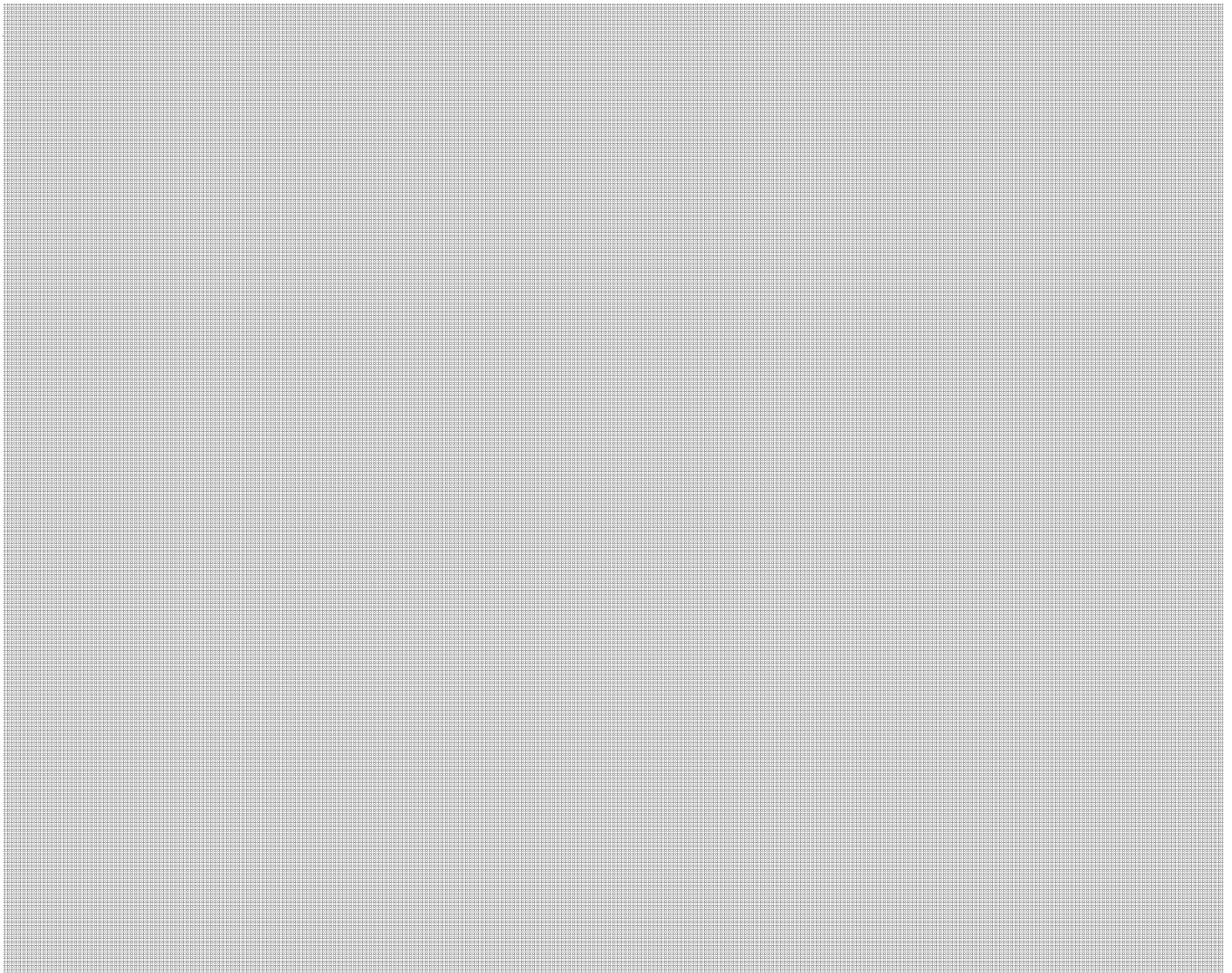
**s.21(1)(b)**

true incidence due to under-reporting.

**5. ASSESSMENT OF RISKS AND BENEFITS**



**6. IDENTIFICATION AND ANALYSIS OF OPTIONS**





## 7. CONSIDERATIONS

s.21(1)(a)

The NHPR are limited in their capacity to control the availability of *S. divinorum* in that *S. divinorum* products are often declared as incense and therefore cannot be considered unapproved natural health products. In addition, compliance and enforcement actions such as voluntary stop-sales, forfeiture, destruction, and administrative seizure, cannot be implemented unless the marketing of the product indicates that it is to be sold for human consumption in order to modify an organic function. Unlicensed natural health products are also permitted to be imported provided they are for personal use only.

s.21(1)(b)

Non-regulatory options for the control of *S. divinorum*, such as the development of an educational campaign to highlight the risks associated with using this plant, were also considered. However, the risks associated with this substance, as well as the confusion concerning its enforcement as a natural health product only when it is sold for use with a health claim, do not make this option viable.

*S. divinorum* meets the criteria for scheduling a substance under the CDSA. While neither the plant nor its main active component salvinorin A are scheduled under any of the UN Drug Control Conventions, a number of countries and American states have taken steps to control the distribution and use of these substances. *S. divinorum* and salvinorin A are pharmacologically similar to other substances included in Schedule III to the CDSA, such as LSD and psilocybin. There are also currently no legitimate therapeutic, commercial or industrial uses for *S. divinorum*. While the addiction potential of *S. divinorum* appears to be low, there is001766

s.21(1)(a)

s.21(1)(b)

for its abuse as a 'legal' hallucinogen. There is very little information with regards to the long-term effects of *S. divinorum* use. There is also evidence of use, particularly by Canadian youth and potential for individual health risks as well as risks to public health and safety.

In light of a recommendation to include *S. divinorum* under Schedule III to the CDSA, it is also recommended that the main psychoactive ingredient of this plant, salvinorin A, be scheduled. Salvinorin A can easily be extracted from *S. divinorum* and this substance gives the plant its hallucinogenic properties. Therefore the use of salvinorin A poses the same risks as *S. divinorum* and should also be controlled under the CDSA in the same manner as *S. divinorum*.

## 8. RECOMMENDATIONS

## 9. CONSULTATIONS

The Drug Analysis Services (DAS) was contacted in order to provide any data available regarding the identification of salvinorin A in samples submitted by law enforcement.

The Royal Canadian Mounted Police (RCMP) was contacted in order to establish their views with respect to *S. divinorum* use in Canada. The RCMP advised that *S. divinorum* is readily available and law enforcement agencies have no legal means to prevent its sale.

OCS has received a number of correspondences from Canada Border Services Agency (CBSA) officers concerning a lack of information regarding the status of *S. divinorum* and how the plant should be treated at the border. CBSA officers have also expressed concern regarding the plant's hallucinogenic properties. At present, only shipments of *S. divinorum* that are represented for sale as health products that modify organic functions can be refused for import under the NHPR.

OCS brought *S. divinorum* to the Controlled Substances Scheduling Working Group (CSS-WG) in August 2010 to discuss the possibility of regulatory control of this substance. After assessing the available information against the six criteria listed in the Context section of this Issue Analysis Summary, the CSS-WG recommended that *S. divinorum* be included under Schedule III to the CDSA.

## 10. IMPLEMENTATION AND EVALUATION

**Page(s) 001768 to\à 001768**

**Is(Are) exempted pursuant to section(s)  
est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**

DRAFT 14  
November 26, 2010

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### Media Lines *Salvia divinorum*

#### Issue

Further to ongoing media interest regarding the availability of *Salvia divinorum* in Canada and reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties, Health Canada has ~~now determined~~ <sup>is</sup> that *Salvia divinorum* should be included in one of the Schedules to the *Controlled Drugs and Substances Act* (CDSA).

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#### Key Messages:

- Health Canada ~~has determined~~ <sup>is proposing</sup> that *S. divinorum* and salvinorin A ~~should~~ be regulated as controlled substances under the *Controlled Drugs and Substances Act* (CDSA). This decision is based on analysis of the information available about *S. divinorum* and salvinorin A as well as an assessment of the possible options to manage the risks associated with the availability of these substances in Canada.
- Health Canada will issue a *Notice to Interested Parties* (NOI) stating that it intends to add *S. divinorum* and its main active ingredient, salvinorin A, to Schedule III to the CDSA. The NOI will provide stakeholders and other interested parties with the opportunity to provide comments on the proposal to regulate these substances as controlled substances.
- The inclusion of *S. divinorum* and salvinorin A in Schedule III to the CDSA will mitigate the risks associated with their use and availability.

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#### Supplementary Messages:

- Canadians should not use products containing *S. divinorum* and/or salvinorin A because very little is known about these substances and their potential effects on the brain and/or body, and their impact on physical and mental functions.
- Because of their hallucinogenic properties, products containing *S. divinorum* and/or salvinorin A meet the definition of a natural health product (NHP) under the Natural Health Products Regulations and the definition of a drug under the Food and Drugs Act.
- It is illegal to sell NHPs in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN). The illegal sale of products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*.

Comment [S1]: Change order of Supplementary Messages?

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Deleted: <#>Because of their hallucinogenic properties, products containing *S. divinorum* and/or salvinorin A meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*. ¶

It is illegal to sell NHPs in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN). The illegal sale of products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*. ¶

- Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and thus, do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions,
- The move to include *S. divinorum* and salvinorin A in Schedule III to the CDSA is consistent with actions taken by several countries (Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) who have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. It is also consistent with the fact that some individual U.S. states have implemented laws restricting their use, sale and/or distribution.

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*Salvia divinorum* as a controlled substance:¶  
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 <#>In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA). ¶  
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**Questions and Answers:**

**Q1 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why isn't it illegal?**

A1 – Health Canada intends to include *S. divinorum* and salvinorin A under Schedule III to the CDSA. In the interim, as *S. divinorum* meets the definition of a Natural Health Product (NHP) under the *Natural Health Product Regulations*, it is illegal to manufacture, sell or provide products containing *S. divinorum* and/or salvinorin A without their being authorized by Health Canada prior to sale.

**Q2 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?**

A2 – The *Natural Health Products Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *Salvia divinorum*. When *S. divinorum* and salvinorin A are included in Schedule III to the CDSA, it will be illegal to possess, import, export, produce and distribute these substance in any form.

*raw materials? CADA unless authorized by Regulation.*

**Q3 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A3 – Once *S. divinorum* and salvinorin A are included in Schedule III to the CDSA, law enforcement will be able to take appropriate action in response to suspected illegal activities with these substances.

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In the interim, *S. divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. Complaints about the illegal sale of drugs containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

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**Q4 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum* as a controlled substance. What does that involve and what stage is it at?**

A4 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada recently concluded its assessment of *S. divinorum* and salvinorin A against the aforementioned factors and intends to include both substances in Schedule III to the CDSA.

*proposes*  
**Q5 – What is the significance of the adverse reaction reports that Health Canada has received with respect to the use of *Salvia divinorum*?**

A5 – Health Canada has received four domestic adverse reaction reports related to the use of *Salvia divinorum* as a hallucinogen through the Canada Vigilance database. The number of reports and the nature of reactions reported are, however, not adequate to fully characterize the risk of similar reactions among the general population

***If pressed on whether Health Canada has issued any kind of warning to Canadians about *Salvia divinorum****

A - Health Canada is developing an It's Your Health (IYH) article on *Salvia divinorum* to help inform the general public about the risks associated with the use of this substance.

### **Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

Data from the 2008-2009 Youth Smoking Survey indicates that:

- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;
- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year; and.

**Deleted:** Health Canada is currently reviewing the available information to determine whether regulation of *Salvia divinorum* under the CDSA is warranted.¶

¶  
**Q5 – Didn't an internal report from Health Canada's Marketed Health Products Directorate recommend that *Salvia divinorum* be scheduled under the CDSA? Why has that recommendation not been acted upon?¶**

¶  
A5 – See A4¶

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- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using Salvia in their lifetime (0.2% in the past year); and
- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that:

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;
- 5.4% of students (grades 7-12) ever used *S. divinorum*; and
- the use of *S. divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

**Prepared by:** Stephanie Chandler and Denis Arsenault, OCS, CSTD

**Deleted:** Cheryl Tremblay

**Input by:** Lisa Mackay IYH/PACCB, Suzanne Desjardins HECSB/ODARS, Hanan Abramovici HECSB/ODARS, Bruna Brands HECSB/ODARS, Jocelyn Kula, HECSB/OCS, Robin Marles HPFB/NHPD, Maggie Graham HPFB/NHPD, Stephanie Collins HPFB/NHPD, Mano Murty HPFB/MHPD, Robert Leitch HPFB/MHPD, Shahid Perwaiz HPFB/MHPD, Collin Pinto, HPFB/HPFBI

**Approved by:**

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Lindsay Blaney, Director, Policy and Regulatory Affairs, NHPD (pending)  
Duc Vu, Director, Marketed Biologics, Biotechnology and Natural Health Products Bureau, MHPD (pending)  
Kim Dayman-Rutkas, Director, HPFBI (pending)  
Diane Allan, Director, OCS, CSTD, HECS (approved, Sept 29, 2010)  
Suzanne Desjardins, Director, ODARS, CSTD, HECS (approved, Sept 30, 2010)  
Cathy Sabiston, DG, CSTD, HECS (pending)  
Chris Turner, DG, MHPD (pending)  
Nancy Richards, DG, NHPD (pending)  
Diana Dowthwaite, DG, HPFBI (pending)  
Ken Polk, Communications Executive, HPFB (pending)  
Jean Tessier, Senior Media Relations, PACCB (pending)  
Warren Braun, Director, Strategic Communications, PACCB (pending)  
Peter Yendall, Director, Public Affairs, PACCB (pending)  
HECS Legal (pending)  
HPFB Legal (pending)  
Paul Glover, ADM, HECSB (pending)  
Meena Ballantyne, ADM, HPFB (pending)  
Anne Lamar, ADM, PACCB (pending)  
DMO (pending)  
MO (pending)

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**Re: Clarification**  
Courtney Smith to: Tiffany Thornton  
Cc: Denis Arsenault, Stephanie Chandler

2010-11-30 03:32 PM

From: Courtney Smith/HC-SC/GC/CA  
To: Tiffany Thornton/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC

---

Hello Tiffany;

I believe I said that the approximate number of records was 12 but that the numbers would be of limited use due to differences in reporting practices over time.

With more thorough searching, I have found a total of 26 (23 refused, 3 released) records of imports and attempted imports of Salvia in our databases.

I'm including some background information to be clear on the source and value of the data. These records come from two old databases used in BC and Ontario only. Other provinces, to my knowledge, were using excel and paper to track this information. These practices have since been replaced by a national database in which only refused shipments are tracked. There is no record of a refused shipment of Salvia in the national database. This may reflect decreased volume, decreased referral by CBSA, or adaptation by importers/sellers to the requirements (i.e. labelling as incense). The older ON and BC databases show a combined total of 26 records between 2003 and 2009.

All of this is meant to emphasize that careful wording is needed to avoid inaccuracy. Please feel free to give me a call if you have any questions.

Denis, the list of stakeholders who may be affected by the decision to schedule Salvia is forthcoming. I've asked Colin and his alternate on the WG to request this info from our regions.

Courtney Smith  
Border Integrity Specialist | Spécialiste, intégrité frontalière  
Border Integrity Unit | Unité d'intégrité frontalière  
Health Products and Food Branch Inspectorate | Inspectorat de la direction générale des produits de santé et des aliments  
Health Canada | Santé Canada  
B206 Graham Spry  
250 Lanark AL2002B  
Ottawa ON K1A 0K9  
Tel: 613-946-6863

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Tiffany Thornton      Hi Courtney, At the last CSS-WG you indicated t...      2010-11-30 08:51:01 AM

From: Tiffany Thornton/HC-SC/GC/CA  
To: Courtney Smith/HC-SC/GC/CA@HWC  
Date: 2010-11-30 08:51 AM  
Subject: Clarification

---

Hi Courtney,

At the last CSS-WG you indicated that you had verified the number of cases related to Salvia was 12 (note what I have said below from the ROD). You said this number was probably not useful but is correct that Suzanne said even though the # is small it still should be included in the IAS but with a caveat explaining



the reason why? Can you please confirm that this is what you said and the action item was that you would fwd the number and caveat to Denis? Please let me know as there is some confusion in the draft ROD over what was said.

Thanks very much,  
Tiffany

Courtney noted that she verified the importation cases at the border related to Salvia. She indicated that a total of twelve cases have been highlighted by CBSA. Suzanne indicated although limited cases exist they should be included in the IAS however a caveat should be inserted to explain the reason/s for the low number.

- Courtney to send Denis the number and caveat explanation

# Issue Analysis Summary

DRAFT

## Scheduling *Salvia Divinorum* under the CDSA

Regulatory Policy Division

Office of Controlled Substances

Controlled Substances and Tobacco and Directorate

December 6, 2010

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#### 1. APPROVALS

This Issue Analysis Summary is approved.

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Jocelyn Kula, A/Director  
Office of Controlled Substances  
Controlled Substances and Tobacco Directorate

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[DD/MM/2010]

#### 2. ISSUE

Health Canada has received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum* (*S. divinorum*) under the *Controlled Drugs and Substances Act* (CDSA). These requests are further to reports from scientific and media sources suggesting that *S. divinorum* is being used by youth specifically for its hallucinogenic properties. Health Canada has also noted an ongoing media interest regarding the availability of *S. divinorum* in Canada.

### 3. PURPOSE

To assess *S. divinorum* against the criteria for the addition of a substance to one of the Schedules to the CDSA, and determine whether this substance should be regulated as a controlled substance in Canada.

### 4. CONTEXT

*S. divinorum* is a species of sage which belongs to the mint family, and which is found in the form of dried leaves, extracts and plant cuttings. Also called "diviner's sage", the plant is known to induce illusions and hallucinations when chewed or smoked. Salvinorin A, the psychoactive ingredient in *S. divinorum* is a neoclerodane diterpene which is found primarily in the leaves, and to a lesser extent in the stem of the plant.<sup>1</sup>

*S. divinorum* is widely touted as a "legal" hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs among adolescents and young adults.<sup>2</sup> While very little is known about how and where *S. divinorum* is sold in Canada, it is suspected that it is mainly purchased over the Internet and/or bought at head shops or alternative life style stores, etc. *S. divinorum* cuttings are also available from a number of garden supply companies.

*S. divinorum* is a substance not currently scheduled under the CDSA. It can be imported and sold legally in Canada to anyone of any age, anywhere in Canada provided it is not sold as a health product or marketed as a hallucinogen. In addition, the *S. divinorum* sold in Canada is currently not subject to any specific quality or safety standards.

The use of *S. divinorum* as a psychotropic agent first came to Health Canada's attention in 2002. In 2004, Health Canada received four adverse drug reaction (ADR) reports associated with the use of *S. divinorum* as a hallucinogen, with three being considered non-serious (requiring no medical attention) and the fourth being considered serious (medical intervention was required). The serious ADR report involved the concomitant use of alcohol in a person diagnosed with Attention Deficit Disorder.

Further to the receipt of the aforementioned ADRs, the Marketed Health Products Directorate (MHPD) and the Natural Health Products Directorate (NHPD) of the Health Products and Food Branch (HPFB) prepared an issue analysis summary (IAS) in November 2005, which recommended that *S. divinorum* and its active ingredient salvinorin A be regulated as controlled substances. This recommendation was maintained when the IAS was updated in November

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<sup>1</sup> U.S. Department of Justice Drug Enforcement Administration. 2002. Drugs and Chemicals of Concern: Salvia Divinorum (salvinorin A, divinorin A) URL:

[http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm) Nov 2008

<sup>2</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.

2006.

Later, in December 2005, MHPD and NHPD prepared a Signal Assessment (SA) (updated in June 2007) that eventually led to the preparation of a Health Risk Assessment (HRA), which concluded that *S. divinorum* or salvinorin A-containing health products would constitute a Type II Health Risk according to the Health Hazard Classification of the Recall Policy of the Health Products and Food Branch Inspectorate (HBFBI). Such a risk is defined as “a situation in which the use of, or exposure to, a product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote”.

Further to a discussion with the Assistant Deputy Minister (ADM) of the Healthy Environments and Consumer Safety Branch (HECSB) in April 2007, the (then) Drug Strategy and Controlled Substances Directorate (DSCSD) (now the Controlled Substances and Tobacco Directorate, CSTD) organized a meeting with MHPD, NHPD and HPFBI to discuss *S. divinorum*. HPFBI was to determine appropriate compliance activities regarding *S. divinorum* and consult with the Canada Border Services Agency (CBSA) regarding the movement of products containing *S. divinorum* into and out of Canada.

On September 13, 2007, a further meeting between DSCSD, MHPD, NHPD and HPFBI led to the conclusion that DSCSD would conduct a scheduling assessment of *S. divinorum* in order to explore the possibility of scheduling this substance under the CDSA.

In September 2008, the Director Generals of DSCSD, MHPD, TPD and the HPFBI agreed that media lines and an “It’s Your Health” article on *S. divinorum* would be prepared.

#### **4.1 Relevant Legislative Frameworks in Canada**

##### **4.1.1 Food and Drug Regulations (under the Food and Drugs Act)**

The *Food and Drug Regulations* (F&DR) serve to ensure the safety, efficacy, and quality of health products offered for sale in Canada, including drugs and medical devices. Prior to being given market authorization, a manufacturer must present substantive scientific evidence that their product is safe, efficacious and of high quality. For drugs, Health Canada reviews this information carefully and, if the review is satisfactory, a Notice of Compliance (NOC) is issued and appropriate Drug Identification Numbers (DINs) are assigned.

A “drug” is defined under the F&DR as any substance or mixture of substances manufactured, sold or represented for use in:

(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,

(b) restoration, correction or modification of organic functions in human beings or animals, or

- (c) disinfection in premises in which food is manufactured, prepared or kept;

As no products containing *S. divinorum* or its extracts have been reviewed and approved by Health Canada as of October 2010, it is illegal to market *S. divinorum* when it is represented as a drug.

#### 4.1.2 Natural Health Products Regulations (under the Food and Drugs Act)

The *Natural Health Products Regulations* (NHPR) aim to provide Canadians with ready access to natural health products (NHPs) that are safe, effective, and of high quality, while respecting freedom of choice and philosophical and cultural diversity. The NHPR require that all licensed products display a Natural Product Number (NPN), or, in the case of a homeopathic medicine, a Drug Identification Number - Homeopathic Medicine (DIN-HM), on their labels. These numbers are issued once a product is authorized for sale in Canada. A product licence may be obtained pursuant to an application in which the applicant attests to all of the conditions set out in a natural health product monograph prepared and published by the Natural Health Products Directorate. Alternatively, an applicant may submit a product license application that provides evidence of quality, safety and efficacy that is assessed as being sufficient and approved by NHPD by the full submission route. The NHPR also require that all manufacturers, packagers, labelers, and importers have a site license issued on the basis of sufficient evidence of procedures respecting distribution records, product recalls, product handling, storage and delivery, and all other aspects of Good Manufacturing Practices as set out in the NHPR.

The definition of an NHP under the NHPR has both a function and substance component. The function component refers to those substances that are manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
- (b) restoring or correcting organic functions in humans; or
- (c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

The substance component refers to the requirement that all of the medicinal ingredients of an NHP must be substances set out in Schedule 1 (a list of included substances) to the NHPR, a traditional medicine or a homeopathic medicine, and none of the ingredients can be substances set out in Schedule 2, a list of excluded substances which includes any substance listed on Schedules I to V of the CDSA. Section 2(2) of the NHPR excludes those substances (except homeopathic medicines) whose sale is required to be pursuant to a prescription as per Section C.01.043 of the F&DR.

As per section 93(1)(b)(vi) of the NHPR, every natural health product must be labeled with its

authorized recommended use or purpose. In the case of *S. divinorum*, it is generally marketed for its hallucinogenic properties which are considered a modification of an organic function. Therefore products that contain *S. divinorum* and are manufactured, sold or represented for use as a hallucinogen meet the definition of an NHP.

As of October 2010, no products containing *S. divinorum* have been authorized by Health Canada. Therefore no NPNs or DIN-HMs have been issued for such products. Therefore sales of *S. divinorum* are illegal under the NHPR if the product is represented for use as a hallucinogen or if other health claims are made.

#### **4.1.3 Controlled Drugs and Substances Act and its Regulations**

The CDSA provides a legislative framework for the control of substances that can alter mental processes and that may produce harm to the health of an individual or to society when diverted or misused. Except as authorized under its regulations, activities such as possession, possession for the purposes of trafficking, trafficking, importation, exportation, possession for the purposes of exportation and production of controlled substances are prohibited under the CDSA.

The substances regulated under the CDSA are grouped into eight Schedules, and each Schedule is associated with particular offences and penalties as described in Part I of the CDSA.

In determining whether a substance should be regulated as a controlled substance, and into which Schedule of the CDSA it should be placed, Health Canada considers the following factors:

- International requirements and trends in control and/or scheduling;
- Chemical and/or pharmacological similarity to substances listed in the Schedules to the CDSA;
- Legitimate use of the substance, including therapeutic, scientific, or industrial uses;
- Potential for abuse and/or addiction liability;
- Evidence of extent of actual abuse of the substance in Canada and internationally; and
- Risk to personal and public health and safety.

#### **4.2 Assessment of *S. Divinorum* for Scheduling Purposes**

##### **4.2.1 International Requirements and Trends in Control and/or Scheduling**

At the present time, neither *S. divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and therefore do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

##### ***Australia***

In June 2002, Australia became the first country to prohibit the sale, supply, possession and use of *S. divinorum* and salvinorin A. Both *S. divinorum* and salvinorin A are listed in Schedule 9 of

Australia's *Standard for the Uniform Scheduling of Drugs and Poisons* on the basis of "high potential for abuse and risk to public health and safety."<sup>3</sup> Schedule 9 is Australia's most restrictive drug schedule, and includes "substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities."<sup>4</sup>

### ***Belgium***

A decree was passed in Belgium on October 22, 2006 which added *S. divinorum* to the list of controlled substances. This list includes substances such as psilocybin mushrooms, khat and peyote cactus.<sup>5</sup>

### ***Denmark***

In 2003, Denmark added *S. divinorum* and salvinorin A to their list of "category B" controlled substances, a category which also includes psilocybin mushrooms, cocaine, amphetamine, and several others substances that are only legal for medicinal and scientific purposes. Illegal possession carries a penalty of up to two years in prison.

### ***Germany***

*S. divinorum* (plant and plant parts) was added to Appendix I of the *Narcotics Act* in Germany on March 1, 2008, making it illegal to produce, traffic, or possess. The law does not specifically mention salvinorin A.

### ***Italy***

On June 25, 2004, the Italian Ministry of Health issued an ordinance prohibiting the sale of *S. divinorum* and its active constituent salvinorin A. On January 11, 2005, the Ministry of Health made possession of *S. divinorum* and salvinorin A illegal by placing them in "*Tabella I*" of the *Tabella Sostanze Stupefacenti o Psicotrope*.

### ***Japan***

On November 9, 2006, the Japanese government added a group of thirty-three drugs to its list of controlled substances, including salvinorin A. The drugs are banned under a revised pharmaceutical law, under which persons involved in their illegal import, production, and sale, i.e. beyond medical treatment or research purposes, will be subject to up to five years

<sup>3</sup> <http://www.tga.gov.au/ndpsc/record/rr200111.pdf>

<sup>4</sup> [http://www.cognitiveliberty.org/news/salvia\\_australia.htm](http://www.cognitiveliberty.org/news/salvia_australia.htm)

<sup>5</sup>

<http://eldd.emcdda.europa.eu/html.cfm/index5176EN.html?pluginMethod=eldd.shownewsdetails&id=20/12/2006BELGIUM:%20New%20substances%20controlled%20include%20mCPP%20and%20khat>

imprisonment or a fine of up to five million yen.

### ***Spain***

On January 28, 2004, the Spanish Ministry of Health and Consumption issued an order prohibiting the sale of *S. divinorum*. The regulation went into effect on May 6, 2004 and only prohibits activities related to commerce. Possession and/or use are not considered to be criminal offences.

### ***Other Countries***

It is illegal to possess or sell *S. divinorum* in Croatia, Latvia, Lithuania, Poland, Romania, South Korea and Sweden. In Russia it is illegal to grow or sell *S. divinorum*, but it is legal to possess it. In Estonia, Finland, Iceland and Norway, *S. divinorum* is treated as a medicinal herb and it is illegal to import it without a relevant prescription from a doctor.

### ***United States of America***

*S. divinorum* and salvinorin A are not included in the Schedules to the United States *Controlled Substances Act*. Although both *S. divinorum* and salvinorin A have been added to a list of chemicals "of concern", this has no legal implications. According to the National Institute for Drug Abuse, the Drug Enforcement Administration is considering classifying *S. divinorum* and/or salvinorin A as Schedule I drugs. This Schedule includes substances such as LSD and marihuana.

At the state level, some state legislatures have implemented laws restricting the use, sale and/or distribution of *S. divinorum* and/or salvinorin A. As of July 2010, a number of states have placed regulatory controls on *S. divinorum* and/or salvinorin A including Delaware, Georgia, Florida, Hawaii, Illinois, Kansas, Kentucky, Maryland, Mississippi, Missouri, Nebraska, North Dakota, Ohio, Oklahoma, South Dakota, Wisconsin, Virginia, California, Louisiana, Maine, North Carolina, and Tennessee. By way of example, additional details regarding the regulation of *S. divinorum* in these last five states are provided below.

#### ***California***

As of January 1, 2009, the sale or distribution of *S. divinorum* or salvinorin A, or any substance or material containing *S. divinorum* or salvinorin A, to any person under 18 years of age is a misdemeanor punishable by imprisonment in a county jail for not more than six months, a fine of no more than \$1,000, or both.

#### ***Louisiana***

In 2005, Louisiana passed a bill which prohibits the possession, production, manufacture and distribution of a material, compound, mixture, or preparation intended for human



consumption and that contains a hallucinogenic plant. A "hallucinogenic plant" is defined as "any part or portion" of a plant on a list of forty plants, which includes *S. divinorum*.

### **Maine**

In Maine, *S. divinorum* and salvinorin A are regulated in the same way as tobacco products; adults eighteen years of age or over can legally purchase and use the material, but selling or providing *S. divinorum* or salvinorin A to anyone under the age of eighteen is a criminal offence. Possession by a minor is a civil violation, punishable by a fine, community service, or both.

### **North Carolina**

On December 1, 2009, the North Carolina State Legislature brought a new law into force which made *S. divinorum* and salvinorin A illegal. The only legal *S. divinorum* activities are the growing for aesthetic, landscaping, or decorative purposes or university-affiliated medical or pharmacological research.

### **Tennessee**

On July 1, 2006, Tennessee classified the deliberate production, manufacture, distribution, or possession of the active chemical ingredient in the hallucinogenic plant *S. divinorum* as a Class A misdemeanor. It is not, however, a criminal offence to possess, plant, cultivate, grow, or harvest *S. divinorum* for aesthetic, landscaping, or decorative purposes. The law also does not apply to any dosage that is legally obtainable from a retail establishment without a prescription when (and if) it is recognized by the Food and Drug Administration as a homeopathic drug.

#### **4.2.2 Chemical and/or Pharmacological Similarity to Substances Listed in the Schedules to the CDSA**

The psychoactive ingredient in *S. divinorum* is the neoclerodane diterpene salvinorin A.<sup>6</sup> As a diterpene, salvinorin A is part of a family of substances that contain terpenoids. Another plant which contains psychotropic terpenoids is *Artemisia absinthium* (wormwood).<sup>7</sup> Salvinorin A is a hallucinogen with a distinct structure and it does not interact with the serotonin type-2A receptor or any other molecular target of classical hallucinogens.<sup>8</sup> Instead, the available research suggests that the psychotropic effects of salvinorin A are mediated by its agonistic actions at the  $\kappa$ -opioid

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<sup>6</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage *Salvia divinorum*. *Life Sci.* 2005 Dec 22;78(5):527-31.

<sup>7</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.

(KOR) receptor.<sup>9</sup> Its mechanism of action is therefore unique.<sup>10</sup>

The psychoactive effects of *S. divinorum* vary in onset and duration and include perceptual distortions such as the sensation of becoming an object, having visions of various two-dimensional surfaces, films and membranes, revisiting places of the past (particularly childhood), perceived loss of the body and/or identity, various sensations of motion (being pulled or twisted by a force of some kind), uncontrollable hysterical laughter, and overlapping realities (perceptions of being in more than one place).<sup>11</sup> Laughter, happiness, a sense of well-being and dissociative effects were deemed the most positive aspects of *S. divinorum* by users, second only to the "trip" that the drug elicits.<sup>12</sup> Depersonalization, speaking gibberish, widening of consciousness and subjective illusions of rapid movement, flying or hovering have also been reported.<sup>13</sup>

The psychotomimetic effects of *S. divinorum* closely resemble the schizoid symptoms induced by lysergic acid diethylamide (LSD) or phencyclidine (PCP).<sup>14</sup> Yet, it is said to have only a weak influence on the prevailing mood of the user which differentiates it from other hallucinogens such as LSD and psilocybin.<sup>15</sup> Its strong dissociative effects are often compared to those of ketamine.<sup>16</sup> Users have reported that the psychedelic effects of *S. divinorum* were most similar to those caused by psilocybin mushrooms.<sup>17</sup> However, users familiar with the effects of other hallucinogens agree that despite certain similarities to classical hallucinogens, the visions and overall experience are quite unique.<sup>18</sup>

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<sup>9</sup> Roth BL, Baner K, Westkaemper R, Siebert D, Rice KC, Steinberg S, Ernsberger P, Rothman RB. Salvinorin A: a potent naturally occurring nonnitrogenous kappa opioid selective agonist. Proc Natl Acad Sci U S A. 2002 Sep 3;99(18):11934-9.

<sup>10</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>11</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>12</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>13</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5 and Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>14</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5.

<sup>15</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>16</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five Salvia divinorum herbal products. Pharmacotherapy. 2006 Sep;26(9):1268-72.

<sup>17</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>18</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6 and González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

*S. divinorum* causes an unusually high degree of sedation, weakness and fatigue, and the increased de-realization is not commonly reported for classical psychedelics.<sup>19</sup> The combination of these effects seems to correlate with that of other KOR agonists such as pentazocine.<sup>20</sup>

The onset and intensity of the effects of *S. divinorum* appear to be related to the route of administration. Traditional uses generally produce mild effects because the leaves are rolled and chewed or crushed and prepared as a foamy infusion whereby the salvinorin A is degraded in the gastrointestinal system before being absorbed into the bloodstream. Hence, the level of effect relates quite closely to the length of time the material spends in the mouth, with the onset of effect generally taking 5-10 minutes. The effects build over the next hour and last for another hour before they begin to subside.<sup>21</sup>

Routes of administration that avoid the hepatic first-pass effect (i.e. inhalation, intravenous, intramuscular and sublingual use) provide the quickest and most intense effect.<sup>22</sup> Salvinorin A can be isolated from the plant to make a powder which can be vaporized and inhaled. The effects felt from vaporizing salvinorin A are experienced in about 30 seconds, last for about 5-10 minutes, and then subside over the next 30 minutes.<sup>23</sup>

Smoking the dried leaves or a concentrated extract using a pipe or bong is by far the most popular method of administration.<sup>24</sup> Dried leaves may also be fortified with a concentrated extract of salvinorin A. A concentrated extract can also be used sublingually. Neither *S. divinorum* nor salvinorin A can be injected because the powder is insoluble in water.<sup>25</sup>

#### 4.2.3 Legitimate Use of the Substance (Therapeutic, Scientific, Industrial)

*S. divinorum* has traditionally been used for spiritual and medicinal purposes by the Mazatec Indians in Oaxaca, Mexico.<sup>26</sup> For medicinal purposes (gastrointestinal problems, headaches,

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<sup>19</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>20</sup> Arasteh K, Poudevida S, Farre M, Roset PN, Cami J. Response patterns of the Spanish version of the 49-item short form of the Addiction Research Center Inventory after the use of sedatives, stimulants, and opioids. *Drug Alcohol Depend.* 1999 Jun 1;55(1-2):117-25.

<sup>21</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>22</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.

<sup>23</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>24</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62 and Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>25</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (*divinorin*) A. *J Psychoactive Drugs.* 1994 Jul-Sep;26(3):277-83.

<sup>26</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

rheumatism, anemia and swelling of the stomach) an infusion of the leaves or the leaves themselves are ingested.<sup>27</sup> However, its main use in Mexico today is believed to be for its psychedelic properties in the aid of producing “mystical” or hallucinogenic experiences as part of spiritual rituals.<sup>28</sup>

Although selective KOR agonists have been shown to produce analgesic effects, adverse effects such as psychotomimesis, dysphoria and diuresis have been observed in studies investigating their therapeutic use.<sup>29</sup> In addition, while it has been speculated that KOR agonists may be useful in the treatment of certain psychiatric disorders including Alzheimer’s disease, schizophrenia, dementia and bipolar disorder, there has been no clinical research to support these hypotheses.<sup>30</sup> There are presently no recognized medical uses for *S. divinorum* in Canada.

Similarly, there are no known industrial or commercial uses for *S. divinorum* in Canada. Most websites offering *S. divinorum* cuttings and seeds for sale appear to do so in the context of growing the plant for “recreational” purposes, rather than out of horticultural interest or for its esthetic appeal. However, it should be acknowledged that this does not preclude the possibility of a person growing this plant for purely decorative purposes. *S. divinorum* is also marketed as incense. However, there is no evidence that *S. divinorum* has any fragrant properties that would legitimize such a use. Therefore it is believed that the marketing of this plant as an incense is a means to avoid compliance and enforcement actions by Health Canada.

#### 4.2.4 Potential for Abuse and/or Addiction Liability

Salvinorin A is a potent, KOR-selective agonist and in contrast to the euphoria produced by MOR agonists such as morphine, KOR agonists are negatively reinforcing and aversive.<sup>31</sup> In addition, KOR agonists have analgesic properties, but are not associated with respiratory depression like MOR agonists.<sup>32</sup> Finally, while MOR agonists increase the release of dopamine, the activation of KOR decreases dopamine release in the nucleus accumbens.<sup>33</sup> In the case of

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<sup>27</sup> Munro, T. The Chemistry of Salvia divinorum. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

<sup>28</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage Salvia divinorum. Life Sci. 2005 Dec 22;78(5):527-31.

<sup>29</sup> Barker RL, Fawcett J, Barkin SJ. 2002. Chronic pain management with a focus on the role of newer antidepressants and centrally acting agents. In: Pain Management: A Practical Guide for Clinicians, 6th edition, Weiner RS ed. CRC Press, Boca Raton, FL. pp. 415-34 and Tidgewell et al., 2004. A facile method for the preparation of deuterium labelled salvinorin A: Biorganic & Medicinal Chemistry Letters, 14: 5099-5102.

<sup>30</sup> Sheffler DJ & Roth BL. Salvinorin A: the ‘magic mint’ hallucinogen finds a molecular target in the kappa opioid receptor. Trends Pharmacol Sci. 2003 Mar;24(3):107-109.

<sup>31</sup> Killinger BA, Peet MM, Baker LE. Salvinorin A fails to substitute for the discriminative stimulus effects of LSD or ketamine in Sprague–Dawley rats. Pharmacology, Biochemistry & Behaviour. 2010 May 96; 260-265.

<sup>32</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.

<sup>33</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.

MOR agonists, the increase of dopamine acts as a positive reinforcer. This action motivates the user to use the drug again, which could lead to drug abuse and/or addiction. For KOR agonists, this is not the case.

The aversive effects of KOR agonists suggest that the risk of addiction to *S. divinorum* is negligible. Users have reported the negative effects of *S. divinorum* as: the short duration of action, lack of control over the experience, persisting negative effects (most often anxiety),<sup>34</sup> sweating, chills, increased diuresis, impaired vigilance,<sup>35</sup> and negative after-effects including tiredness, feeling head heavy, dizziness, physical exhaustion, and some degree of malaise or 'hangover' as they 'comedown' from the drug.<sup>36</sup> Despite these reports, very few controlled scientific studies of the physical and psychotropic effects of *S. divinorum* on humans have been carried out and the results have been conflicting. For example, one author states: "Many who have used salvinorin A find the experience extremely unnerving, frightening and overly intense and most have no desire to repeat the experience."<sup>37</sup> However, another study suggested that this is not the experience of all recreational users of *S. divinorum*.<sup>38</sup> Over eighty percent of users surveyed on a web-based questionnaire about their *S. divinorum* use said that they would probably or definitely use *S. divinorum* again.<sup>39</sup>

In addition, some users have noted that they require increasing doses of salvinorin A in order to achieve the desired effect and the stimulated cerebral KOR may act as a mechanism of tolerance.<sup>40</sup> Therefore, it is difficult to predict with certainty its potential for addiction and abuse. In studies that have been conducted, there is conflicting information around the addiction liability of *S. divinorum* in both animals and humans. Further studies in this area and on the KOR mediated decrease of dopamine are also required in order to fully understand the addiction potential of this substance.

While concerns for the potential of abuse were initially considered minimal given that 1 kg of

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<sup>34</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>35</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>36</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>37</sup> Turner DM. *Salvinorin - The Psychedelic Essence of Salvia Divinorum*. Panther Press, San Francisco, CA 1996.

<sup>38</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62, Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5, and Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs*. 1994 Jul-Sep;26(3):277-83.

<sup>39</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>40</sup> Bucheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

dried leaves only yield 3 to 6 human doses of salvinorin A for oral consumption, it was then discovered that vaporizing and inhaling 200-500 micrograms has profound hallucinogenic effects.<sup>41</sup> Given that only small doses of this substance are now necessary to achieve the desired effects through inhalation, the potential for abuse is much higher. Also, the extraction of salvinorin A from the plant is simple, and with care, approximately 1.5 grams of pure salvinorin A per kilogram of dried leaves (8kg of fresh leaves) can be isolated. This is enough for 2000 oral doses.<sup>42</sup>

#### 4.2.5 Evidence of Extent of Actual Abuse of the Substance in Canada and Internationally

In Canada, the prevalence of use of *S. divinorum* has recently been documented. Questions about the use of salvia were included in the 2009 Ontario Student Drug Use and Health Survey, the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey.\*

The results from the 2009 Ontario Student Drug Use and Health Survey were published on November 18, 2009 and indicate that:

- Among all responding students in Ontario, 4.4% reported using *S. divinorum* at least once in the past year. In comparison, 58.2% indicated they had used alcohol, 25.6% indicated they had used cannabis and 5.0% indicated they had used hallucinogens other than LSD and PCP in the past year;
- Males (6.2%) were significantly more likely than females (2.3%) to report using *S. divinorum*;
- There is significant grade variation, with *S. divinorum* use most likely among 11<sup>th</sup> graders (8.6%) and 12<sup>th</sup> graders (8.4%); and

The results of the 2008-2009 Youth Smoking Survey were published on May 31, 2010 and indicate that:

- 4.9% of students stated that they had used salvia in the last twelve months. In comparison, 53.0% indicated they had used alcohol, 27.3% indicated they had used cannabis and 6.9% indicated they had used other hallucinogens in the last twelve months;
- 2.6% of students in Grades 7-9 and 7.0% of students in Grades 10-12 had used salvia in the last twelve months; and

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<sup>41</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>42</sup> Valdès LJ 3rd. Salvia divinorum and the unique diterpene hallucinogen, Salvinorin (divinorin) A. J Psychoactive Drugs. 1994 Jul-Sep;26(3):277-83.

\* It should be noted that in some cases it is not clear if responses indicate the use of *S. divinorum* or salvinorin A given the use of the term "salvia" within the survey question.

- Males (6.6%) were more likely to have used salvia in the past twelve months compared to females (3.2%).

The Canadian Alcohol and Drug Use Monitoring Survey specifically examined salvia for the first time in 2009. An estimated 1.6% of Canadians, aged 15 years and older, reported that they had used salvia in their lifetime, and 0.2% reported using it in the past-year. In comparison, the prevalence of past-year cannabis use among Canadians 15 years of age and older was 10.6%, while 1.2% of respondents reported using cocaine or crack in the past 12 months, 0.9% ecstasy and 0.7% illicit hallucinogens. In conclusion, 'salvia' appears to be a substance that is tried largely by youth with a 7.3% prevalence of lifetime use.

According to the 2009 Monitoring the Future survey, the annual prevalence of use of *S. divinorum* among 12th graders in the United States is 5.7%. The American Substance Abuse and Mental Health Services Administration's 2006 National Survey on Drug Use and Health found that, of respondents aged 12 or older, 1.8 million had used *S. divinorum* at least once in their lifetime and 756,000 had used the substance in the past year. Among youth aged 12 to 17, males were more likely than females to have used *S. divinorum* in the past year (0.9% vs. 0.3%).

Health Canada's Drug Analysis Services (DAS) has identified salvinorin A in a number of samples seized by law enforcement, ranging from 9 samples in 2006 to 20 samples in 2009. It is, however, difficult to determine how this data reflects the extent of actual abuse of salvinorin A in Canada, given that it is not an illegal substance and would likely only be seized accidentally or during the seizure of other controlled substances.

Between 2003 and 2009, the Border Integrity Unit of the Health Products and Food Branch Inspectorate (HPFBI) reported that a total of 26 (23 refused, 3 released) records of imports and attempted imports of *Salvia divinorum* products in their databases. These records represent British Columbia and Ontario only. Data for other provinces is not available. However, the practice of recording imports has since been replaced by a national database in which only refused shipments are tracked. As of November 2010, there is no record of a refused shipment of *Salvia divinorum* in the national database. This may reflect decreased volume of incoming shipments, decreased referral of such shipments by Canada Border Services Agency (CBSA), or adaptation by importers/sellers to import requirements (e.g. labelling as incense).

The National Forensic Laboratory Information System (NFLIS) and the System to Retrieve Information from Drug Evidence (STRIDE) in the United States are Drug Enforcement Administration (DEA) databases that collect scientifically verified data on analyzed samples in state and local forensic labs as well as samples from DEA labs. While in 2000 no seized samples were found to contain *S. divinorum* or salvinorin A, 70 samples tested positive in 2008. Once again, it is difficult to determine how this data can be used to reflect the actual extent of abuse of *S. divinorum* and salvinorin A in the United States as neither substance is listed in the *Controlled Substances Act*.

The increase in both the number of enquiries to Health Canada from various municipalities and members of the public and the amount of media interest regarding the availability of *S. divinorum* in Canada may be an indication that the recreational use of *S. divinorum* as a

hallucinogen is on the rise. However, it may also reflect an increased awareness of the phenomenon, rather than an increased incidence of use.

#### 4.2.6 Risk to Personal and Public Health and Safety

The potential for harm to the user and/or other individuals is primarily related to the hallucinogenic properties of the substance. As this substance is typically smoked, there is no risk of infectious disease transmission as is the case when a drug is injected. Users may get up and walk around without apparent awareness of their movements, behaviour or surroundings, and distinction between self and surroundings is often lost. At doses greater than 1mg of salvinorin A, out of body experiences are frequent and loss of consciousness has been reported.<sup>43</sup> There is little information regarding the social behaviours of persons under the influence of *S. divinorum* products, and what risks their activities such as operating a motorized vehicle may pose to the general public. There is also very little data regarding the toxicity, teratogenicity or other long-term effects of *S. divinorum* use.<sup>44</sup>

As far as law enforcement is concerned, the Department has only received a limited number of communications indicating concern with respect to *S. divinorum*. The Royal Canadian Mounted Police (RCMP) has stated that while *S. divinorum* is readily available, it has not become a popular drug in Canada, probably due to its aversive effects such as anxiety and introversion.

A handful of case reports regarding physiological and psychotropic effects of *S. divinorum* use have been published in the scientific/medical literature. For example, an international case report described the perceptions of a 19 year-old man after inhaling *S. divinorum* smoke. The peak psychotropic effects, including prickling of the skin, fever-like hot flashes, muscular tremor, and depersonalization, were reached in less than five minutes after inhalation of an unknown amount of smoke from burning dried leaves.<sup>45</sup> Another report involved a 15-year-old male who presented to psychiatric emergency services with acute onset of paranoia, déjà vu, blunted affect, difficulties in thought processing and slowed speech after smoking *S. divinorum* over an unknown period of time. During his hospitalization all symptoms improved significantly except the feeling of déjà vu. Based on this case presentation, the author suggested that the feelings of déjà vu may be a long-term effect of *S. divinorum* use.<sup>46</sup> However, given that this is the only case report in which déjà vu was associated with the use of *S. divinorum*, more reports are needed to substantiate this finding.

In addition to the above-mentioned reports, in 2006, a case was reported in the U.S. in which a 17-year-old boy committed suicide after smoking *S. divinorum* for an unknown period of time.<sup>47</sup> It should be noted that alcohol and general depression were the main confounders in this case. After this case was reported, the state of Delaware passed a law which classified *S. divinorum* as a Schedule I controlled substance along with other hallucinogenic substances.

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<sup>43</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>44</sup> Grundmann O, Phipps SM, Zadezensky I, Butterweck V. *Salvia divinorum* and Salvinorin A: An Update on Pharmacology and Analytical Methodology. Planta Med 2007 Jun;73:1039-1046.

<sup>46</sup> Singh S. (2007) Adolescent salvia substance abuse. Addiction. 102, 823-824.

<sup>47</sup> <http://www.kvbc.com/Global/story.asp?S=4893692>



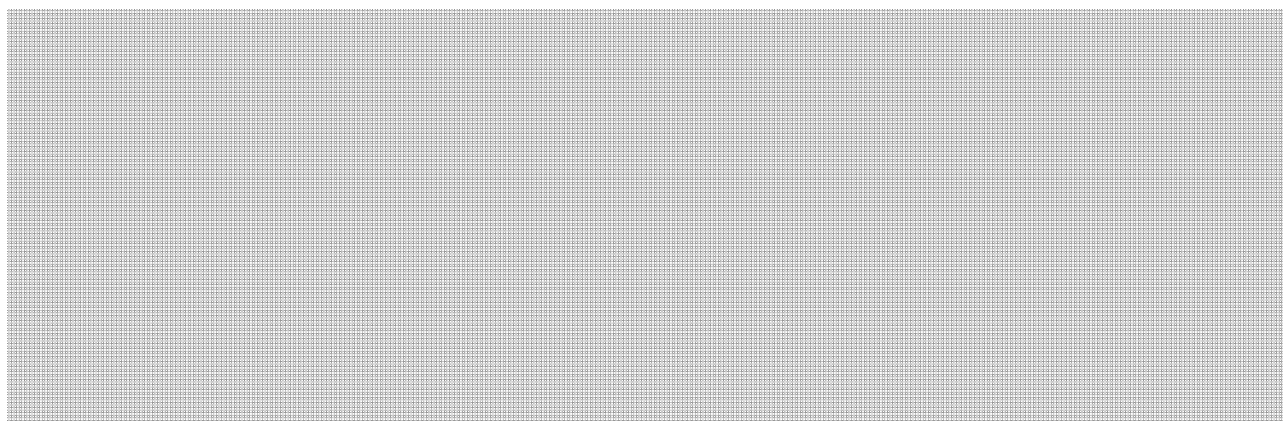
**s.21(1)(a)**

**s.21(1)(b)**

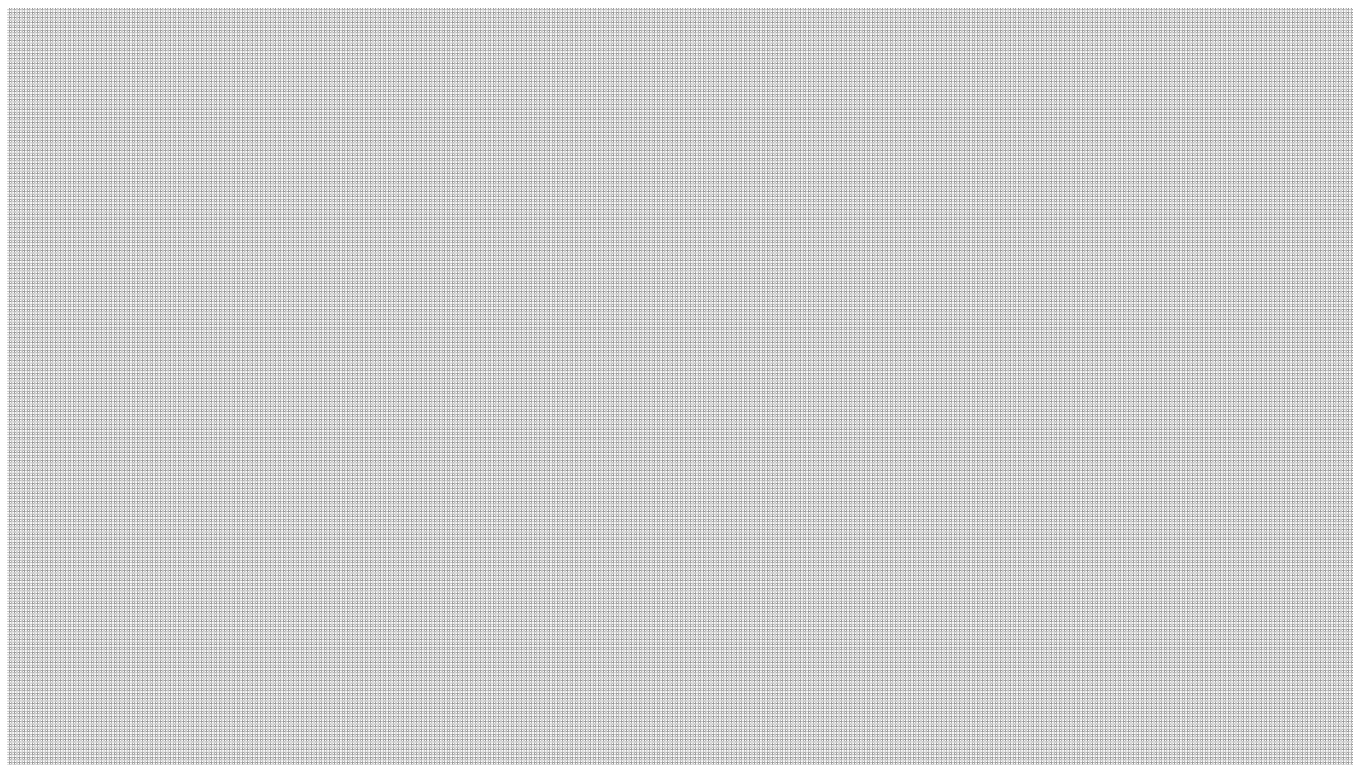
Like many drugs of abuse, users are often unaware of the potency and adulterants in the product they purchase. A study by Wolowich *et al.* (2006), showed that the salvinorin A content in five out of five *S. divinorum* products was falsely indicated on the label and 4 out of 5 products contained unidentified adulterants (i.e. vitamin E, caffeine).<sup>48</sup>

There are also several reports of domestic adverse reactions related to the use of *S. divinorum* that have been received through the Canada Vigilance database. However, this does not reflect true incidence due to under-reporting.

## **5. ASSESSMENT OF RISKS AND BENEFITS**



## **6. IDENTIFICATION AND ANALYSIS OF OPTIONS**



<sup>48</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

## 7. CONSIDERATIONS

The NHPR are limited in their capacity to control the availability of *S. divinorum* in that *S. divinorum* products are often declared as incense and therefore cannot be considered unapproved natural health products. In addition, compliance and enforcement actions such as voluntary stop-sales, forfeiture, destruction, and administrative seizure, cannot be implemented unless the marketing of the product indicates that it is to be sold for human consumption in order to modify an organic function. Unlicensed natural health products are also permitted to be imported provided they are for personal use only.

Non-regulatory options for the control of *S. divinorum*, such as the development of an educational campaign to highlight the risks associated with using this plant, were also

considered. However, the risks associated with this substance, as well as the confusion concerning its enforcement as a natural health product only when it is sold for use with a health claim, do not make this option viable.

*S. divinorum* meets the criteria for scheduling a substance under the CDSA. While neither the plant nor its main active component salvinorin A are scheduled under any of the UN Drug Control Conventions, a number of countries and American states have taken steps to control the distribution and use of these substances. *S. divinorum* and salvinorin A are pharmacologically similar to other substances included in Schedule III to the CDSA, such as LSD and psilocybin. There are also currently no legitimate therapeutic, commercial or industrial uses for *S. divinorum*.

While the addiction potential of *S. divinorum* appears to be low, there is a significant potential for its abuse as a 'legal' hallucinogen. There is very little information with regards to the long-term effects of *S. divinorum* use. There is also evidence of use, particularly by Canadian youth and potential for individual health risks as well as risks to public health and safety.

In light of a recommendation to include *S. divinorum* under Schedule III to the CDSA, it is also recommended that the main psychoactive ingredient of this plant, salvinorin A, be scheduled. Salvinorin A can easily be extracted from *S. divinorum* and this substance gives the plant its hallucinogenic properties. Therefore the use of salvinorin A poses the same risks as *S. divinorum* and should also be controlled under the CDSA in the same manner as *S. divinorum*.

## 8. RECOMMENDATIONS

## 9. CONSULTATIONS

The Drug Analysis Services (DAS) was contacted in order to provide any data available regarding the identification of salvinorin A in samples submitted by law enforcement.

The Royal Canadian Mounted Police (RCMP) was contacted in order to establish their views with respect to *S. divinorum* use in Canada. The RCMP advised that *S. divinorum* is readily available and law enforcement agencies have no legal means to prevent its sale.

OCS has received a number of correspondences from Canada Border Services Agency (CBSA) officers concerning a lack of information regarding the status of *S. divinorum* and how the plant should be treated at the border. CBSA officers have also expressed concern regarding the plant's hallucinogenic properties. At present, only shipments of *S. divinorum* that are represented for sale as health products that modify organic functions can be refused for import under the NHPR.

OCS brought *S. divinorum* to the Controlled Substances Scheduling Working Group (CSS-WG) in August 2010 to discuss the possibility of regulatory control of this substance. After assessing the available information against the six criteria listed in the Context section of this Issue Analysis Summary, the CSS-WG recommended that *S. divinorum* be included under Schedule III to the CDSA.

**Page(s) 001793 to\à 001793**

**Is(Are) exempted pursuant to section(s)  
est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**



**Salvia MLs and NOI - REVISED**  
Denis Arsenault to: Jocelyn Kula  
Cc: CSTD-OCS-DO, Stephanie Chandler

2010-12-06 09:41 AM

Hi Jocelyn,

Below for your review and approval are revised versions of the salvia MLs and NOI.

Denis

---

Denis Arsenault, A/Manager / Gestionnaire p.i.  
Regulatory Policy Division /  
Division des politiques réglementaires,  
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----- Forwarded by Denis Arsenault/HC-SC/GC/CA on 2010-12-06 09:39 AM -----

From: Stephanie Chandler/HC-SC/GC/CA  
To: Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2010-12-06 09:33 AM  
Subject: Salvia MLs and NOI

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Hi Denis,

Here are the revised Salvia MLs and NOI.



Salvia Media Lines\_Dec 6.doc



DRAFT Salvia NOI\_Dec 6.wpd

Stephanie

DRAFT 14  
November 26, 2010

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### Media Lines *Salvia divinorum*

#### Issue

Further to ongoing media interest regarding the availability of *Salvia divinorum* in Canada and reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties, Health Canada is now proposing that *Salvia divinorum* should be included in one of the Schedules to the *Controlled Drugs and Substances Act (CDSA)*.

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#### Key Messages:

- Health Canada is proposing that *S. divinorum* and salvinorin A be regulated as controlled substances under the *Controlled Drugs and Substances Act (CDSA)*. This decision is based on analysis of the information available about *S. divinorum* and salvinorin A as well as an assessment of the possible options to manage the risks associated with the availability of these substances in Canada.
- Health Canada will issue a *Notice to Interested Parties (NOI)* stating that it intends to add *S. divinorum* and its main active ingredient, salvinorin A, to Schedule III to the CDSA. The NOI will provide stakeholders and other interested parties with the opportunity to provide comments on the proposal to regulate these substances as controlled substances.
- The inclusion of *S. divinorum* and salvinorin A in Schedule III to the CDSA will mitigate the risks associated with their use and availability.

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#### Supplementary Messages:

- Canadians should not use products containing *S. divinorum* and/or salvinorin A because very little is known about these substances and their potential effects on the brain and/or body, and their impact on physical and mental functions.
- Because of their hallucinogenic properties, products containing *S. divinorum* and/or salvinorin A meet the definition of a natural health product (NHP) under the Natural Health Products Regulations and the definition of a drug under the Food and Drugs Act.
- It is illegal to sell NHPs in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN). The illegal sale of products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*.

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Deleted: <#>Because of their hallucinogenic properties, products containing *S. divinorum* and/or salvinorin A meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*. ¶  
It is illegal to sell NHPs in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN). The illegal sale of products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*. ¶

- Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and thus, do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.
- The move to include *S. divinorum* and salvinorin A in Schedule III to the CDSA is consistent with actions taken by several countries (Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) who have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. It is also consistent with the fact that some individual U.S. states have implemented laws restricting their use, sale and/or distribution.

#### Questions and Answers:

**Q1 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why isn't it illegal?**

A1 – Health Canada intends to include *S. divinorum* and salvinorin A under Schedule III to the CDSA. In the interim, as *S. divinorum* meets the definition of a Natural Health Product (NHP) under the *Natural Health Product Regulations*, it is illegal to manufacture, sell or provide products containing *S. divinorum* and/or salvinorin A without their being authorized by Health Canada prior to sale.

**Q2 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?**

A2 – The *Natural Health Products Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *Salvia divinorum*. When *S. divinorum* and salvinorin A are included in Schedule III to the CDSA, it will be illegal to possess, import, export, produce and distribute these substance in any form unless authorized by regulation.

**Q3 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A3 – Once *S. divinorum* and salvinorin A are included in Schedule III to the CDSA, law enforcement will be able to take appropriate action in response to suspected illegal activities with these substances.

In the interim, *S. divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. Complaints about the illegal sale of drugs containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

**Q4 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum* as a controlled substance. What does that involve and what stage is it at?**

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*Salvia divinorum* as a controlled substance:¶  
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<#>In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA). ¶  
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A4 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada recently concluded its assessment of *S. divinorum* and salvinorin A against the aforementioned factors and proposes to include both substances in Schedule III to the CDSA.

**Q5 – What is the significance of the adverse reaction reports that Health Canada has received with respect to the use of *Salvia divinorum*?**

A5 – Health Canada has received four domestic adverse reaction reports related to the use of *Salvia divinorum* as a hallucinogen through the Canada Vigilance database. The number of reports and the nature of reactions reported are, however, not adequate to fully characterize the risk of similar reactions among the general population

***If pressed on whether Health Canada has issued any kind of warning to Canadians about *Salvia divinorum****

A - Health Canada is developing an It's Your Health (IYH) article on *Salvia divinorum* to help inform the general public about the risks associated with the use of this substance.

### **Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

Data from the 2008-2009 Youth Smoking Survey indicates that:

- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;
- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year; and.

**Deleted:** Health Canada is currently reviewing the available information to determine whether regulation of *Salvia divinorum* under the CDSA is warranted.¶

¶  
**Q5 – Didn't an internal report from Health Canada's Marketed Health Products Directorate recommend that *Salvia divinorum* be scheduled under the CDSA? Why has that recommendation not been acted upon?**¶

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A5 – See A4¶

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- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using Salvia in their lifetime (0.2% in the past year); and
- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that:

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;
- 5.4% of students (grades 7-12) ever used *S. divinorum*; and
- the use of *S. divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

**Prepared by:** Stephanie Chandler and Denis Arsenault, OCS, CSTD

**Deleted:** Cheryl Tremblay

**Input by:** Lisa Mackay IYH/PACCB, Suzanne Desjardins HECSB/ODARS, Hanan Abramovici HECSB/ODARS, Bruna Brands HECSB/ODARS, Jocelyn Kula, HECSB/OCS, Robin Marles HPFB/NHPD, Maggie Graham HPFB/NHPD, Stephanie Collins HPFB/NHPD, Mano Murty HPFB/MHPD, Robert Leitch HPFB/MHPD, Shahid Perwaiz HPFB/MHPD, Collin Pinto, HPFB/HPFBI

**Approved by:**

Robin Marles, Director, Bureau of Clinical Trials, NHPD (pending)  
Lindsay Blaney, Director, Policy and Regulatory Affairs, NHPD (pending)  
Duc Vu, Director, Marketed Biologics, Biotechnology and Natural Health Products Bureau, MHPD (pending)  
Kim Dayman-Rutkas, Director, HPFBI (pending)  
Diane Allan, Director, OCS, CSTD, HECS (approved, Sept 29, 2010)  
Suzanne Desjardins, Director, ODARS, CSTD, HECS approved, Sept 30, 2010)  
Cathy Sabiston, DG, CSTD, HECS (pending)  
Chris Turner, DG, MHPD (pending)  
Nancy Richards, DG, NHPD (pending)  
Diana Dowthwaite, DG, HPFBI (pending)  
Ken Polk, Communications Executive, HPFB (pending)  
Jean Tessier, Senior Media Relations, PACCB (pending)  
Warren Braun, Director, Strategic Communications, PACCB (pending)  
Peter Yendall, Director, Public Affairs, PACCB (pending)  
HECS Legal (pending)  
HPFB Legal (pending)  
Paul Glover, ADM, HECSB (pending)  
Meena Ballantyne, ADM, HPFB (pending)  
Anne Lamar, ADM, PACCB (pending)  
DMO (pending)  
MO (pending)

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PCO (pending)

**DRAFT V.3**

DEPARTMENT OF HEALTH

CONTROLLED DRUGS AND SUBSTANCES ACT

*Notice to interested parties - Proposal regarding the addition of Salvia divinorum and salvinorin A to Schedule III to the Controlled Drugs and Substances Act*

This notice provides interested stakeholders with the opportunity to provide preliminary comments on Health Canada's proposal to add the plant *Salvia divinorum* (*S. divinorum*) and its active ingredient salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA), and to identify themselves for inclusion in any future consultation.

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are generally chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant. Neither *S. divinorum* nor salvinorin A are currently included in any of the Schedules to the CDSA.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs. *S. divinorum* and salvinorin A are pharmacologically similar to other substances included in Schedule III to the CDSA, such as LSD and psilocybin. Health Canada is thus concerned that *S. divinorum* and salvinorin A pose a risk to the health and safety of Canadians and is therefore considering regulating them as controlled substances.

While these substances are not currently included in any of the United Nations Drug Control Conventions, a number of countries have chosen to regulate one or both as controlled substances. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden have all placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. Although some individual American states have implemented laws restricting its use, sale and/or distribution, *S. divinorum* and salvinorin A are not regulated under the federal *Controlled Substances Act* in the United States.

Placing these substances within Schedule III to the CDSA would prohibit the following activities with these substances unless authorized by regulation: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation).

As this action is not intended to interfere with the use and availability of *S. divinorum* and/or salvinorin A for a legitimate medical, scientific or industrial purpose, Health Canada is seeking information from stakeholders on whether there are any such legitimate uses for these aforementioned substances in Canada. Information received in response to this notice will be instrumental in determining appropriate scheduling under the CDSA. 001800

The publication of this notice begins a 30-day comment period. There will be additional opportunities to provide comments following prepublication of the scheduling proposal in *Canada Gazette*, Part I.

If you are interested in this process or have comments on this proposal, please contact Stephanie Chandler, Regulatory Policy Division, Office of Controlled Substances, Address Locator: 3503D, 123 Slater St., Ottawa, Ontario, Canada, K1A 1B9, by fax at (613) 946-4224 or by email at [OCS\\_Policy\\_and\\_Regulatory\\_Affairs@hc-sc.gc.ca](mailto:OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca).

Cathy A. Sabiston  
Director General  
Controlled Substances and Tobacco Directorate

Date \_\_\_\_\_



**CSS-WG Meeting: ROD November 16**

Colette Strnad, Collin Pinto, Courtney Smith,  
Denis Arsenault, Evelyn Soo, Hanan

Tiffany Thornton to: Abramovici, Jocelyn Kula, Robin Marles,  
Suzanne Desjardins, Tanja Kalajdzic, Tiana  
Branch, Bruna Brands

2010-12-06 12:57 PM

cc: Stephanie Chandler, Laura Cooney, Isabel Shanahan

Please find attached the ROD from November 16. Should you have any revisions/feedback please do not hesitate to send them to me for incorporation. The meeting for Wednesday December 15 is still tentative at this time - most likely it will be cancelled if there are no emerging issues for discussion.



CSS-WG November 16 2010 Meeting ROD\_TB.doc

Thank you,  
Tiffany

----- Forwarded by Tiffany Thornton/HC-SC/GC/CA on 2010-12-06 12:51 PM -----

**CSS-WG Meeting**



**2010-11-16 Tue 10:30 AM - 12:00  
PM**

Location: 123 Slater Street, Rm 629B

Required:

Colette Strnad/HC-SC/GC/CA@HWC, Collin Pinto/HC-SC/GC/CA@HWC, Courtney Smith/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, Evelyn Soo/HC-SC/GC/CA@HWC, Hanan Abramovici/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Robin Marles/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC, Tanja Kalajdzic/HC-SC/GC/CA@HWC, Tiana Branch/HC-SC/GC/CA@HWC

Optional:

Isabel Shanahan/HC-SC/GC/CA@HWC, Laura Cooney/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC, Valence Nebie/HC-SC/GC/CA@HWC

**Description**

Hi everyone,

Please mark your calendars. The Agenda for the next meeting and the Record of Discussion from October 27 to follow shortly. Please find attached (from Robin)

- the most recent versions of the Salvia divinorum HRA and IAS documents prepared by MHPD and NHPD and
- background information on "morning glory"

Thanks,  
Tiffany

\*\*\*\*\*



Health Risk Assessment of Salvia divinorum as a Health Product 2010-08-25.doc



Salvia divinorum IAS 2006-11-03.doc

At the last CSS-WG meeting we reviewed the deck "Scheduling Substances under the *Controlled Drugs and Substances Act*". On slide 7, I pointed out that "morning glory" was identified as a plant with psychoactive properties but that may be a bit misleading because the psychoactive species are not the common morning glory that people have in their gardens. I promised I would provide details by e-mail.

The psychoactive "morning glory" plant, species name *Turbina corymbosa* (L.) Raf., Convolvulaceae, widely published synonym *Rivea corymbosa* (L.) Hallier f., is better known in the scientific literature by its Mexican Nahuatl name of "Ololiuqui". Horticulturally it has the English common names "Christmaspops" or "Christmasvine." The seeds were consumed in water traditionally by the Mexican Chinotec, Mazatec, Mixtec and Zapotec peoples as a narcotic hallucinogen for purposes of divination by traditional healers. Hallucinations occur during the somnambulistic stage of intoxication.

The psychoactive properties are due to biosynthesis of ergoline alkaloids by fungi of the order Clavicipitales (related to ergot) that colonize the adaxial (upper) leaf surface and seeds of certain members of the morning glory family, especially *Turbina corymbosa* and *Ipomoea asarifolia*. A closely related fungus is found on *Ipomoea violacea*. The fungus-derived ergoline alkaloids: chanoclavine, lysergic acid-alpha-hydroxyethylamide, lysergic acid amide, and ergonovine, accumulate in the leaves and seeds of the host plant. The fungi are seed-transmitted to the next generation of plants.

The common garden morning glory is *Ipomoea purpurea* (L.) Roth. Additional horticultural species include *I. pes-caprae*, *I. pandurata*, *I. carnea*, *I. cairica*, *I. quamoclit*, *I. tricolor*, *I. hederifolia*, *I. nil*, *I. aquatica*, *Convolvulus tricolor*, *Argyreia nervosa*, and *Merremia tuberosa*. The wild morning glory or bindweed plants that infest our gardens as noxious weeds are *Convolvulus arvensis* L. (small-flowered) and *Calystegia sepium* (L.) R.Br. (greater bindweed).



Markert et al ergoline alkaloids fungi and Convolvulaceae.pdf

# Protected B Draft

## Record of Discussion (ROD)

**Controlled Substances Scheduling (CSS) Working Group Meeting  
Tuesday November 16<sup>th</sup>, 2010, 10:30-12:00am  
123 Slater Street, Rm 629B**

### **Present:**

- Suzanne Desjardins, Office of Research and Surveillance ,(ORS), Controlled Substances and Tobacco Directorate (CSTD), Healthy Environments Consumer Safety Branch (HECSB) (Chair)
- Tiana Branch, OCS, CSTD, HECSB
- Robin Marles, Bureau of Clinical Trials and Health Sciences, Natural Health Products Directorate (NHPD), HPFB
- Denis Arsenault, OCS, CSTD, HECSB
- Hanan Abramovici, ODARS, CSTD, HECBS Hanan Abramovici, ODARS, CSTD, HECBS
- Courtney Smith, Emergency Preparedness Unit, Compliance, Enforcement & Coordination Division #2, HPFB
- Colette Strnad, Office of Science, Therapeutic Products Directorate (TPD) via phone
- Evelyn Soo, OCS, CSTD, HECSB
- Tiffany Thornton (Secretariat) ODARS, CSTD, HECSB

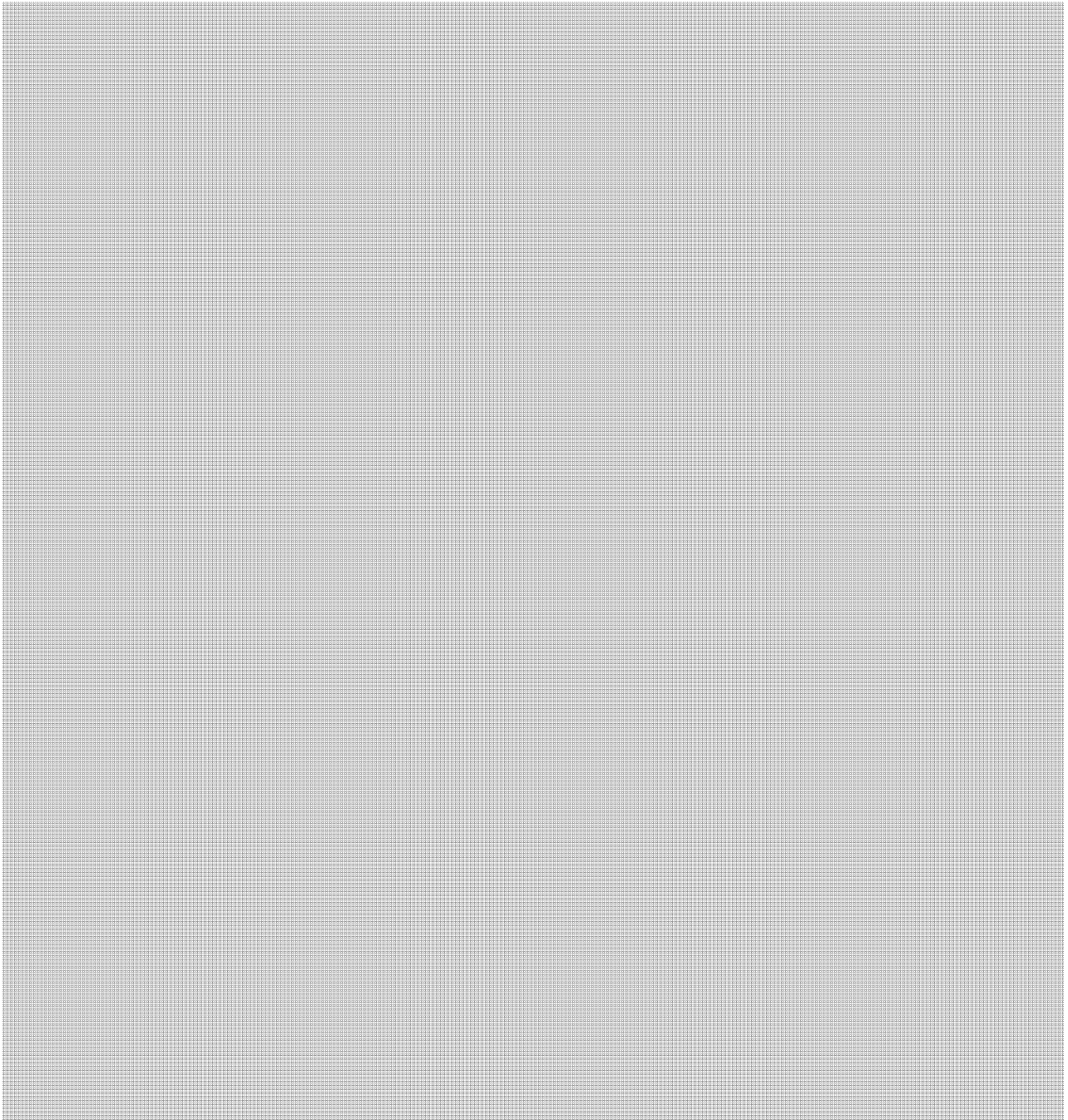
### **Regrets:**

- Bruna Brands, ODARS, CSTD, HECSB
- Colin Pinto, Drug Compliance and Investigations Unit, Health Products and Food Branch Inspectorate, HPFB
- Tanja Kalajdzic, Marketed Pharmaceuticals & Medical Devices Division, Marketed Health Products Directorate, Health Products and Food Branch (HPFB)

**s.21(1)(a)**

**s.21(1)(b)**

- 1. Welcome & Introductions**  
Suzanne welcomed the working group members.
- 2. Approval of Agenda Items**  
Agenda approved.
- 3. Approval of ROD from October 27<sup>th</sup>, 2010**  
The ROD for Wednesday, October 27<sup>th</sup> was approved.





**Page(s) 001806 to\à 001806**

**Is(Are) exempted pursuant to section(s)  
est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**

DRAFT 14  
December 8, 2010

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**Media Lines**  
*Salvia divinorum*

**Issue**

Further to ongoing media interest regarding the availability of *Salvia divinorum* in Canada and reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties, Health Canada has concluded that *Salvia divinorum* and its main active ingredient salvinorin A should be included in one of the Schedules to the *Controlled Drugs and Substances Act (CDSA)*.

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**Key Messages:**

- Health Canada is proposing that *S. divinorum* and salvinorin A be regulated as controlled substances under the *Controlled Drugs and Substances Act (CDSA)*. ~~Further to an analysis of the information available about *S. divinorum* and salvinorin A and the risks associated with the availability of these substances in Canada.~~
- Health Canada intends to inform stakeholders of its decision via the publication of a *Notice to Interested Parties (NOI)* in *Canada Gazette, Part I*. The NOI will provide stakeholders and other interested parties with the opportunity to provide comments on the proposal to regulate these substances as controlled substances.
- The inclusion of *S. divinorum* and salvinorin A in the Schedules to the CDSA will mitigate the risks associated with their ready availability and potential abuse.

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**Supplementary Messages:**

- Canadians should not use products containing *S. divinorum* and/or salvinorin A because very little is known about these substances and their potential effects on the brain and/or body, and their impact on physical and mental functions.
- Because of their hallucinogenic properties, products containing *S. divinorum* and/or salvinorin A meet the definition of a natural health product (NHP) under the Natural Health Products Regulations and the definition of a drug under the Food and Drugs Act.
- It is illegal to sell NHPs in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN). The illegal sale of products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*.

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Deleted: <#>Because of their hallucinogenic properties, products containing *S. divinorum* and/or salvinorin A meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*. ¶  
It is illegal to sell NHPs in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN). The illegal sale of products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*. ¶

- Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and thus, do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions,
- The move to include *S. divinorum* and salvinorin A in the Schedules to the CDSA is consistent with actions taken by several countries (Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. It is also consistent with the fact that some individual U.S. states have implemented laws restricting their use, sale and/or distribution.

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*Salvia divinorum as a controlled substance:* ¶  
¶  
<#>In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA). ¶  
¶

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**Deleted:** *Salvia divinorum* and salvinorin A are not regulated under the federal *Controlled Substances Act* in the United States. ¶

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#### Questions and Answers:

**Q1 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum* as a controlled substance. What does that involve and what stage is it at?**

A1 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada recently concluded its assessment of *S. divinorum* and salvinorin A against the aforementioned factors and proposes to include both substances in one of the Schedules to the CDSA.

**Q2 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why isn't it illegal?**

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A2 – Health Canada intends to include *S. divinorum* and salvinorin A under one of the Schedules to the CDSA. In the interim, as *S. divinorum* meets the definition of a Natural Health Product (NHP) under the *Natural Health Product Regulations*, it is illegal to manufacture, sell or provide products containing *S. divinorum* and/or salvinorin A without their being authorized by Health Canada prior to sale.

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**Q3 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?**

**Deleted:** Health Canada is currently reviewing all the available information regarding *Salvia divinorum*, including the prevalence of its use in Canada, to determine whether it should be regulated under the *Controlled Drugs and Substances Act*. ¶

A3 – The *Natural Health Products Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *Salvia divinorum*. When *S. divinorum* and salvinorin A are included in the

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Schedules to the CDSA, it will be illegal to possess, import, export, produce and distribute these substances in any form unless authorized by regulation.

**Q4 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

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A4 – Once *S. divinorum* and salvinorin A are included in the Schedules to the CDSA, law enforcement will be able to take appropriate action in response to suspected illegal activities with these substances.

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In the interim, *S. divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. Complaints about the illegal sale of drugs containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

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**Q5 – What is the significance of the adverse reaction reports that Health Canada has received with respect to the use of *Salvia divinorum*?**

Deleted: Q4 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum* as a controlled substance. What does that involve and what stage is it at?

A5 – Health Canada has received four domestic adverse reaction reports related to the use of *Salvia divinorum* as a hallucinogen through the Canada Vigilance database. The number of reports and the nature of reactions reported are, however, not adequate to fully characterize the risk of similar reactions among the general population

A4 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:  
<#>International requirements and trends in international control;  
<#>Chemical and pharmacological similarity to other substances already regulated under the CDSA;  
<#>Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);  
<#>Potential for abuse and risk of addiction associated with the substance;  
<#>Extent of actual abuse of the substance in Canada and internationally; and  
<#>Overall risk to public health and safety posed by the substance.

***If pressed on whether Health Canada has issued any kind of warning to Canadians about *Salvia divinorum****

A - Health Canada is developing an It's Your Health (IYH) article on *Salvia divinorum* to help inform the general public about the risks associated with the use of this plant.

Health Canada is currently reviewing the available information to determine whether regulation of *Salvia divinorum* under the CDSA is warranted.

**Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

Q5 – Didn't an internal report from Health Canada's Marketed Health Products Directorate recommend that *Salvia divinorum* be scheduled under the CDSA? Why has that recommendation not been acted upon?

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

A5 – See A4

Data from the 2008-2009 Youth Smoking Survey indicates that:

- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;

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- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year; and.
- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using Salvia in their lifetime (0.2% in the past year); and
- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that:

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;
- 5.4% of students (grades 7-12) ever used *S. divinorum*; and
- the use of *S. divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

**Prepared by:** Stephanie Chandler and Denis Arsenaault, OCS, CSTD

**Deleted:** Cheryl Tremblay

**Input by:** Lisa Mackay IYH/PACCB, Suzanne Desjardins HECSB/ODARS, Hanan Abramovici HECSB/ODARS, Bruna Brands HECSB/ODARS, Jocelyn Kula, HECSB/OCS, Robin Marles HPFB/NHPD, Maggie Graham HPFB/NHPD, Stephanie Collins HPFB/NHPD, Mano Murty HPFB/MHPD, Robert Leitch HPFB/MHPD, Shahid Perwaiz HPFB/MHPD, Collin Pinto, HPFB/HPFBI

**Approved by:**

Robin Marles, Director, Bureau of Clinical Trials, NHPD (pending)  
Lindsay Blaney, Director, Policy and Regulatory Affairs, NHPD (pending)  
Duc Vu, Director, Marketed Biologics, Biotechnology and Natural Health Products Bureau, MHPD (pending)  
Kim Dayman-Rutkas, Director, HPFBI (pending)  
Diane Allan, Director, OCS, CSTD, HECS (approved, Sept 29, 2010)  
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Paul Glover, ADM, HECSB (pending)  
Meena Ballantyne, ADM, HPFB (pending)  
Anne Lamar, ADM, PACCB (pending)

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**DRAFT V.4**

DEPARTMENT OF HEALTH

CONTROLLED DRUGS AND SUBSTANCES ACT

*Notice to interested parties - Proposal regarding the addition of Salvia divinorum and salvinorin A to Schedule III to the Controlled Drugs and Substances Act*

This notice provides interested stakeholders with the opportunity to provide preliminary comments on Health Canada's proposal to add the plant *Salvia divinorum* (*S. divinorum*) and its active ingredient salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA), and to identify themselves for inclusion in any future consultation.

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are generally chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant. Neither *S. divinorum* nor salvinorin A are currently included in any of the Schedules to the CDSA.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs. As *S. divinorum* and salvinorin A are pharmacologically similar to other substances included in Schedule III to the CDSA, such as LSD and psilocybin, Health Canada is concerned that their ready availability poses a risk to the health and safety of Canadians.

While these substances are not currently included in any of the United Nations Drug Control Conventions, a number of countries have chosen to regulate one or both as controlled substances. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden have all placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. Some individual American states have also implemented laws restricting its use, sale and/or distribution.

Placing these substances within Schedule III to the CDSA would prohibit the following activities with these substances unless authorized by regulation: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation).

As this action is not intended to interfere with the use and availability of *S. divinorum* and/or salvinorin A for a legitimate medical, scientific or industrial purpose, Health Canada is seeking information from stakeholders on whether there are any such legitimate uses for these aforementioned substances in Canada. Information received in response to this notice will be instrumental in determining appropriate regulation under the CDSA, as required.

The publication of this notice begins a 30-day comment period. There will be additional opportunities to provide comments following prepublication of the scheduling proposal in *Canada Gazette*, Part I.

If you are interested in this process or have comments on this proposal, please contact Stephanie Chandler, Regulatory Policy Division, Office of Controlled Substances, Address Locator: 3503D, 123 Slater St., Ottawa, Ontario, Canada, K1A 1B9, by fax at (613) 946-4224 or by email at [OCS\\_Policy\\_and\\_Regulatory\\_Affairs@hc-sc.gc.ca](mailto:OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca).

Cathy A. Sabiston  
Director General  
Controlled Substances and Tobacco Directorate

Date \_\_\_\_\_



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DRAFT V.4

DEPARTMENT OF HEALTH

CONTROLLED DRUGS AND SUBSTANCES ACT

Notice to interested parties - Proposal regarding the addition of *Salvia divinorum* and salvinorin A to Schedule III to the Controlled Drugs and Substances Act

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*S. divinorum* / *Sho may also*  
*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are generally chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant. Neither *S. divinorum* nor salvinorin A are currently included in any of the Schedules to the CDSA.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs. As *S. divinorum* and salvinorin A are pharmacologically similar to other substances included in Schedule III to the CDSA, such as LSD and psilocybin, Health Canada is concerned that their ready availability poses a risk to the health and safety of Canadians, *particularly youth*.

While these substances are not currently included in any of the United Nations Drug Control Conventions, a number of countries have chosen to regulate one or both as controlled substances. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden have all placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. Some ~~individual~~ American states have also implemented laws restricting its use, sale and/or distribution.

Placing these substances within Schedule III to the CDSA would prohibit the following activities with these substances unless authorized by regulation: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation).

As this action is not intended to interfere with the use and availability of *S. divinorum* and/or salvinorin A for a legitimate medical, scientific or industrial purpose, Health Canada is seeking information from stakeholders on whether there are any such legitimate uses for these aforementioned substances in Canada. Information received in response to this notice will be instrumental in determining appropriate regulation under the CDSA, ~~as required~~.

*Shouldn't this be more relevant include surveillance data?*

The publication of this notice begins a 30-day comment period. There will be additional opportunities to provide comments following prepublication of the scheduling proposal in *Canada Gazette*, Part I.

If you are interested in this process or have comments on this proposal, please contact Stephanie Chandler, Regulatory Policy Division, Office of Controlled Substances, Address Locator: 3503D, 123 Slater St., Ottawa, Ontario, Canada, K1A 1B9, by fax at (613) 946-4224 or by email at [OCS\\_Policy\\_and\\_Regulatory\\_Affairs@hc-sc.gc.ca](mailto:OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca)

Cathy A. Sabiston  
Director General  
Controlled Substances and Tobacco Directorate

Date \_\_\_\_\_

- youth angle.  
- allows LEA to take over (see wording in RCMP media lines)

**DRAFT V.4**

DEPARTMENT OF HEALTH

CONTROLLED DRUGS AND SUBSTANCES ACT

*Notice to interested parties - Proposal regarding the addition of Salvia divinorum and salvinorin A to Schedule III to the Controlled Drugs and Substances Act*

This notice provides interested stakeholders with the opportunity to provide preliminary comments on Health Canada's proposal to add the plant *Salvia divinorum* (*S. divinorum*) and its active ingredient salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA), and to identify themselves for inclusion in any future consultation.

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are generally chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant. Neither *S. divinorum* nor salvinorin A are currently included in any of the Schedules to the CDSA.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs. As *S. divinorum* and salvinorin A are pharmacologically similar to other substances included in Schedule III to the CDSA, such as LSD and psilocybin, Health Canada is concerned that their ready availability poses a risk to the health and safety of Canadians.

While these substances are not currently included in any of the United Nations Drug Control Conventions, a number of countries have chosen to regulate one or both as controlled substances. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden have all placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. Some individual American states have also implemented laws restricting its use, sale and/or distribution.

Placing these substances within Schedule III to the CDSA would prohibit the following activities with these substances unless authorized by regulation: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation).

As this action is not intended to interfere with the use and availability of *S. divinorum* and/or salvinorin A for a legitimate medical, scientific or industrial purpose, Health Canada is seeking information from stakeholders on whether there are any such legitimate uses for these aforementioned substances in Canada. Information received in response to this notice will be instrumental in determining appropriate regulation under the CDSA, as required.

The publication of this notice begins a 30-day comment period. There will be additional opportunities to provide comments following prepublication of the scheduling proposal in *Canada Gazette*, Part I.

If you are interested in this process or have comments on this proposal, please contact Stephanie Chandler, Regulatory Policy Division, Office of Controlled Substances, Address Locator: 3503D, 123 Slater St., Ottawa, Ontario, Canada, K1A 1B9, by fax at (613) 946-4224 or by email at [OCS\\_Policy\\_and\\_Regulatory\\_Affairs@hc-sc.gc.ca](mailto:OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca).

Cathy A. Sabiston  
Director General  
Controlled Substances and Tobacco Directorate

Date \_\_\_\_\_

## Complementary and Alternative Medicine

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# Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use

Cathi E Dennehy, Candy Tsourounis, and Amy E Miller

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**BACKGROUND:** The Internet is a popular tool for marketing and purchasing herbal dietary supplements (DS). Various Web sites sell these products purely for recreational use.

**OBJECTIVE:** To describe the content of Web sites that advertise and market herbal DS for recreational use (ie, for the purpose of altering mood/behavior/or perception, "getting high," or as a substitute for a drug of abuse).

**METHODS:** Four major search engines and the search terms "buy herbal high" and "buy legal high" were used to identify Web sites selling herbal DS for recreational use. Web sites were evaluated for their country of origin and for compliance with the Dietary Supplement Health and Education Act (DSHEA). Products were evaluated for their ingredient lists, effect claims, comparisons with illicit drugs, adverse effects, drug interactions, and contraindications.

**RESULTS:** Twenty-eight unique Web sites with 119 products were evaluated. Most sites were in the US (54%) and were in compliance with DSHEA. Forty-seven percent of the products were likened to illicit drugs, typically marijuana (48%) or 3-,4-methylene dioxymphetamine (Ecstasy; 23%). The most common product ingredients were ephedra alkaloids (27%), *Salvia divinorum* (17%), kava (10%), guarana (10%), *Acorus calamus* (10%), and damiana (10%). Effect claims frequently involved the products' use as a hallucinogen (51%) or stimulant (39%). Sixty-four percent of the sites mentioned adverse effects, and 54% mentioned drug interactions.

**CONCLUSIONS:** This study demonstrates that herbal DS are being marketed for use as legal alternatives to illicit drugs of abuse. Healthcare professionals need to be aware of this trend and the products that are involved.

**KEY WORDS:** Internet, recreational dietary supplement, recreational herb.

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The 2003 National Survey on Drug Use and Health (NSDUH) indicated that 8.2% of Americans use illicit drugs, with the highest prevalence among those 18–20 years old. Marijuana was used most frequently, followed by psychotherapeutic agents (eg, prescription pain relievers, tranquilizers, stimulants, sedatives), cocaine, hallucinogens (including lysergic acid diethylamide, phencyclidine, peyote, mescaline, mushrooms, 3-,4-methylene dioxymphetamine [Ecstasy]), and inhalants.<sup>1</sup>

Herbal dietary supplements (DS) have also been used for recreational purposes (eg, to alter mood, perception,

behavior). Emergency care and hospitalizations have been reported in persons ingesting moonflower (*Datura innoxia*), Hawaiian baby woodrose (*Argyrea nervosa*), and "Herbal Ecstasy" products.<sup>2-5</sup>

DS are regulated by the Food and Drug Administration (FDA) under the Dietary Supplement Health and Education Act (DSHEA). DSHEA requires that products being sold as DS be labeled as such. It also requires manufacturers making product structure–function claims to state the FDA disclaimer, "This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease."<sup>6</sup>

The Internet is a discreet and easy method of marketing and purchasing supplements. Given the popularity of this market, there has been an emergence of Web sites marketing DS purely for recreational use. The objective of this

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Author information provided at the end of the text.

This research was presented as a poster at the American College of Clinical Pharmacy Annual Meeting, September 2004, Dallas, TX.

study was to describe the content of these Web sites and their products.

## Methods

In February 2004, an Internet search was performed using Google, Yahoo!, AOL, and MSN.<sup>7,8</sup> Search terms were "buy herbal high" and "buy legal high." These terms were chosen after testing numerous search term combinations and determining that these terms retrieved the most sites. The first 100 Web sites for each search term and search engine were screened, and the first 20 unique sites were reviewed. Web sites were included if they claimed to sell herbal DS to US consumers for recreational use. "Recreational use" was defined as the use of a product for the purpose of altering mood/behavior/or perception, "getting high," or as a substitute for an illicit drug. Products marketed solely as aphrodisiacs or sexual stimulants were excluded.

Our selection of products for review was based on Web site presence (ie, prominence of an item on the Web site) until a maximum of 5 products had been evaluated. Products that appeared on the home page and received a majority of the advertising space were evaluated first, followed by the "top seller" or "best seller" links, then followed by the first product appearing under the links provided.

Web site coding took place in February and March. Two investigators evaluated each site separately. Web sites were evaluated for location (US or other), presence of seller's contact information, and, if located in the US, compliance with the DSHEA. Web sites were considered compliant if they identified their products as DS and listed the FDA disclaimer if a structure-function claim was present.

Products were evaluated for their ingredient list, effect claims (eg, hallucinogen, stimulant, sedative), presence of testimonials or journal articles to support effect claims, comparisons with illicit drugs, adverse effects, drug and disease interactions, contraindications, and formulation. If no ingredient list was provided but contact information was present, one investigator E-mailed the company with the phrase, "I'm interested in trying this product. Can you tell me what's in it?" If no reply was received and the company was located within the US, we attempted to phone the manufacturer. Effect claims were grouped (Table 1).

## SURVEY TOOL AND INTERRATER RELIABILITY

The survey tool was designed so that, if a particular item (eg, structure or function claim, adverse effect claim) appeared on the Web site, it would be recorded as "yes" or, if absent, as "no." Additional descriptive information was recorded using the terminology listed on the Web site. After both investigators had completed their coding, all responses were compared for interrater reliability. If discrepancies existed, the investigators met, revisited the Web site, and came to a consensus. Interrater reliability was performed using Cohen's kappa statistic, where a value of >0.7 was considered satisfactory.<sup>9</sup>

## COMPLIANCE WITH EPHEDRA BAN

In February 2004, the FDA had just published a final rule declaring that DS containing ephedra alkaloids were adulterated because of the risk of illness and injury to consumers. The ban prohibited the sale of DS containing ephedra, *ma huang*, *Sida cordifolia*, or *Pinellia* spp. and re-

quired that these supplements be removed from the market by April 12, 2004.<sup>10,11</sup> After the study was completed, Web sites distributing ephedra products were revisited to check for compliance with this ban.

## Results

### WEB SITE SUMMARY

Twenty-eight Web sites were identified, and 119 products were evaluated (average 4.3 products per Web site). The majority of the suppliers were located in the US (54%, n = 15) and the UK (36%, n = 10). There was one site in the Netherlands and one in Canada; another did not specify a location. Products on all foreign Web sites stated that they would ship products to the US.

The 15 US-based sites were evaluated for compliance with DSHEA. Among these, 73% (n = 11) identified one or more product as a DS, 93% (n = 14) made at least one structure-function claim, and 67% (n = 10) included the FDA disclaimer.

### PRODUCTS AND INGREDIENTS

Products that occurred with a frequency of ≥2% are listed in Table 2. Of the 119 products evaluated, *Salvia divinorum* was the most prevalent. Web sites that sold *Salvia* often included an "S-A-L-V-I-A scale," where the "trip" was described in levels dependent on the amount ingested (Table 3).<sup>12</sup> Many sites selling *Salvia* recommended that the user have a "sitter" (a person not under the influence of any mind-altering substance) to oversee their behavior for safety reasons.

Seventy-seven percent (n = 92) of the products provided an ingredient list; ingredient lists for an additional 9% (n = 11) were obtained by contacting the company by E-mail or phone. No ingredient list was identified for 16 products. The most common product ingredients are listed in Table 4. Ephedra was the most common product, followed by *Salvia*. The majority of products were single- (59%) versus multi-ingredient (41%).

### EFFECT CLAIMS

Forty-seven percent (n = 56) of the products were likened to a specific illicit drug. The most common were marijuana (48%), Ecstasy (23%), LSD (14%), cocaine or speed (13%), and mushrooms (5%). A small percentage (5%) of suppliers also likened their products to benzodiazepines, opium, and "roofies" (ie, flunitrazepam). In 7% of the cases, more than one illicit drug was cited as being similar to a DS product.

Seventy-nine percent (n = 94) of the products advertised effect claims. The claims were generally supported by testimonial evidence (94%, n = 15) compared with journal citations (6%, n = 1) and were present on 57% (n = 16) of the 28 Web sites. Fifty-one percent (n = 48) of the products were categorized as hallucinogens, 39% as stimulants, 31% as euphoria producing, and 24% as sedatives. Products that qualified as stimulants most commonly contained

Table 1. Characterization of Effect Claims

Effect Claim	Description
Sedatives	have sedative or relaxing effects; decrease stress and anxiety
Euphorics	enhance mood; produce a state of euphoria
Hallucinogens	expand the mind; produce hallucinations; have psychedelic properties
Stimulants	increase energy; have stimulant, cocaine, or speed-like effects

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ephedra and made claims such as increasing emotional energy or mental clarity.

### Adverse Effects, Contraindications, and Drug Interactions

Sixty-four percent (n = 18) of the Web sites stated at least one or more potential adverse effect, with the most common (68%, n = 14) being impaired motor coordination, which was implied by the disclaimer, "Do not drive or operate machinery after using this product." Thirty-nine percent of the sites also reported nausea as a possible adverse effect. Other adverse effects that were listed with a frequency  $\geq 10\%$  included nervousness (22%), tremor (22%), insomnia/sleeplessness (22%), loss of appetite (22%), headache (22%), increased heart rate (17%), dizziness (11%), and mucous membrane irritation (11%).

Fifty-seven percent (n = 16) of the Web sites reported at least one contraindication to product use and 54% (n = 15) reported one or more drug interaction. The most common contraindication was a standard disclaimer present on 75% (n = 12) of sites that stated, "Do not use this product if you are pregnant or nursing, or if you have heart disease, thyroid disease, diabetes, high blood pressure, depression or other psychiatric condition, glaucoma, difficulty urinating, prostate enlargement, or a seizure disorder." Similarly, the

most common drug interaction was also part of the above disclaimer and included the phrase, "Do not use this product if you are using a monoamine oxidase inhibitor (MAOI), any other prescription drug, or an over-the-counter drug containing ephedrine, pseudoephedrine, or phenylpropranolamine (ingredients found in certain allergy, asthma, cough/cold, and weight control products)." Of the Web sites stating this disclaimer, 50% (n = 8) sold ephedra-containing products and 38% (n = 6) sold *Salvia*. Other contraindications that occurred with a frequency  $\geq 10\%$  included hepatitis (13%), liver disease (13%), and the use of alcohol (13%).

### FORMULATION

Products were most often delivered as pills for oral administration (52%, n = 62) or in a cigarette-based or loose, leaf form that could be smoked (47%). Four percent of products did not state a delivery method, 4% recommended use as incense, and 1% recommended sublingual administration. In 8% of the cases, products listed more than one delivery method (eg, ingested orally or smoked).

### INTERRATER RELIABILITY

Kappa values for interrater reliability met our predefined cut-off level for satisfactory agreement, except for

Table 2. Commonly Encountered Products

Product	Frequency, % (n)	Ingredient	Likened to	Claim
<i>Salvia</i>	15 (18)	<i>Salvia divinorum</i>	marijuana, LSD	hallucinogen
Bliss Extra	5 (6)	<i>Acorus calamus</i> , <i>Sida cordifolia</i> , Siberian ginseng, L-phenylalanine, GABA	Ecstasy <sup>a</sup>	euphoric, hallucinogen, stimulant
EX-1	5 (6)	<i>Sida cordifolia</i>	speed <sup>b</sup>	euphoric, stimulant
Druids Fantasy	3 (4)	morning glory, Hawaiian baby woodrose ( <i>Argyreia nervosa</i> ), <i>Acorus calamus</i> , Siberian ginseng, kava kava	LSD	hallucinogen
Trip2Night	3 (3)	<i>ma huang</i> , guarana, 5-HTP, Bioperine, Indian bromine, cinnamon, cola nut, niacin, Fo-ti	Ecstasy, <sup>a</sup> LSD	stimulant
Absinthe herb	2 (2)	<i>Artemisia absinthium</i>	marijuana, LSD	hallucinogen
Damiana <sup>c</sup>	2 (2)	damiana herb	marijuana	aphrodisiac, euphoric, sedative
Hawaiian baby woodrose	2 (2)	<i>Argyreia nervosa</i>	LSD	euphoric, hallucinogen, stimulant
Hawaiian Herbal Hybrid Buds	2 (2)	lettuce opium ( <i>Lactusa virosa</i> )	marijuana	euphoric
Kanzak	2 (2)	Kanna	NA	euphoric, sedative
Kratom	2 (2)	<i>Mitragyna speciosa</i>	marijuana	euphoric, hallucinogen, stimulant
Red Dawn	2 (2)	guarana, 5-HTP, Bioperine, Indian bromine, cinnamon, cola nut, niacin, Fo-ti	NA	aphrodisiac, euphoric, stimulant
Road Runner Super	2 (2)	<i>Sida cordifolia</i> , Siberian ginseng, GABA, L-taurine, <i>Paulina cupana</i> <sup>d</sup>	speed <sup>b</sup>	stimulant
Uraeus Liquid Speed	2 (2)	guarana, gotu kola, <i>Ginkgo</i> , lemon balm	speed <sup>b</sup>	hallucinogen, stimulant

GABA =  $\gamma$ -aminobutyric acid; 5-HTP = 5-hydroxytryptophan; LSD = lysergic acid diethylamide; NA = not applicable.

<sup>a</sup>3,4-methylene dioxymethamphetamine.

<sup>b</sup>Amphetamine or methamphetamine.

<sup>c</sup>There were 2 single-ingredient damiana products and an additional 8 products that included damiana as part of a multi-ingredient list.

<sup>d</sup>A form of Brazilian guarana.

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the 3 questions related to compliance with DSHEA. An overall kappa statistic of 0.48 was calculated for these 3 questions, as there were only 15 responses (ie, based on number of US sites) for each.

COMPLIANCE WITH EPHEDRA BAN

Initially, 54% (n = 15) of the sites had been selling ephedra products; 7 of these were located in the US. By May 2004, 6 of those suppliers had removed these products from their Web site. Among the 8 foreign distributors of ephedra, one Web site was no longer operational, one no longer shipped ephedra-containing products to US customers, and 6 continued to sell the products to US consumers. Therefore, 47% of Web sites continued to market ephedra products after the ban.<sup>10,11</sup>

Discussion

After this study was completed, the FDA released a warning to consumers not to purchase or consume DS products that claimed to be "safe legal highs" or that were being marketed as "street drug alternatives." The warning stated that DS products promoted as such were considered to be misbranded and qualified as unapproved new drugs. They recognized the potential for misuse and abuse and identified this market as a potential public health concern.<sup>10,11</sup> Our findings substantiate this concern.

WEB SITE SUMMARY

As the study was under development, we expected that a large number of Web sites would be promoting DS for recreational use; however, only 28 unique sites were identified. We had anticipated finding more, given the popularity of the Internet and DS. The large number of sites outside the US may be reflective of the popularity of herbal DS in Europe. It is unclear where Americans would preferentially buy their products from US manufacturers, but a foreign site might be preferred if it is perceived to be more discreet.

Our overall kappa score for the presence or absence of information relating to DSHEA was 0.48. This represents a moderate level of agreement and the difficulty in interpreting and assessing compliance with DSHEA.

PRODUCTS AND INGREDIENTS

Many of the product names seemed to coincide with the concept of producing a blissful or fantasy-like state (eg, Bliss Extra, EX-1, Druids Fantasy, Trip2Night). The pharmacology of commonly encountered ingredients also coincides with the potential for central nervous systems (CNS) alteration. Specifically, *S. divinorum* is a type of sage that results in psychedelic effects when smoked.<sup>13</sup> Kava kava has sedative and anxiolytic properties, while guarana contains 2.5–7% caffeine and acts as a CNS stimulant.<sup>13</sup> *A. calamus* contains asarone, which is converted to trimethoxyamphetamine in the body, a psychedelic compound and the basic building block of amphetamines.<sup>14</sup> Damiana and lettuce opium are both smokeable herbs with relaxing effects.<sup>13</sup> Bioperine is an extract of the black pepper fruit and has been shown to significantly increase the bioavailability of some nutrients.<sup>15</sup> Lastly, Fo-ti may enhance mental clarity, *A. nervosa* may have hallucinogenic properties, and  $\gamma$ -aminobutyric acid may relieve anxiety and elevate mood.<sup>13,16</sup>

EFFECT CLAIMS

Products were most often likened to marijuana, which was not surprising given the results of the NSDUH.<sup>1</sup> On the other hand, product effect claims most commonly fell into the hallucinogen category, which did not coincide with the NSDUH survey, where stimulant use exceeded that of hallucinogens.<sup>1</sup>

ADVERSE EFFECTS, CONTRAINDICATIONS, AND DRUG INTERACTIONS

The Salvia scale was included as part of these results because we were alarmed by the "loss of consciousness" described in level 6 and by the recommendation that a "sitter" may be necessary. Given these 2 claims, it is clear that this herb has a serious potential for harm. It also raises concerns if it is taken with other CNS-acting agents that affect consciousness or respiration.

More than half of the Web sites evaluated stated an adverse effect, with impaired motor coordination being the most common. Given that these products were being recommended for the purpose of altering mood, perception, or behavior, this disclaimer seems warranted. Other common adverse effects, such as nervousness, insomnia, and increased heart rate, coincided with the stimulant nature of ephedra and caffeine, which were frequently present in these products. Of course, with any ephedra product, the greatest concern remains its ability to produce myocardial infarction, stroke, or death, which was the impetus behind the FDA ban.<sup>10,11</sup>

Kava was a commonly encountered ingredient. Healthcare providers should be aware that this herb has been associated with cases of liver toxicity and failure, leading to a ban on its sale in several countries.<sup>17</sup> Altered mental sta-

Table 3. SALVIA Scale<sup>12</sup>

Level	Effect
1	Subtle effects, such as relaxation and increased sensual appreciation
2	Altered perception, such as more pronounced colors and textures; thinking becomes less logical and more playful; may be short-term memory loss
3	Light visionary state, such as closed-eye visuals
4	Vivid visionary state, such as complex 3-dimensional realistic scenes appearing; shamanistic journeying to other lands; "dream time"
5	Immaterial existence, in which one is no longer aware of having a body and identity is lost
6	Anesthesia, in which consciousness is lost for several minutes



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tus and ataxia have also been observed in cases of acute kava ingestion.<sup>18</sup>

#### LIMITATIONS

All of the Web site coding was performed within a 2-month time period, but site changes occurred during this time that may have affected investigator coding. Our overall kappa scores, however, were good to excellent in most areas (>0.7), suggesting that these differences were minor.

Our method of defining search terms was somewhat random. The terms we eventually decided upon may not have been optimal and could have led us to identify fewer Web sites than actually exist. Researchers interested in duplicating this type of study may wish to include other search terms, such as those described by the FDA in their warning to consumers about these products (ie, "safe legal highs," street drug alternatives).

Finally, we never attempted to purchase any DS products. As a result, it is difficult to verify whether all of these sites would actually ship products to US consumers, even though all sites stated that they would.

#### COMPLIANCE WITH EPHEDRA BAN

The majority of US Web sites were in compliance with the ephedra ban, whereas only 25% of foreign distributors were. This is not surprising, as the ban was issued by the FDA and was limited to products being sold within the US or to US residents. Given the large number of ephedra-based products that we identified, this legislation is likely to have a positive effect on this market.

It is apparent that the FDA is continuing to conduct surveillance of DS products that may pose a risk to con-

sumers. In February 2004, they issued a release not to purchase an herbal Ecstasy product known as Green Hornet due to case reports of seizures, tachycardia, and hypertension.<sup>19,20</sup> Although our study did not identify this product, it does fall within the category of DS marketed for recreational use.

#### Conclusions

The findings from this study indicate that herbal DS are being marketed for recreational purposes and as alternatives to illicit drugs. Most of the products were likened to marijuana or Ecstasy, and most claimed to have hallucinogenic or stimulating properties. Products containing ephedra and *S. divinorum* were the most commonly encountered. Even after the FDA ban on the distribution of ephedra-containing DS in the US, we were able to identify a number of sites that continued to sell them. Healthcare professionals should be familiar with these products so that they are better able to identify products, ingredients, and causes of toxicity in persons utilizing DS for recreational purposes.

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**Table 4. Commonly Encountered Product Ingredients**

Product	Frequency, % (n) <sup>a</sup>
Ephedra	27 (28)
<i>Sida cordifolia</i>	17 (17)
ma huang	6 (6)
Ephedra alkaloids	5 (5)
<i>Salvia divinorum</i>	17 (18)
<i>Acorus calamus</i>	10 (10)
Damiana	10 (10)
Guarana	10 (10)
Kava kava	10 (10)
Lettuce opium ( <i>Lactuca virosa</i> )	9 (9)
Siberian ginseng ( <i>Eleutherococcus senticosus</i> )	8 (8)
<i>Argyrea nervosa</i>	6 (6)
Bioperine	6 (6)
Fo-ti	6 (6)
GABA	6 (6)

GABA =  $\gamma$ -aminobutyric acid.  
<sup>a</sup>Total number is 103; we were unable to obtain an ingredient list for 16 products.

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18. Perez J, Holmes JF. Altered mental status and ataxia secondary to acute kava ingestion. J Emerg Med 2005;28:49-51.
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20. FDA expands warning about "Green Hornet" to include all other products by Cytotec Solutions, Inc. April 9, 2004. www.fda.gov/bbs/topics/NEWS/2004/NEW01049.html (accessed 2004 May 3).

#### EXTRACTO

**TRASFONDO:** La red de informática Internet es una herramienta popular de mercadeo y venta de suplementos nutricionales. Varios sitios de la red Web venden estos productos para uso puramente recreativo.

**OBJETIVO:** El objetivo de este estudio es describir el contenido de los sitios de la red Web que anuncian y mercadean suplementos botánicos para uso recreativo, específicamente con el propósito de alterar el estado de ánimo (alegría, relajamiento o euforia), el comportamiento, la percepción, o como un sustituto de una droga de abuso.

**MÉTODOS:** Se utilizaron 4 motores de búsqueda con los términos "comprar euforia/nota/arrebato herbal" y "comprar euforia/nota/arrebato legal" para identificar los sitios de la red Web vendiendo los suplementos de uso recreativo. Los sitios de la red se evaluaron para determinar su país de origen y el cumplimiento con la Ley de Salud y Educación de Suplementos Nutricionales, conocido por sus siglas en inglés DSHEA. Se evaluaron los productos para determinar si tenían lista de ingredientes, reclamo de efecto, comparación a drogas ilícitas, efectos adversos, y contraindicaciones.

**RESULTADOS:** Se evaluaron 28 sitios de la red con 119 productos. La mayoría de los sitios se encontraban en los Estados Unidos de América

#### Evaluation of Herbal Dietary Supplements Marketed for Recreational Use

del Norte (54%) y estaban en cumplimiento con el DSHEA. Cuarenta y siete por ciento de los productos se compararon con drogas ilícitas, típicamente marihuana (48%) o éxtasis (23%). Los ingredientes más comunes hallados en los productos fueron alcaloides de efedra (27%), *Salvia divinorum* (17%), kava (10%), guarana (10%), *Acorus calamus* (10%) y damiana (10%). El reclamo de efectos frecuentemente involucraba productos con acción alucinógena (51%) o estimulante (39%). Un 64% de los sitios mencionaron efectos adversos y 54% mencionaron interacciones a con medicamentos.

**CONCLUSIONES:** Este estudio demostró que algunos suplementos nutricionales botánicos se están mercadeando como alternativas legales para sustancias ilícitas de abuso. Los profesionales de la salud deben conocer esta tendencia y los productos que están involucrados.

Jorge R Miranda Massari

#### RÉSUMÉ

**OBJECTIF:** L'objectif de cette étude est de décrire le contenu des sites internet qui annoncent et vendent des suppléments diététiques pour usage récréatif.

**MÉTHODES:** Quatre moteurs de recherche et les mots clés suivants "buy herbal high" et "buy legal high" ont été utilisés afin d'identifier les sites internet qui vendent ces produits. Les sites internet ont été évalués selon leurs pays d'origine et la conformité avec le "Dietary Supplement Health and Education Act (DSHEA)." Les éléments suivants ont été évalués: la liste des ingrédients, les effets annoncés, la comparaison avec les drogues illicites, les effets indésirables, les interactions médicamenteuses, et les contre indications.

**RÉSULTATS:** Un nombre de 28 sites internet avec 119 produits ont été évalués. La majorité de sites était retrouvé aux États-Unis (54%) et étaient conformes avec le DSHEA. Quarante-sept pour cent des produits étaient associés à des drogues illicites, typiquement la marijuana (48%) ou l'éctasie (23%). Les ingrédients les plus souvent retrouvés étaient l'éphédra (27%), la *Salvia divinorum* (17%), le kava (10%), le guarana (10%), l'*Acorus calamus* (10%), et le damiana (10%). Les effets annoncés impliquaient souvent les produits utilisés comme hallucinogènes (51%) ou stimulants (39%). Soixante-quatre pour cent des sites décrivaient les effets indésirables et 54% les interactions médicamenteuses.

**CONCLUSIONS:** Cette étude démontre que les suppléments diététiques sont utilisés comme alternative aux drogues illicites. Les professionnels de la santé doivent être au courant de cette tendance et connaître les produits impliqués.

Louise Mallet

DRAFT V.4

DEPARTMENT OF HEALTH

CONTROLLED DRUGS AND SUBSTANCES ACT

*Notice to interested parties - Proposal regarding the addition of Salvia divinorum and salvinorin A to Schedule III to the Controlled Drugs and Substances Act*

This notice provides interested stakeholders with the opportunity to provide preliminary comments on Health Canada's proposal to add the plant *Salvia divinorum* (*S. divinorum*) and its active ingredient salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA), and to identify themselves for inclusion in any future consultation.

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are generally chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant. Neither *S. divinorum* nor salvinorin A are currently included in any of the Schedules to the CDSA.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs. As *S. divinorum* and salvinorin A are pharmacologically similar to other substances included in Schedule III to the CDSA, such as LSD and psilocybin, Health Canada is concerned that their ready availability poses a risk to the health and safety of Canadians. particularly youth

While these substances are not currently included in any of the United Nations Drug Control Conventions, a number of countries have chosen to regulate one or both as controlled substances. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden have all placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. Some individual American states have also implemented laws restricting its use, sale and/or distribution.

Placing these substances within Schedule III to the CDSA would prohibit the following activities with these substances unless authorized by regulation: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation).

As this action is not intended to interfere with the use and availability of *S. divinorum* and/or salvinorin A for a legitimate medical, scientific or industrial purpose, Health Canada is seeking information from stakeholders on whether there are any such legitimate uses for these aforementioned substances in Canada. Information received in response to this notice will be instrumental in determining appropriate regulation under the CDSA, as required.

Need for stronger statements as to risk; include evidence

The publication of this notice begins a 30-day comment period. There will be additional opportunities to provide comments following prepublication of the scheduling proposal in *Canada Gazette*, Part I.

If you are interested in this process or have comments on this proposal, please contact Stephanie Chandler, Regulatory Policy Division, Office of Controlled Substances, Address Locator: 3503D, 123 Slater St., Ottawa, Ontario, Canada, K1A 1B9, by fax at (613) 946-4224 or by email at [OCS\\_Policy\\_and\\_Regulatory\\_Affairs@hc-sc.gc.ca](mailto:OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca).

Cathy A. Sabiston  
Director General  
Controlled Substances and Tobacco Directorate

Date \_\_\_\_\_

DRAFT V.5

DEPARTMENT OF HEALTH

CONTROLLED DRUGS AND SUBSTANCES ACT

Notice to interested parties - Proposal regarding the addition of *Salvia divinorum* and salvinorin A to Schedule III to the Controlled Drugs and Substances Act

This notice provides interested stakeholders with the opportunity to provide preliminary comments on Health Canada's proposal to add the plant *Salvia divinorum* (*S. divinorum*) and its active ingredient salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA). Stakeholders may also identify themselves for inclusion in any future consultation.

*S. divinorum* is a species of sage belonging to the mint family. Its leaves are generally chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant. Neither *S. divinorum* nor salvinorin A are currently included in any of the Schedules to the CDSA.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs. Results from the Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that, in 2009, 1.6% of Canadians aged 15 years and older reported having used *S. divinorum* at least once in their lifetime. Youth, ages 15-24 were much more likely to have used it than adults. The results from the Canadian 2008-2009 Youth Smoking Survey show that 5% of 15 year olds have used *Salvia divinorum* in the past year. Health Canada is concerned about the potential abuse and unknown effects of these substances. As *S. divinorum* and salvinorin A are pharmacologically similar to other substances included in Schedule III to the CDSA, such as LSD and psilocybin, Health Canada is concerned that their ready availability poses a risk to the health and safety of Canadians, particularly youth.

Note 8  
Page 2  
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Mexico

While these substances are not currently included in any of the United Nations Drug Control Conventions, a number of countries have chosen to regulate one or both as controlled substances. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden have all placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. Some American states have also implemented laws restricting its use, sale and/or distribution.

Placing these substances within Schedule III to the CDSA would prohibit the following activities with these substances unless authorized by regulation: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation). The control of *S. divinorum* and salvinorin A under the CDSA will enable law enforcement agencies to take action against suspected illegal activities involving these substances.

As this action is not intended to interfere with the use and availability of *S. divinorum* and/or salvinorin A for a legitimate medical, scientific or industrial purpose, Health Canada is seeking information from stakeholders on whether there are any such legitimate uses for these aforementioned substances in Canada. Information received in response to this notice will be instrumental in determining appropriate regulation under the CDSA.

The publication of this notice begins a 30-day comment period. There will be additional opportunities to provide comments following prepublication of the scheduling proposal in *Canada Gazette*, Part I.

If you are interested in this process or have comments on this proposal, please contact Stephanie Chandler, Regulatory Policy Division, Office of Controlled Substances, Address Locator: 3503D, 123 Slater St., Ottawa, Ontario, Canada, K1A 1B9, by fax at (613) 946-4224 or by email at [OCS\\_Policy\\_and\\_Regulatory\\_Affairs@hc-sc.gc.ca](mailto:OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca).

Cathy A. Sabiston  
Director General  
Controlled Substances and Tobacco Directorate

Date \_\_\_\_\_

Stephanie,  
Come and see me in Jorelyn's office.  
-DMIS

DRAFT V.6

DEPARTMENT OF HEALTH

CONTROLLED DRUGS AND SUBSTANCES ACT

Notice to interested parties - Proposal regarding the addition of *Salvia divinorum* and salvinorin A to Schedule III to the Controlled Drugs and Substances Act

This notice provides interested stakeholders with the opportunity to provide preliminary comments on Health Canada's proposal to add the plant *Salvia divinorum* (*S. divinorum*) and its active ingredient salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA). Stakeholders may also identify themselves for inclusion in any future consultation.

*S. divinorum* is a species of sage belonging to the mint family. Its leaves are generally chewed or smoked to obtain psychotropic effects. While uncertainty remains surrounding the health risks of *S. divinorum*, the known effects are thought to be short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant. Neither *S. divinorum* nor salvinorin A are currently included in any of the Schedules to the CDSA.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. *S. divinorum* is widely touted as a "legal" hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs. Moreover, results from the Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that, in 2009, 1.6% of Canadians aged 15 years and older reported having used *S. divinorum* at least once in their lifetime. Youth, ages 15-24 were much more likely to have used it than adults. The results from the Canadian 2008-2009 Youth Smoking Survey show that 5% of 15 year olds have used *S. divinorum* in the past year. ~~Health Canada is troubled by the potential abuse and unknown effects of these substances.~~

Given their pharmacological similarity to other substances included in Schedule III to the CDSA, such as LSD and psilocybin, Health Canada is concerned that the ready availability and use of *S. divinorum* and salvinorin A pose a risk to the health and safety of Canadians, particularly youth.

While these substances are not currently included in any of the United Nations Drug Control Conventions, a number of countries have chosen to regulate one or both as controlled substances. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden have all placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. Some American states have also implemented laws restricting its use, sale and/or distribution.

Placing these substances within Schedule III to the CDSA would prohibit the following activities with these substances unless authorized by regulation: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation). The control of *S. divinorum* and salvinorin A under the CDSA will

reported

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will

enable law enforcement agencies to take action against suspected illegal activities involving these substances.

As this action is not intended to interfere with the use and availability of *S. divinorum* and/or salvinorin A for a legitimate medical, scientific or industrial purpose, Health Canada is seeking information from stakeholders on whether there are any such legitimate uses for these aforementioned substances in Canada. Information received in response to this notice will be instrumental in determining appropriate regulation under the CDSA.

The publication of this notice begins a 30-day comment period. There will be additional opportunities to provide comments following prepublication of the scheduling proposal in *Canada Gazette*, Part I.

If you are interested in this process or have comments on this proposal, please contact Stephanie Chandler, Regulatory Policy Division, Office of Controlled Substances, Address Locator: 3503D, 123 Slater St., Ottawa, Ontario, Canada, K1A 1B9, by fax at (613) 946-4224 or by email at [OCS\\_Policy\\_and\\_Regulatory\\_Affairs@hc-sc.gc.ca](mailto:OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca).

Cathy A. Sabiston  
Director General  
Controlled Substances and Tobacco Directorate

Date \_\_\_\_\_



DRAFT V.6

DEPARTMENT OF HEALTH

CONTROLLED DRUGS AND SUBSTANCES ACT

Notice to interested parties - Proposal regarding the addition of *Salvia divinorum* and salvinorin A to Schedule III to the Controlled Drugs and Substances Act

This notice provides interested stakeholders with the opportunity to provide preliminary comments on Health Canada's proposal to add the plant *Salvia divinorum* (*S. divinorum*) and its active ingredient salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA). Stakeholders may also identify themselves for inclusion in any future consultation.

*S. divinorum* is a species of sage belonging to the mint family. Its leaves are generally chewed or smoked to obtain psychotropic effects. While uncertainty remains surrounding the health risks of *S. divinorum*, known effects are reported to be short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant. Neither *S. divinorum* nor salvinorin A are currently included in any of the Schedules to the CDSA.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. *S. divinorum* is widely touted as a "legal" hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs. Moreover, results from the Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that, in 2009, 1.6% of Canadians aged 15 years and older reported having used *S. divinorum* at least once in their lifetime, <sup>and that</sup> youth, aged 15-24 were much more likely to have used it than adults. The results from the Canadian 2008-2009 Youth Smoking Survey show that 5% of 15 year olds have used *S. divinorum* in the past year. Given ~~that~~ <sup>these</sup> unknown effects and pharmacological similarity to other substances included in Schedule III to the CDSA, such as LSD and psilocybin, Health Canada is concerned that the ready availability and use of *S. divinorum* ~~and salvinorin A~~ <sup>also</sup> pose a risk to the health and safety of Canadians, particularly youth.

\* add referen

used by XX and older

While ~~these substances~~ <sup>are</sup> not currently included in any of the United Nations Drug Control Conventions, a number of countries have chosen to regulate one or both as controlled substances. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden have all placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. Some American states have also implemented laws restricting ~~the~~ <sup>their</sup> use, sale and/or distribution.

salvia divinorum and salvinorin A

~~Including~~ <sup>including</sup> these substances within Schedule III to the CDSA would prohibit ~~the following~~ <sup>the following</sup> activities with these substances unless authorized by regulation: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation). The control of *S. divinorum* and salvinorin A under

the CDSA will enable law enforcement agencies to take action against suspected illegal activities involving these substances.

As this action is not intended to interfere with the use and availability of *S. divinorum* and/or salvinorin A for ~~the~~ legitimate medical, scientific or industrial purposes, Health Canada is seeking information from stakeholders on whether there are any such ~~legitimate uses for these aforementioned substances~~ in Canada. Information received in response to this notice will be instrumental in determining appropriate regulation under the CDSA, *as required*.

*removed from post draft by Cathy SC.*

The publication of this notice begins a 30-day comment period. There will be additional opportunities to provide comments following prepublication of the scheduling proposal in *Canada Gazette*, Part I.

If you are interested in this process or have comments on this proposal, please contact Stephanie Chandler, Regulatory Policy Division, Office of Controlled Substances, Address Locator: 3503D, 123 Slater St., Ottawa, Ontario, Canada, K1A 1B9, by fax at (613) 946-4224 or by email at [OCS\\_Policy\\_and\\_Regulatory\\_Affairs@hc-sc.gc.ca](mailto:OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca).

Cathy A. Sabiston  
Director General  
Controlled Substances and Tobacco Directorate

Date \_\_\_\_\_

**DRAFT V.7**

DEPARTMENT OF HEALTH

CONTROLLED DRUGS AND SUBSTANCES ACT

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*S. divinorum* is a species of sage belonging to the mint family. Its leaves are generally chewed or smoked to obtain psychotropic effects. While uncertainty remains surrounding the health risks of *S. divinorum*, known effects are reported to be short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant. Neither *S. divinorum* nor salvinorin A are currently included in any of the Schedules to the CDSA.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. *S. divinorum* is widely touted as a "legal" hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs.<sup>1</sup> Results from the *Canadian Alcohol and Drug Use Monitoring Survey* (CADUMS) reveal that, in 2009, 1.6% of Canadians aged 15 years and older reported having used *S. divinorum* at least once in their lifetime, and that youth aged 15-24 were much more likely to have used it than adults aged 25 years and older. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *S. divinorum* in the past year. Moreover, the 2009 *Ontario Student Drug Use and Health Survey* (OSDUHS) indicated that 5.4% of Ontario students in grades 7-12 reported ever using *S. divinorum* and 4.4% of these students reported using this substance in the past year. Given its unknown effects and pharmacological similarity to other substances included in Schedule III to the CDSA such as LSD and psilocybin, Health Canada is concerned that the ready availability and use of *S. divinorum* poses a risk to the health and safety of Canadians, particularly youth.

While *S. divinorum* and salvinorin A are not currently included in any of the United Nations Drug Control Conventions, a number of countries have chosen to regulate one or both as controlled substances. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden have all placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. Some American states have also implemented laws restricting their use, sale and/or distribution.

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<sup>1</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.

Including these substances within Schedule III to the CDSA would prohibit: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation). The control of *S. divinorum* and salvinorin A under the CDSA will enable law enforcement agencies to take action against suspected illegal activities involving these substances.

As this action is not intended to interfere with the use and availability of *S. divinorum* and/or salvinorin A for legitimate medical, scientific or industrial purposes, Health Canada is seeking information from stakeholders on whether there are any such uses in Canada. Information received in response to this notice will be instrumental in determining appropriate regulation under the CDSA.

The publication of this notice begins a 30-day comment period. There will be additional opportunities to provide comments following prepublication of the scheduling proposal in *Canada Gazette, Part I*.

If you are interested in this process or have comments on this proposal, please contact Stephanie Chandler, Regulatory Policy Division, Office of Controlled Substances, Address Locator: 3503D, 123 Slater St., Ottawa, Ontario, Canada, K1A 1B9, by fax at (613) 946-4224 or by email at [OCS\\_Policy\\_and\\_Regulatory\\_Affairs@hc-sc.gc.ca](mailto:OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca).

Cathy A. Sabiston  
Director General  
Controlled Substances and Tobacco Directorate

Date \_\_\_\_\_



**Re: Salvia MLs and NOI - REVISED**

Jocelyn Kula to: Denis Arsenault

Cc: Stephanie Chandler

2010-12-08 11:16 AM

but it is the name of an Act and should always be italicized.....ergo non-italicize the rest of the text or put it all in italics... was just coming to see Stephanie re one last change

JK

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

Denis Arsenault

Hi Jocelyn, Below are revised version of the ML...

2010-12-08 10:52:22 AM

---

From: Denis Arsenault/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: CSTD-OCS-DO, Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2010-12-08 10:52 AM  
Subject: Salvia MLs and NOI - REVISED

---

Hi Jocelyn,

Below are revised version of the MLs and NOI as per your comments.

Based on your comments on the MLs, note that we have removed all specific references to Schedule III.

Also, for the title of the NOI, we have kept "Controlled Drugs and Substances Act" non-italicized to differentiate it from the rest of the title which is italicized.

Denis

---

Denis Arsenault, A/Manager / Gestionnaire p.i.  
Regulatory Policy Division /  
Division des politiques réglementaires,  
Office of Controlled Substances /  
Bureau des substances contrôlées,  
Health Canada / Santé Canada  
Tel/Tél: (613) 957-6828  
Fax / Télécopieur : (613) 946-4224  
E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca

----- Forwarded by Denis Arsenault/HC-SC/GC/CA on 2010-12-08 10:47 AM -----

---

From: Stephanie Chandler/HC-SC/GC/CA  
To: Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2010-12-08 10:21 AM  
Subject: Revised Salvia MLs and NOI

---

Hi Denis,

001834

Revised as per Jocelyn's comments. To be returned to the DO by COB. I'll bring over JK's comments shortly.

[attachment "Salvia Media Lines\_Dec 8.doc" deleted by Jocelyn Kula/HC-SC/GC/CA] [attachment "DRAFT Salvia NOI\_Dec 8.wpd" deleted by Jocelyn Kula/HC-SC/GC/CA]

Thanks,

Stephanie



**Salvia MLs and NOI - REVISED**

Denis Arsenault to: Jocelyn Kula  
Cc: CSTD-OCS-DO, Stephanie Chandler

2010-12-08 10:52 AM

Hi Jocelyn,

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Denis

---

Denis Arsenault, A/Manager / Gestionnaire p.i.  
Regulatory Policy Division /  
Division des politiques réglementaires,  
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Health Canada / Santé Canada  
Tel/Tél: (613) 957-6828  
Fax / Télécopieur : (613) 946-4224  
E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca

----- Forwarded by Denis Arsenault/HC-SC/GC/CA on 2010-12-08 10:47 AM -----

From: Stephanie Chandler/HC-SC/GC/CA  
To: Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2010-12-08 10:21 AM  
Subject: Revised Salvia MLs and NOI

Hi Denis,

Revised as per Jocelyn's comments. To be returned to the DO by COB. I'll bring over JK's comments shortly.



Salvia Media Lines\_Dec 8.doc DRAFT Salvia NOI\_Dec 8.wpd

Thanks,

Stephanie

DRAFT 14  
December 8, 2010

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### Media Lines *Salvia divinorum*

#### Issue

Further to ongoing media interest regarding the availability of *Salvia divinorum* in Canada and reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties, Health Canada has concluded that *Salvia divinorum* and its main active ingredient salvinorin A should be included in one of the Schedules to the *Controlled Drugs and Substances Act* (CDSA).

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#### Key Messages:

- Health Canada is proposing that *Salvia divinorum* and salvinorin A be regulated as controlled substances under the *Controlled Drugs and Substances Act* (CDSA). The inclusion of *Salvia divinorum* and salvinorin A in the Schedules to the CDSA will mitigate the risks associated with their ready availability and potential abuse.
- Health Canada intends to inform stakeholders of its decision via the publication of a *Notice to Interested Parties* (NOI) in *Canada Gazette*, Part I. The NOI will provide stakeholders and other interested parties with the opportunity to provide comments on the proposal to regulate these substances as controlled substances.

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#### Supplementary Messages:

- Canadians should not use products containing *S. divinorum* and/or salvinorin A because very little is known about these substances and their potential effects on the brain and/or body, and their impact on physical and mental functions.
- Because of their hallucinogenic properties, products containing *S. divinorum* and/or salvinorin A meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*.
- It is illegal to sell NHPs in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN). The illegal sale of products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*.
- Neither *Salvia divinorum* nor salvinorin A are listed under the *United Nations Drug Control Conventions* and thus, do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

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*Salvia divinorum* as a controlled substance.¶

<#>In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA). ¶

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DRAFT 14  
December 8, 2010

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### Media Lines *Salvia divinorum*

#### Issue

Further to ongoing media interest regarding the availability of *Salvia divinorum* in Canada and reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties, Health Canada has concluded that *Salvia divinorum* and its main active ingredient salvinorin A should be included in one of the Schedules to the *Controlled Drugs and Substances Act* (CDSA).

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#### Key Messages:

- Health Canada is proposing that *Salvia divinorum* and salvinorin A be regulated as controlled substances under the *Controlled Drugs and Substances Act* (CDSA). The inclusion of *S. divinorum* and salvinorin A in the Schedules to the CDSA will mitigate the risks associated with their ready availability and potential abuse.
- Health Canada intends to inf...  
Notice to Interested Parties (stakeholders and other intere...  
proposal to regulate these su...

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#### Supplementary Messages:

- Canadians should not use p... very little is known about th... body, and their impact on p...
- Because of their hallucinoy... salvinorin A meet the defn... Health Products Regulatio...
- It is illegal to sell NHPs in... authorized for sale. NHP: a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN). The illegal sale of products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*.
- Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and thus, do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

Approved but pls change wording to "in one of the Schedules" in several places (marked) Go ahead and send to Canada

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It is illegal to sell NHPs in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN). The illegal sale of products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*. ¶  
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¶  
<#>In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA). ¶  
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- The move to include *S. divinorum* and salvinorin A in the Schedules to the CDSA is consistent with actions taken by several countries (Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. It is also consistent with the fact that some individual U.S. states have implemented laws restricting their use, sale and/or distribution.

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Questions and Answers:

**Q1 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum* as a controlled substance. What does that involve and what stage is it at?**

A1 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

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Health Canada recently concluded its assessment of *S. divinorum* and salvinorin A against the aforementioned factors and proposes to include both substances in one of the Schedules to the CDSA.

**Q2 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why isn't it illegal?**

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A2 – Health Canada intends to include *S. divinorum* and salvinorin A under one of the Schedules to the CDSA. In the interim, as *S. divinorum* meets the definition of a Natural Health Product (NHP) under the *Natural Health Product Regulations*, it is illegal to manufacture, sell or provide products containing *S. divinorum* and/or salvinorin A without their being authorized by Health Canada prior to sale.

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**Q3 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?**

Deleted: Health Canada is currently reviewing all the available information regarding *Salvia divinorum*, including the prevalence of its use in Canada, to determine whether it should be regulated under the *Controlled Drugs and Substances Act*. ¶

A3 – The *Natural Health Products Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *Salvia divinorum*. When *S. divinorum* and salvinorin A are included in the Schedules to the CDSA, it will be illegal to possess, import, export, produce and distribute these substances in any form unless authorized by regulation.

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one of

**Q4 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

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A4 – Once *S. divinorum* and salvinorin A are included in the Schedules to the CDSA, law enforcement will be able to take appropriate action in response to suspected illegal activities with these substances.

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In the interim, *S. divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. Complaints about the illegal sale of drugs containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

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**Q5 – What is the significance of the adverse reaction reports that Health Canada has received with respect to the use of *Salvia divinorum*?**

A5 – Health Canada has received four domestic adverse reaction reports related to the use of *Salvia divinorum* as a hallucinogen through the Canada Vigilance database. The number of reports and the nature of reactions reported are, however, not adequate to fully characterize the risk of similar reactions among the general population

Deleted: Q4 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum* as a controlled substance. What does that involve and what stage is it at?

***If pressed on whether Health Canada has issued any kind of warning to Canadians about *Salvia divinorum****

A4 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:  
<#>International requirements and trends in international control;  
<#>Chemical and pharmacological similarity to other substances already regulated under the CDSA;  
<#>Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);  
<#>Potential for abuse and risk of addiction associated with the substance;  
<#>Extent of actual abuse of the substance in Canada and internationally; and  
<#>Overall risk to public health and safety posed by the substance.

A - Health Canada is developing an It's Your Health (IYH) article on *Salvia divinorum* to help inform the general public about the risks associated with the use of this plant.

**Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

Health Canada is currently reviewing the available information to determine whether regulation of *Salvia divinorum* under the CDSA is warranted.

Q5 – Didn't an internal report from Health Canada's Marketed Health Products Directorate recommend that *Salvia divinorum* be scheduled under the CDSA? Why has that recommendation not been acted upon?

Data from the 2008-2009 Youth Smoking Survey indicates that:

- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;
- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year; and.
- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

A5 – See A4

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Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using Salvia in their lifetime (0.2% in the past year); and
- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that:

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;
- 5.4% of students (grades 7-12) ever used *S. divinorum*; and
- the use of *S. divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

**Prepared by:** Stephanie Chandler and Denis Arsenaault, OCS, CSTD

**Deleted:** Cheryl Tremblay

**Input by:** Lisa Mackay IYH/PACCB, Suzanne Desjardins HECSB/ODARS, Hanan Abramovici HECSB/ODARS, Bruna Brands HECSB/ODARS, Jocelyn Kula, HECSB/OCS, Robin Marles HPFB/NHPD, Maggie Graham HPFB/NHPD, Stephanie Collins HPFB/NHPD, Mano Murty HPFB/MHPD, Robert Leitch HPFB/MHPD, Shahid Perwaiz HPFB/MHPD, Collin Pinto, HPFB/HPFBI

**Approved by:**

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Lindsay Blaney, Director, Policy and Regulatory Affairs, NHPD (pending)  
Duc Vu, Director, Marketed Biologics, Biotechnology and Natural Health Products  
Bureau, MHPD (pending)  
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Diane Allan, Director, OCS, CSTD, HECS (approved, Sept 29, 2010)  
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HECS Legal (pending)  
HPFB Legal (pending)  
Paul Glover, ADM, HECSB (pending)  
Meena Ballantyne, ADM, HPFB (pending)  
Anne Lamar, ADM, PACCB (pending)  
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DRAFT 14  
December 9, 2010

### Media Lines *Salvia divinorum*

#### Issue

Further to ongoing media interest regarding the availability of *Salvia divinorum* in Canada and reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties, Health Canada has concluded that *Salvia divinorum* and its main active ingredient salvinorin A should be included in one of the Schedules to the *Controlled Drugs and Substances Act (CDSA)*.

#### Key Messages:

- Health Canada has concluded its assessment of *S. divinorum* and salvinorin A and is proposing to include both substances in one of the Schedules to the CDSA.
- The inclusion of *S. divinorum* and salvinorin A in one of the Schedules to the CDSA will reduce the potential health and safety risks associated with their ready availability and potential abuse.
- Health Canada will inform stakeholders of its decision by publishing a *Notice to Interested Parties (NOI)* in *Canada Gazette, Part I*. The NOI will provide stakeholders and other interested parties with the opportunity to provide comments on the proposal to regulate these substances as controlled substances.

#### Supplementary Messages:

- Canadians should not use products containing *S. divinorum* and/or salvinorin A because very little is known about these substances and their potential effects on the brain and/or body, and their impact on physical and mental functions.
- Because of their hallucinogenic properties, products containing *S. divinorum* and/or salvinorin A meet the definition of a natural health product (NHP) under the Natural Health Products Regulations and the definition of a drug under the Food and Drugs Act.
- It is illegal to sell NHPs in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN). The illegal sale of products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*.
- Neither *S. divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and thus, do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

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- The move to include *S. divinorum* and salvinorin A in one of the Schedules to the CDSA is consistent with actions taken by several countries (Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. It is also consistent with the fact that some individual U.S. states have implemented laws restricting their use, sale and/or distribution.

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**Questions and Answers:**

**Q1 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum* as a controlled substance. What does that involve and what stage is it at?**

A1 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
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Health Canada recently concluded its assessment of *S. divinorum* and salvinorin A against the aforementioned factors and proposes to include both substances in one of the Schedules to the CDSA.

**Q2 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why isn't it illegal?**

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A2 – Health Canada intends to include *S. divinorum* and salvinorin A under one of the Schedules to the CDSA. In the interim, as *S. divinorum* meets the definition of a Natural Health Product (NHP) under the *Natural Health Product Regulations*, it is illegal to manufacture, sell or provide products containing *S. divinorum* and/or salvinorin A without their being authorized by Health Canada prior to sale.

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**Q3 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?**

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**Q4 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

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A4 – Once *S. divinorum* and salvinorin A are included in one of the Schedules to the CDSA, law enforcement will be able to take appropriate action in response to suspected illegal activities with these substances.

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***If pressed on whether Health Canada has issued any kind of warning to Canadians about *Salvia divinorum****

A - Health Canada is developing an It's Your Health article on *Salvia divinorum* to help inform the general public about the risks associated with the use of this plant.

Health Canada is currently reviewing the available information to determine whether regulation of *Salvia divinorum* under the CDSA is warranted.

**Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

Q5 – Didn't an internal report from Health Canada's Marketed Health Products Directorate recommend that *Salvia divinorum* be scheduled under the CDSA? Why has that recommendation not been acted upon?

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

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A5 – See A4

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- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;
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- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

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- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

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**Prepared by:** Stephanie Chandler and Denis Arsenault, OCS, CSTD

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**Input by:** Lisa Mackay IYH/PACCB, Suzanne Desjardins HECSB/ODARS, Hanan Abramovici HECSB/ODARS, Bruna Brands HECSB/ODARS, Jocelyn Kula, HECSB/OCS, Robin Marles HPFB/NHPD, Maggie Graham HPFB/NHPD, Stephanie Collins HPFB/NHPD, Mano Murty HPFB/MHPD, Robert Leitch HPFB/MHPD, Shahid Perwaiz HPFB/MHPD, Collin Pinto, HPFB/HPFBI

**Approved by:**

Robin Marles, Director, Bureau of Clinical Trials, NHPD (pending)  
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Warren Braun, Director, Strategic Communications, PACCB (pending)  
Peter Yendall, Director, Public Affairs, PACCB (pending)  
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Anne Lamar, ADM, PACCB (pending)  
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STCHANDL

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Because of their hallucinogenic properties, products containing *S. divinorum* and/or salvinorin A meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*.

It is illegal to sell NHPs in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN). The illegal sale of products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*.

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STCHANDL

2010-11-26 2:27:00 PM

***Salvia divinorum as a controlled substance:***

In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA).

Overall focus: we need to crystallize why we are scheduling: → abuse potential → increasing use → unknown effects

Need for stronger rationale for NOZ

DRAFT 14  
December 9, 2010

~~NOZ~~

**Media Lines**  
**Salvia divinorum**

**Issue**

Further to ongoing media interest regarding the availability of *Salvia divinorum* in Canada and reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties, Health Canada has concluded that *Salvia divinorum* and its main active ingredient salvinorin A should be included in one of the Schedules to the *Controlled Drugs and Substances Act* (CDSA).

X# number of kids using it

HC concerned about increased use... see CADUMS

**Key Messages:**

- Health Canada has concluded its assessment of *S. divinorum* and salvinorin A and is proposing to include both substances in one of the Schedules to the CDSA.
- The inclusion of *S. divinorum* and salvinorin A in one of the Schedules to the CDSA will reduce the potential health and safety risks associated with their ready availability and potential abuse.
- Health Canada will inform stakeholders of its decision by publishing a *Notice to Interested Parties* (NOI) in *Canada Gazette*, Part I. The NOI will provide stakeholders and other interested parties with the opportunity to provide comments on the proposal to regulate these substances as controlled substances.

~~NOZ~~

**Supplementary Messages:**

- Canadians should not use products containing *S. divinorum* and/or salvinorin A because very little is known about these substances and their potential effects on the brain and/or body, and their impact on physical and mental functions.
- Because of their hallucinogenic properties, products containing *S. divinorum* and/or salvinorin A meet the definition of a natural health product (NHP) under the Natural Health Products Regulations and the definition of a drug under the Food and Drugs Act.
- It is illegal to sell NHPs in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN). The illegal sale of products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*.
- Neither *S. divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and thus, do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

Def. of NHP

Currently, salvia and salvinorin are captured as NHP as it is not about and ~~not~~ alters brain functions. This... 001847

- The move to include *S. divinorum* and salvinorin A in one of the Schedules to the CDSA is consistent with actions taken by several countries (Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. It is also consistent with the fact that some individual U.S. states have implemented laws restricting their use, sale and/or distribution.

**Questions and Answers:**

**Q1 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum* as a controlled substance. What does that involve and what stage is it at?**

A1 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Why are we scheduling? Potential for abuse given increasing use.

Health Canada recently concluded its assessment of *S. divinorum* and salvinorin A against the aforementioned factors and proposes to include both substances in one of the Schedules to the CDSA.

**Q2 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why isn't it illegal?**

A2 – Health Canada intends to include *S. divinorum* and salvinorin A under one of the Schedules to the CDSA. In the interim, as *S. divinorum* meets the definition of a Natural Health Product (NHP) under the *Natural Health Product Regulations*, it is illegal to manufacture, sell or provide products containing *S. divinorum* and/or salvinorin A without their being authorized by Health Canada prior to sale.

**Q3 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?**

A3 – The *Natural Health Products Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *S. divinorum*. When *S. divinorum* and salvinorin A are included in one of the Schedules to the CDSA, it will be illegal to possess, import, export, produce and distribute these substances in any form unless authorized by regulation.

→ by scheduling, it will become illegal / could eliminate perception that it is not

**Q4 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A4 – Once *S. divinorum* and salvinorin A are included in one of the Schedules to the CDSA, law enforcement will be able to take appropriate action in response to suspected illegal activities with these substances.

In the interim, *S. divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. Complaints about the illegal sale of drugs containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

**Q5 – What is the significance of the adverse reaction reports that Health Canada has received with respect to the use of *Salvia divinorum*?**

A5 – Health Canada has received four domestic adverse reaction reports related to the use of *Salvia divinorum* as a hallucinogen through the Canada Vigilance database. The number of reports and the nature of reactions reported are, however, not adequate to fully characterize the risk of similar reactions among the general population

***If pressed on whether Health Canada has issued any kind of warning to Canadians about *Salvia divinorum****

A - Health Canada is developing an It's Your Health article on *Salvia divinorum* to help inform the general public about the risks associated with the use of this plant.

**Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

Data from the 2008-2009 Youth Smoking Survey indicates that:

- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;
- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year; and
- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using Salvia in their lifetime (0.2% in the past year); and
- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that:

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;
- 5.4% of students (grades 7-12) ever used *S. divinorum*; and
- the use of *S. divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

**Prepared by:** Stephanie Chandler and Denis Arsenault, OCS, CSTD

**Input by:** Lisa Mackay IYH/PACCB, Suzanne Desjardins HECSB/ODARS, Hanan Abramovici HECSB/ODARS, Bruna Brands HECSB/ODARS, Jocelyn Kula, HECSB/OCS, Robin Marles HPFB/NHPD, Maggie Graham HPFB/NHPD, Stephanie Collins HPFB/NHPD, Mano Murty HPFB/MHPD, Robert Leitch HPFB/MHPD, Shahid Perwaiz HPFB/MHPD, Collin Pinto, HPFB/HPFBI

**Approved by:**

Robin Marles, Director, Bureau of Clinical Trials, NHPD (pending)  
Lindsay Blaney, Director, Policy and Regulatory Affairs, NHPD (pending)  
Duc Vu, Director, Marketed Biologics, Biotechnology and Natural Health Products Bureau, MHPD (pending)  
Kim Dayman-Rutkas, Director, HPFBI (pending)  
Diane Allan, Director, OCS, CSTD, HECS (approved, Sept 29, 2010)  
Suzanne Desjardins, Director, ODARS, CSTD, HECS approved, Sept 30, 2010)  
Cathy Sabiston, DG, CSTD, HECS (pending)  
Chris Turner, DG, MHPD (pending)  
Nancy Richards, DG, NHPD (pending)  
Diana Dowthwaite, DG, HPFBI (pending)  
Ken Polk, Communications Executive, HPFB (pending)  
Jean Tessier, Senior Media Relations, PACCB (pending)  
Warren Braun, Director, Strategic Communications, PACCB (pending)  
Peter Yendall, Director, Public Affairs, PACCB (pending)  
HECS Legal (pending)  
HPFB Legal (pending)  
Paul Glover, ADM, HECSB (pending)  
Meena Ballantyne, ADM, HPFB (pending)  
Anne Lamar, ADM, PACCB (pending)  
DMO (pending)  
MO (pending)  
PCO (pending)

→ 5 bundles MDS  
to Acus →  
NOI  
→ Drop point  
about adverse  
reactions.



**Re: Revised Salvia MLs and NOI**   
Jocelyn Kula to: Stephanie Chandler

2010-12-09 12:13 AM

History: This message has been replied to.

thx Stephanie; try again tomorrow but if you have not heard anything by 12 noon, try calling Christine Roush (she is Nicole's manager)...

JK

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

---

Stephanie Chandler Hi Jocelyn, I have updated the Media Lines for... 2010-12-08 04:08:46 PM

---

From: Stephanie Chandler/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Denis Arseneault/HC-SC/GC/CA@HWC  
Date: 2010-12-08 04:08 PM  
Subject: Revised Salvia MLs and NOI

Hi Jocelyn,

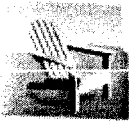
I have updated the Media Lines for Salvia as requested. However, I haven't been able to get in touch with Nicole Prentice today with regards to having Cathy approve the MLs and NOI together. I'll let you know once I hear back from her.

[attachment "Salvia Media Lines\_Dec 8.doc" deleted by Jocelyn Kula/HC-SC/GC/CA] [attachment "DRAFT Salvia NOI\_Dec 8.wpd" deleted by Jocelyn Kula/HC-SC/GC/CA]

Regards,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca



**Re: Salvia MLs-Revised** 

Nicole Prentice to: Stephanie Chandler

2010-12-09 03:14 PM

Cc: Christine Roush, CSTD-OCS-DO, Denis Arsenault, Jocelyn Kula

History: This message has been forwarded.

---

Hi Stephanie,

As promised, here are the MLs with a few changes from Christine and a question for policy to answer. If you have any questions, please let us know.

When you send to CSTD DGO for approval, can you please cc Christine Roush and myself on the email. Once Cathy approves, we can discuss the next steps in the approval process (as discussed earlier, the media lines have about 10 more approvals after Cathy).

Thanks!  
Nicole



Salvia Media Lines\_Dec 8\_(revcr).doc

**Nicole Prentice**

Junior Communications Officer | Agente junior des Communications  
Regulatory Communications and Media Relations Division | Division des communications réglementaires et des relations avec les médias  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la consultation et des communications  
Health Canada | Santé Canada  
Tel: 613.941.3107  
Fax: 613.948.8085

Stephanie Chandler Hi Nicole, Here are the revised Salvia Media Li...

2010-12-09 01:05:47 PM

From: Stephanie Chandler/HC-SC/GC/CA  
To: Nicole Prentice/HC-SC/GC/CA@HWC  
Cc: Christine Roush/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, CSTD-OCS-DO  
Date: 2010-12-09 01:05 PM  
Subject: Salvia MLs-Revised

---

Hi Nicole,

Here are the revised Salvia Media Lines, approved by the Director, OCS.  
[attachment "Salvia Media Lines\_Dec 8.doc" deleted by Nicole Prentice/HC-SC/GC/CA]

As we discussed this morning, it would be appreciated if your group could review and approve the MLs and then return them to OCS. We will then forward them to the CSTD DGO for approval along with the Salvia NOI so that these documents can be reviewed by Cathy together.

Regards,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca



DRAFT 14  
December 8, 2010

### Media Lines *Salvia divinorum*

#### Issue

Further to ongoing media interest regarding the availability of *Salvia divinorum* in Canada and reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties, Health Canada has concluded that *Salvia divinorum* and its main active ingredient salvinorin A should be included in one of the Schedules to the *Controlled Drugs and Substances Act* (CDSA).

#### Key Messages:

- Health Canada has concluded its assessment of *S. divinorum* and salvinorin A and is proposing to include both substances in one of the Schedules to the CDSA.
- The inclusion of *S. divinorum* and salvinorin A in one of the Schedules to the CDSA will reduce the risks associated with their ready availability and potential abuse. (Message is unclear – reduce what risks (to health, security, i.e., enforcement).
- Health Canada will inform stakeholders of its decision by publishing a *Notice to Interested Parties* (NOI) in *Canada Gazette*, Part I. The NOI will provide stakeholders and other interested parties with the opportunity to provide comments on the proposal to regulate these substances as controlled substances.

#### Supplementary Messages:

- Canadians should not use products containing *S. divinorum* and/or salvinorin A because very little is known about these substances and their potential effects on the brain and/or body, and their impact on physical and mental functions.
- Because of their hallucinogenic properties, products containing *S. divinorum* and/or salvinorin A meet the definition of a natural health product (NHP) under the Natural Health Products Regulations and the definition of a drug under the Food and Drugs Act.
- It is illegal to sell NHPs in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN). The illegal sale of products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*.
- Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and thus, do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

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- Deleted: Since 2006, Health Canada has noted
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- Deleted: proposing that *S. divinorum* and salvinorin A be regulated as controlled substances under the *Controlled Drugs and Substances Act* (CDSA).
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- Deleted: <#>Because of their hallucinogenic properties, products containing *S. divinorum* and/or salvinorin A meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*. ¶ ... [1]
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- The move to include *S. divinorum* and salvinorin A in one of the Schedules to the CDSA is consistent with actions taken by several countries (Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. It is also consistent with the fact that some individual U.S. states have implemented laws restricting their use, sale and/or distribution.

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Deleted: *Salvia divinorum* and salvinorin A are not regulated under the federal *Controlled Substances Act* in the United States.¶  
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#### Questions and Answers:

**Q1 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum* as a controlled substance. What does that involve and what stage is it at?**

A1 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

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Health Canada recently concluded its assessment of *S. divinorum* and salvinorin A against the aforementioned factors and proposes to include both substances in one of the Schedules to the CDSA.

**Q2 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why isn't it illegal?**

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A2 – Health Canada intends to include *S. divinorum* and salvinorin A under one of the Schedules to the CDSA. In the interim, as *S. divinorum* meets the definition of a Natural Health Product (NHP) under the *Natural Health Product Regulations*, it is illegal to manufacture, sell or provide products containing *S. divinorum* and/or salvinorin A without their being authorized by Health Canada prior to sale.

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**Q3 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?**

A3 – The *Natural Health Products Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *Salvia divinorum*. When *S. divinorum* and salvinorin A are included in one of the Schedules to the CDSA, it will be illegal to possess, import, export, produce and distribute these substances in any form unless authorized by regulation.

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**Q4 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

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A4 – Once *S. divinorum* and salvinorin A are included in one of the Schedules to the CDSA, law enforcement will be able to take appropriate action in response to suspected illegal activities with these substances.

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In the interim, *S. divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. Complaints about the illegal sale of drugs containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

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**Q5 – What is the significance of the adverse reaction reports that Health Canada has received with respect to the use of *Salvia divinorum*?**

A5 – Health Canada has received four domestic adverse reaction reports related to the use of *Salvia divinorum* as a hallucinogen through the Canada Vigilance database. The number of reports and the nature of reactions reported are, however, not adequate to fully characterize the risk of similar reactions among the general population

***If pressed on whether Health Canada has issued any kind of warning to Canadians about *Salvia divinorum****

A - Health Canada is developing an It's Your Health article on *Salvia divinorum* to help inform the general public about the risks associated with the use of this plant.

**Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

Data from the 2008-2009 Youth Smoking Survey indicates that:

- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;
- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year; and.
- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

Deleted: Q4 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum* as a controlled substance. What does that involve and what stage is it at?

A4 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:  
<#>International requirements and trends in international control;  
<#>Chemical and pharmacological similarity to other substances already regulated under the CDSA;  
<#>Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);  
<#>Potential for abuse and risk of addiction associated with the substance;  
<#>Extent of actual abuse of the substance in Canada and internationally; and  
<#>Overall risk to public health and safety posed by the substance.

Health Canada is currently reviewing the available information to determine whether regulation of *Salvia divinorum* under the CDSA is warranted.

Q5 – Didn't an internal report from Health Canada's Marketed Health Products Directorate recommend that *Salvia divinorum* be scheduled under the CDSA? Why has that recommendation not been acted upon?

A5 – See A4

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Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using Salvia in their lifetime (0.2% in the past year); and
- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

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- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;
- 5.4% of students (grades 7-12) ever used *S. divinorum*; and
- the use of *S. divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

**Prepared by:** Stephanie Chandler and Denis Arsenault, OCS, CSTD

Deleted: Cheryl Tremblay

**Input by:** Lisa Mackay IYH/PACCB, Suzanne Desjardins HECSB/ODARS, Hanan Abramovici HECSB/ODARS, Bruna Brands HECSB/ODARS, Jocelyn Kula, HECSB/OCS, Robin Marles HPFB/NHPD, Maggie Graham HPFB/NHPD, Stephanie Collins HPFB/NHPD, Mano Murty HPFB/MHPD, Robert Leitch HPFB/MHPD, Shahid Perwaiz HPFB/MHPD, Collin Pinto, HPFB/HPFBI

**Approved by:**

Robin Marles, Director, Bureau of Clinical Trials, NHPD (pending)  
Lindsay Blaney, Director, Policy and Regulatory Affairs, NHPD (pending)  
Duc Vu, Director, Marketed Biologics, Biotechnology and Natural Health Products Bureau, MHPD (pending)  
Kim Dayman-Rutkas, Director, HPFBI (pending)  
Diane Allan, Director, OCS, CSTD, HECS (approved, Sept 29, 2010)  
Suzanne Desjardins, Director, ODARS, CSTD, HECS approved, Sept 30, 2010)  
Cathy Sabiston, DG, CSTD, HECS (pending)  
Chris Turner, DG, MHPD (pending)  
Nancy Richards, DG, NHPD (pending)  
Diana Dowthwaite, DG, HPFBI (pending)  
Ken Polk, Communications Executive, HPFB (pending)  
Jean Tessier, Senior Media Relations, PACCB (pending)  
Warren Braun, Director, Strategic Communications, PACCB (pending)  
Peter Yendall, Director, Public Affairs, PACCB (pending)  
HECS Legal (pending)  
HPFB Legal (pending)  
Paul Glover, ADM, HECSB (pending)  
Meena Ballantyne, ADM, HPFB (pending)  
Anne Lamar, ADM, PACCB (pending)  
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STCHANDL

2010-11-26 2:35:00 PM

Because of their hallucinogenic properties, products containing *S. divinorum* and/or salvinorin A meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*.

It is illegal to sell NHPs in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN). The illegal sale of products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*.

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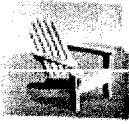
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STCHANDL

2010-11-26 2:27:00 PM

***Salvia divinorum as a controlled substance:***

In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA).



**Re: Fw: Updated Media Lines and Draft Notice of Intent for Salvia** 

Nicole Prentice to: Stephanie Chandler

2010-12-10 09:21 AM

Cc: Christine Roush, Jocelyn Kula

History: This message has been replied to.

Thanks.

Please advise us when Cathy approves and provide us her feedback.

Have a good weekend.

**Nicole Prentice**

Junior Communications Officer | Agente junior des Communications  
Regulatory Communications and Media Relations Division | Division des communications  
réglementaires et des relations avec les médias  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires  
publiques, de la consultation et des communications  
Health Canada | Santé Canada  
Tel: 613.941.3107  
Fax: 613.948.8085

Stephanie Chandler Hi Nicole and Christine, Sorry you weren't cc'e... 2010-12-10 09:07:59 AM

From: Stephanie Chandler/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC, Nicole Prentice/HC-SC/GC/CA@HWC  
Cc: Jocelyn Kula/HC-SC/GC/CA@HWC  
Date: 2010-12-10 09:07 AM  
Subject: Fw: Updated Media Lines and Draft Notice of Intent for Salvia

Hi Nicole and Christine,

Sorry you weren't cc'ed on this... but the Salvia MLs and NOI have gone to DGO.

Regards,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca  
----- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2010-12-10 09:04 AM -----

From: Jocelyn Kula/HC-SC/GC/CA  
To: stephanie.szick@hc-sc.gc.ca  
Cc: CSTD-DGO; Stephanie Chandler/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2010-12-09 06:19 PM

*Media  
Lines*

DRAFT 14  
December 10, 2010

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**Media Lines**  
***Salvia divinorum***

**Issue**

Further to ongoing media interest regarding the availability of *Salvia divinorum* in Canada and reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties, Health Canada has concluded that *Salvia divinorum* and its main active ingredient salvinorin A should be included in one of the Schedules to the *Controlled Drugs and Substances Act* (CDSA).

*regulated for the health & safety of Canadians, particularly youth*

**Key Messages:**

- Health Canada has concluded its assessment of *S. divinorum* and salvinorin A and is proposing to include both substances in one of the Schedules to the CDSA.
- The inclusion of *S. divinorum* and salvinorin A in one of the Schedules to the CDSA will reduce the potential health and safety risks associated with their ready availability and potential abuse.
- Health Canada will inform stakeholders of its decision by publishing a *Notice to Interested Parties* (NOI) in *Canada Gazette*, Part I. The NOI will provide stakeholders and other interested parties with the opportunity to provide comments on the proposal to regulate these substances as controlled substances.

*following activities will be illegal*

*currently law enforcement can't ...*

**Supplementary Messages:**

- Canadians should not use products containing *S. divinorum* and/or salvinorin A because very little is known about these substances and their potential effects on the brain and/or body, and their impact on physical and mental functions.
- Because of their hallucinogenic properties, products containing *S. divinorum* and/or salvinorin A meet the definition of a natural health product (NHP) under the Natural Health Products Regulations and the definition of a drug under the Food and Drugs Act.
- It is illegal to sell NHPs in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN). The illegal sale of products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*.

*why are we regulating/ sched*

Neither *S. divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and thus, do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

*Q&A*

- The move to include *S. divinorum* and salvinorin A in one of the Schedules to the CDSA is consistent with actions taken by several countries (Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. It is also consistent with the fact that some individual U.S. states have implemented laws restricting their use, sale and/or distribution.

Q&A

**Questions and Answers:**

**Q1 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum* as a controlled substance. What does that involve and what stage is it at?**

A1 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada recently concluded its assessment of *S. divinorum* and salvinorin A against the aforementioned factors and proposes to include both substances in one of the Schedules to the CDSA.

**Q2 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why isn't it illegal?**

A2 – Health Canada intends to include *S. divinorum* and salvinorin A under one of the Schedules to the CDSA. In the interim, as *S. divinorum* meets the definition of a Natural Health Product (NHP) under the *Natural Health Product Regulations*, it is illegal to manufacture, sell or provide products containing *S. divinorum* and/or salvinorin A without their being authorized by Health Canada prior to sale.

**Q3 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?**

A3 – The *Natural Health Products Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *S. divinorum*. When *S. divinorum* and salvinorin A are included in one of the Schedules to the CDSA, it will be illegal to possess, import, export, produce and distribute these substances in any form unless authorized by regulation.

|| what did we determine abuse? \* potential for abuse?



**Q4 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A4 – Once *S. divinorum* and salvinin A are included in one of the Schedules to the CDSA, law enforcement will be able to take appropriate action in response to suspected illegal activities with these substances.

In the interim, *S. divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. Complaints about the illegal sale of drugs containing *S. divinorum* and/or salvinin A can be referred to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

**Q5 – What is the significance of the adverse reaction reports that Health Canada has received with respect to the use of *Salvia divinorum*?**

A5 – Health Canada has received four domestic adverse reaction reports related to the use of *Salvia divinorum* as a hallucinogen through the Canada Vigilance database. The number of reports and the nature of reactions reported are, however, not adequate to fully characterize the risk of similar reactions among the general population

***If pressed on whether Health Canada has issued any kind of warning to Canadians about *Salvia divinorum****

A - Health Canada is developing an It's Your Health article for the departmental web site about *Salvia divinorum* to help inform the general public about the risks associated with the use of this plant.

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**Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

Data from the 2008-2009 Youth Smoking Survey indicates that:

- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;
  - 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year;
- and.

- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using Salvia in their lifetime (0.2% in the past year); and
- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that:

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;
- 5.4% of students (grades 7-12) ever used *S. divinorum*; and
- the use of *S. divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

**Prepared by:** Stephanie Chandler and Denis Arsenault, OCS, CSTD

**Input by:** Lisa Mackay IYH/PACCB, Suzanne Desjardins HECSB/ODARS, Hanan Abramovici HECSB/ODARS, Bruna Brands HECSB/ODARS, Jocelyn Kula, HECSB/OCS, Robin Marles HPFB/NHPD, Maggie Graham HPFB/NHPD, Stephanie Collins HPFB/NHPD, Mano Murty HPFB/MHPD, Robert Leitch HPFB/MHPD, Shahid Perwaiz HPFB/MHPD, Collin Pinto, HPFB/HPFBI

**Approved by:**

Robin Marles, Director, Bureau of Clinical Trials, NHPD (pending)  
Lindsay Blaney, Director, Policy and Regulatory Affairs, NHPD (pending)  
Duc Vu, Director, Marketed Biologics, Biotechnology and Natural Health Products  
Bureau, MHPD (pending)  
Kim Dayman-Rutkas, Director, HPFBI (pending)  
Diane Allan, Director, OCS, CSTD, HECS (approved, Sept 29, 2010)  
Suzanne Desjardins, Director, ODARS, CSTD, HECS approved, Sept 30, 2010)  
Cathy Sabiston, DG, CSTD, HECS (pending)  
Chris Turner, DG, MHPD (pending)  
Nancy Richards, DG, NHPD (pending)  
Diana Dowthwaite, DG, HPFBI (pending)  
Ken Polk, Communications Executive, HPFB (pending)  
Jean Tessier, Senior Media Relations, PACCB (pending)  
Warren Braun, Director, Strategic Communications, PACCB (pending)  
Peter Yendall, Director, Public Affairs, PACCB (pending)  
HECS Legal (pending)  
HPFB Legal (pending)  
Paul Glover, ADM, HECSB (pending)  
Meena Ballantyne, ADM, HPFB (pending)  
Anne Lamar, ADM, PACCB (pending)  
DMO (pending)  
MO (pending)  
PCO (pending)



**Re: Updated Media Lines and Draft Notice of Intent for Salvia** 

Stephanie Szick to: Jocelyn Kula

2010-12-10 08:01 AM

Cc: "Denis Arsenault", "Stephanie Chandler"

ha, ha...my I figured as much but like to ask to be sure!  
I see Cathy is to sign off yes, but I expect others up the line will at  
least want to see it before it goes to CG1....and yes, for the Outlook  
table but once we have a sense of timing.

From: Jocelyn Kula/HC-SC/GC/CA  
To: Stephanie Szick/HC-SC/GC/CA@HWC  
Cc: "Stephanie Chandler" <stephanie.chandler@hc-sc.gc.ca>, "Denis  
Arsenault" <denis.arsenault@hc-sc.gc.ca>  
Date: 12/10/2010 07:57 AM  
Subject: Re: Updated Media Lines and Draft Notice of Intent for  
Salvia

NOI gets published in CG I (weren't you just at the PPR on scheduling  
process?! Lol) and yes, DG sign off is typical. If it needs higher  
approval, that's fine (and yes we would put in docket and do 3 month  
report etc) but we need to know if that is required. In any case, don't  
see that anyone other than Cathy's name would be on it.

JK  
Sent by blackberry

Jocelyn Kula  
A/ Director/ Directrice par interim  
Office of Controlled Substances/ Bureau des substances contrôllées

----- Original Message -----

From: Stephanie Szick  
Sent: 2010-12-10 07:26 AM EST  
To: Jocelyn Kula  
Cc: CSTD-DGO; Denis Arsenault; Stephanie Chandler  
Subject: Re: Updated Media Lines and Draft Notice of Intent for Salvia

Thanks Jocelyn

Will have a look this morning and pass on to Cathy for her approval.

Please refresh my memory -- the NOI is posted publicly where? I expect  
this will need to go up the line given the subject matter -- is this the  
standard process however -- i.e. beyond DG approval for the NOI to be  
posted?

Thanks,

Stephanie Szick  
Director General's Office / Bureau du directeur général  
Controlled Substances & Tobacco Directorate (CSTD) /  
Direction des substances contrôllées et de la lutte au tabagisme (DSCLT)  
Health Canada / Santé Canada

Tel / Tél: (613) 948-8651

From: Jocelyn Kula/HC-SC/GC/CA  
To: stephanie.szick@hc-sc.gc.ca  
Cc: CSTD-DGO, Stephanie Chandler/HC-SC/GC/CA@HWC, Denis  
Arsenault/HC-SC/GC/CA@HWC  
Date: 12/09/2010 06:19 PM  
Subject: Updated Media Lines and Draft Notice of Intent for Salvia

Hi Stephanie,

Per previous instruction from Cathy and for Cathy's review and approval, please find attached a copy of the revised media lines for Salvia as well as our proposed Notice of Intent. We have worked with Comms on the media lines, and they are comfortable with us submitting them for Cathy's approval ourselves as we know that Cathy wanted to see both the media lines and the draft NOI at the same time. For this reason, we are not submitting the IYH for approval at this point; our thinking is that we would hold off on issuing that until the NOI was in print. We have already revised the text to be consistent however.

[attachment "Salvia Media Lines\_Dec 9\_OCS + CR.doc" deleted by Stephanie Szick/HC-SC/GC/CA] (with track changes)

[attachment "Salvia Media Lines\_Dec 9\_Clean.doc" deleted by Stephanie Szick/HC-SC/GC/CA] (clean version)

[attachment "DRAFT Salvia NOI\_Dec 8.wpd" deleted by Stephanie Szick/HC-SC/GC/CA]

Jocelyn

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la  
santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

DRAFT 14  
December 9, 2010

### Media Lines *Salvia divinorum*

#### Issue

Further to ongoing media interest regarding the availability of *Salvia divinorum* in Canada and reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties, Health Canada has concluded that *Salvia divinorum* and its main active ingredient salvinorin A should be included in one of the Schedules to the *Controlled Drugs and Substances Act* (CDSA).

#### Key Messages:

- Health Canada has concluded its assessment of *S. divinorum* and salvinorin A and is proposing to include both substances in one of the Schedules to the CDSA.
- The inclusion of *S. divinorum* and salvinorin A in one of the Schedules to the CDSA will reduce the potential health and safety risks associated with their ready availability and potential abuse.
- Health Canada will inform stakeholders of its decision by publishing a *Notice to Interested Parties* (NOI) in *Canada Gazette*, Part I. The NOI will provide stakeholders and other interested parties with the opportunity to provide comments on the proposal to regulate these substances as controlled substances.

#### Supplementary Messages:

- Canadians should not use products containing *S. divinorum* and/or salvinorin A because very little is known about these substances and their potential effects on the brain and/or body, and their impact on physical and mental functions.
- Because of their hallucinogenic properties, products containing *S. divinorum* and/or salvinorin A meet the definition of a natural health product (NHP) under the Natural Health Products Regulations and the definition of a drug under the Food and Drugs Act.
- It is illegal to sell NHPs in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN). The illegal sale of products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*.
- Neither *S. divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and thus, do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

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- Deleted: September 16
- Deleted: Since 2006, Health Canada has noted
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- Deleted: Health Canada has also received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum*, particularly given
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- Deleted: proposing that *S. divinorum* and salvinorin A be regulated as controlled substances under the *Controlled Drugs and Substances Act* (CDSA).
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- The move to include *S. divinorum* and salvinorin A in one of the Schedules to the CDSA is consistent with actions taken by several countries (Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. It is also consistent with the fact that some individual U.S. states have implemented laws restricting their use, sale and/or distribution.

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**Deleted:** *Salvia divinorum* and salvinorin A are not regulated under the federal *Controlled Substances Act* in the United States. ¶  
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**Questions and Answers:**

**Q1 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum* as a controlled substance. What does that involve and what stage is it at?**

A1 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

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Health Canada recently concluded its assessment of *S. divinorum* and salvinorin A against the aforementioned factors and proposes to include both substances in one of the Schedules to the CDSA.

**Q2 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why isn't it illegal?**

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A2 – Health Canada intends to include *S. divinorum* and salvinorin A under one of the Schedules to the CDSA. In the interim, as *S. divinorum* meets the definition of a Natural Health Product (NHP) under the *Natural Health Product Regulations*, it is illegal to manufacture, sell or provide products containing *S. divinorum* and/or salvinorin A without their being authorized by Health Canada prior to sale.

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**Q3 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?**

A3 – The *Natural Health Products Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *S. divinorum*. When *S. divinorum* and salvinorin A are included in one of the Schedules to the CDSA, it will be illegal to possess, import, export, produce and distribute these substances in any form unless authorized by regulation.

**Deleted:** Health Canada is currently reviewing all the available information regarding *Salvia divinorum*, including the prevalence of its use in Canada, to determine whether it should be regulated under the *Controlled Drugs and Substances Act*. ¶  
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**Deleted:** *alvia*

**Q4 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

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**A4 – Once *S. divinorum* and salvinorin A are included in one of the Schedules to the CDSA, law enforcement will be able to take appropriate action in response to suspected illegal activities with these substances.**

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In the interim, *S. divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. Complaints about the illegal sale of drugs containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

Deleted: alvia

**Q5 – What is the significance of the adverse reaction reports that Health Canada has received with respect to the use of *Salvia divinorum*?**

**A5 – Health Canada has received four domestic adverse reaction reports related to the use of *Salvia divinorum* as a hallucinogen through the Canada Vigilance database. The number of reports and the nature of reactions reported are, however, not adequate to fully characterize the risk of similar reactions among the general population**

***If pressed on whether Health Canada has issued any kind of warning to Canadians about *Salvia divinorum****

**A - Health Canada is developing an It's Your Health article on *Salvia divinorum* to help inform the general public about the risks associated with the use of this plant.**

**Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

Data from the 2008-2009 Youth Smoking Survey indicates that:

- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;
- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year; and.
- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

Deleted: Q4 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum* as a controlled substance. What does that involve and what stage is it at?¶

¶ A4 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:¶  
<#>International requirements and trends in international control;¶  
<#>Chemical and pharmacological similarity to other substances already regulated under the CDSA;¶  
<#>Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);¶  
<#>Potential for abuse and risk of addiction associated with the substance;¶  
<#>Extent of actual abuse of the substance in Canada and internationally; and¶  
<#>Overall risk to public health and safety posed by the substance.¶

¶ Health Canada is currently reviewing the available information to determine whether regulation of *Salvia divinorum* under the CDSA is warranted.¶

¶ Q5 – Didn't an internal report from Health Canada's Marketed Health Products Directorate recommend that *Salvia divinorum* be scheduled under the CDSA? Why has that recommendation not been acted upon?¶

¶ A5 – See A4¶

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Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using Salvia in their lifetime (0.2% in the past year); and
- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that:

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;
- 5.4% of students (grades 7-12) ever used *S. divinorum*; and
- the use of *S. divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

**Prepared by:** Stephanie Chandler and Denis Arsenault, OCS, CSTD

Deleted: Cheryl Tremblay

**Input by:** Lisa Mackay IYH/PACCB, Suzanne Desjardins HECSB/ODARS, Hanan Abramovici HECSB/ODARS, Bruna Brands HECSB/ODARS, Jocelyn Kula, HECSB/OCS, Robin Marles HPFB/NHPD, Maggie Graham HPFB/NHPD, Stephanie Collins HPFB/NHPD, Mano Murty HPFB/MHPD, Robert Leitch HPFB/MHPD, Shahid Perwaiz HPFB/MHPD, Collin Pinto, HPFB/HPFBI

**Approved by:**

Robin Marles, Director, Bureau of Clinical Trials, NHPD (pending)  
Lindsay Blaney, Director, Policy and Regulatory Affairs, NHPD (pending)  
Duc Vu, Director, Marketed Biologics, Biotechnology and Natural Health Products  
Bureau, MHPD (pending)  
Kim Dayman-Rutkas, Director, HPFBI (pending)  
Diane Allan, Director, OCS, CSTD, HECS (approved, Sept 29, 2010)  
Suzanne Desjardins, Director, ODARS, CSTD, HECS approved, Sept 30, 2010)  
Cathy Sabiston, DG, CSTD, HECS (pending)  
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Diana Dowthwaite, DG, HPFBI (pending)  
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Jean Tessier, Senior Media Relations, PACCB (pending)  
Warren Braun, Director, Strategic Communications, PACCB (pending)  
Peter Yendall, Director, Public Affairs, PACCB (pending)  
HECS Legal (pending)  
HPFB Legal (pending)  
Paul Glover, ADM, HECSB (pending)  
Meena Ballantyne, ADM, HPFB (pending)  
Anne Lamar, ADM, PACCB (pending)  
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STCHANDL

2010-11-26 2:35:00 PM

Because of their hallucinogenic properties, products containing *S. divinorum* and/or salvinorin A meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*.

It is illegal to sell NHPs in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN). The illegal sale of products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*.

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STCHANDL

2010-11-26 2:27:00 PM

***Salvia divinorum as a controlled substance:***

In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA).

**DRAFT V.4**

DEPARTMENT OF HEALTH

CONTROLLED DRUGS AND SUBSTANCES ACT

*Notice to interested parties - Proposal regarding the addition of Salvia divinorum and salvininorin A to Schedule III to the Controlled Drugs and Substances Act*

This notice provides interested stakeholders with the opportunity to provide preliminary comments on Health Canada's proposal to add the plant *Salvia divinorum* (*S. divinorum*) and its active ingredient salvininorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA), and to identify themselves for inclusion in any future consultation.

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are generally chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant. Neither *S. divinorum* nor salvininorin A are currently included in any of the Schedules to the CDSA.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs. As *S. divinorum* and salvininorin A are pharmacologically similar to other substances included in Schedule III to the CDSA, such as LSD and psilocybin, Health Canada is concerned that their ready availability poses a risk to the health and safety of Canadians.

While these substances are not currently included in any of the United Nations Drug Control Conventions, a number of countries have chosen to regulate one or both as controlled substances. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden have all placed controls on the import and/or sale of *S. divinorum* and/or salvininorin A. Some individual American states have also implemented laws restricting its use, sale and/or distribution.

Placing these substances within Schedule III to the CDSA would prohibit the following activities with these substances unless authorized by regulation: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation).

As this action is not intended to interfere with the use and availability of *S. divinorum* and/or salvininorin A for a legitimate medical, scientific or industrial purpose, Health Canada is seeking information from stakeholders on whether there are any such legitimate uses for these aforementioned substances in Canada. Information received in response to this notice will be instrumental in determining appropriate regulation under the CDSA, as required.

The publication of this notice begins a 30-day comment period. There will be additional opportunities to provide comments following prepublication of the scheduling proposal in *Canada Gazette*, Part I.

If you are interested in this process or have comments on this proposal, please contact Stephanie Chandler, Regulatory Policy Division, Office of Controlled Substances, Address Locator: 3503D, 123 Slater St., Ottawa, Ontario, Canada, K1A 1B9, by fax at (613) 946-4224 or by email at [OCS\\_Policy\\_and\\_Regulatory\\_Affairs@hc-sc.gc.ca](mailto:OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca).

Cathy A. Sabiston  
Director General  
Controlled Substances and Tobacco Directorate

Date \_\_\_\_\_

DRAFT 14  
December 9, 2010

### **Media Lines** ***Salvia divinorum***

#### **Issue**

Further to ongoing media interest regarding the availability of *Salvia divinorum* in Canada and reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties, Health Canada has concluded that *Salvia divinorum* and its main active ingredient salvinorin A should be included in one of the Schedules to the *Controlled Drugs and Substances Act* (CDSA).

#### **Key Messages:**

- Health Canada has concluded its assessment of *S. divinorum* and salvinorin A and is proposing to include both substances in one of the Schedules to the CDSA.
- The inclusion of *S. divinorum* and salvinorin A in one of the Schedules to the CDSA will reduce the potential health and safety risks associated with their ready availability and potential abuse.
- Health Canada will inform stakeholders of its decision by publishing a *Notice to Interested Parties* (NOI) in *Canada Gazette*, Part I. The NOI will provide stakeholders and other interested parties with the opportunity to provide comments on the proposal to regulate these substances as controlled substances.

#### **Supplementary Messages:**

- Canadians should not use products containing *S. divinorum* and/or salvinorin A because very little is known about these substances and their potential effects on the brain and/or body, and their impact on physical and mental functions.
- Because of their hallucinogenic properties, products containing *S. divinorum* and/or salvinorin A meet the definition of a natural health product (NHP) under the Natural Health Products Regulations and the definition of a drug under the Food and Drugs Act.
- It is illegal to sell NHPs in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN). The illegal sale of products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*.
- Neither *S. divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and thus, do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

- The move to include *S. divinorum* and salvinorin A in one of the Schedules to the CDSA is consistent with actions taken by several countries (Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. It is also consistent with the fact that some individual U.S. states have implemented laws restricting their use, sale and/or distribution.

#### Questions and Answers:

#### **Q1 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum* as a controlled substance. What does that involve and what stage is it at?**

A1 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada recently concluded its assessment of *S. divinorum* and salvinorin A against the aforementioned factors and proposes to include both substances in one of the Schedules to the CDSA.

#### **Q2 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why isn't it illegal?**

A2 – Health Canada intends to include *S. divinorum* and salvinorin A under one of the Schedules to the CDSA. In the interim, as *S. divinorum* meets the definition of a Natural Health Product (NHP) under the *Natural Health Product Regulations*, it is illegal to manufacture, sell or provide products containing *S. divinorum* and/or salvinorin A without their being authorized by Health Canada prior to sale.

#### **Q3 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?**

A3 – The *Natural Health Products Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *S. divinorum*. When *S. divinorum* and salvinorin A are included in one of the Schedules to the CDSA, it will be illegal to possess, import, export, produce and distribute these substances in any form unless authorized by regulation.

**Q4 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A4 – Once *S. divinorum* and salvinorin A are included in one of the Schedules to the CDSA, law enforcement will be able to take appropriate action in response to suspected illegal activities with these substances.

In the interim, *S. divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. Complaints about the illegal sale of drugs containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

**Q5 – What is the significance of the adverse reaction reports that Health Canada has received with respect to the use of *Salvia divinorum*?**

A5 – Health Canada has received four domestic adverse reaction reports related to the use of *Salvia divinorum* as a hallucinogen through the Canada Vigilance database. The number of reports and the nature of reactions reported are, however, not adequate to fully characterize the risk of similar reactions among the general population

***If pressed on whether Health Canada has issued any kind of warning to Canadians about *Salvia divinorum****

A - Health Canada is developing an It's Your Health article on *Salvia divinorum* to help inform the general public about the risks associated with the use of this plant.

**Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

Data from the 2008-2009 Youth Smoking Survey indicates that:

- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;
- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year; and.
- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using Salvia in their lifetime (0.2% in the past year); and
- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that:

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;
- 5.4% of students (grades 7-12) ever used *S. divinorum*; and
- the use of *S. divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

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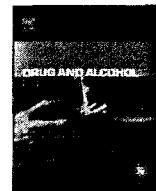
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Short communication

### Human psychopharmacology and dose-effects of salvinorin A, a kappa opioid agonist hallucinogen present in the plant *Salvia divinorum*

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#### ABSTRACT

Salvinorin A is a potent, selective nonnitrogenous kappa opioid agonist and the known psychoactive constituent of *Salvia divinorum*, a member of the mint family that has been used for centuries by Mazatec shamans of Mexico for divination and spiritual healing. *S. divinorum* has over the last several years gained increased popularity as a recreational drug. This is a double-blind, placebo controlled study of salvinorin A in 4 psychologically and physically healthy hallucinogen-using adults. Across sessions, participants inhaled 16 ascending doses of salvinorin A and 4 intermixed placebo doses under comfortable and supportive conditions. Doses ranged from 0.375 µg/kg to 21 µg/kg. Subject-rated drug strength was assessed every 2 min for 60 min after inhalation. Orderly time- and dose-related effects were observed. Drug strength ratings peaked at 2 min (first time point) and definite subjective effects were no longer present at approximately 20 min after inhalation. Dose-related increases were observed on questionnaire measures of mystical-type experience (Mysticism Scale) and subjective effects associated with classic serotonergic (5-HT<sub>2A</sub>) hallucinogens (Hallucinogen Rating Scale). Salvinorin A did not significantly increase heart rate or blood pressure. Participant narratives indicated intense experiences characterized by disruptions in vestibular and interoceptive signals (e.g., change in spatial orientation, pressure on the body) and unusual and sometimes recurring themes across sessions such as revisiting childhood memories, cartoon-like imagery, and contact with entities. Under these prepared and supportive conditions, salvinorin A occasioned a unique profile of subjective effects having similarities to classic hallucinogens, including mystical-type effects.

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#### 1. Introduction

Shamans of the Mazatec people of Oaxaca, Mexico have used *Salvia divinorum*, a member of the mint family, for at least centuries in ethnomedical practices including divination and spiritual healing (Valdes, 1994; Ott, 1995, 1996; Siebert, 1994). *S. divinorum* contains the known psychoactive constituent salvinorin A, which is a neoclerodane diterpene and a potent nonnitrogenous kappa opioid agonist with no activity at the 5-HT<sub>2A</sub> serotonin receptor, the principal site of activity of classic hallucinogens such as LSD, psilocybin, dimethyltryptamine, and mescaline (Roth et al., 2002; Prisinzano, 2005). Studies in monkeys show salvinorin A produces discriminative stimulus effects similar to other high efficacy kappa agonists (Butelman et al., 2004). A kappa-like profile of antinociceptive and behavioral effects has also been demonstrated in rodents

(Fantegrossi et al., 2005; Wang et al., 2005; Zhang et al., 2005; McCurdy et al., 2006; Carlezon et al., 2006). Nonhuman research with salvinorin A has shown mixed results regarding abuse potential. Evidence suggestive of no or low abuse potential includes research showing salvinorin A to elevate thresholds for intracranial stimulation and decrease extracellular dopamine concentrations in the nucleus accumbens in rats (Carlezon et al., 2006), and produce conditioned place aversion in mice (Zhang et al., 2005). Evidence suggestive of abuse potential are recent findings demonstrating intracerebroventricular salvinorin A self-administration and conditioned place preference in mice at relatively low doses (Braidia et al., 2008).

Although the ethnomedical use of *S. divinorum* by shamans dates back at least for hundreds of years, an understanding of the psychoactive effects of salvinorin A by American and European drug users dates back only about 15 years (Siebert, 1994; Ott, 1995). In traditional Mexican use, the leaves of *S. divinorum* are chewed or made into an infusion and swallowed (Valdes, 1994; Siebert, 1994; Ott, 1995). Outside the Mazatec, drug users typically inhale the drug

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via smoking or, less frequently, via volatilization, although buccal administration also occurs (Baggott et al., 2004; González et al., 2006). Internet vendors and “head shops” sell *S. divinorum* plants, dried leaves, leaf extracts with increased salvinorin A concentrations (for smoking), and tinctures (for buccal administration). As of 2006 at least 1.8 million people age 12 or older have used the drug in the United States (Office of Applied Studies, 2007), and the prevalence is likely higher now. Survey research suggests that effects are brief and that users claim positive after-effects such as increased insight and improved mood (Baggott et al., 2010). One study found high scores on a measure of state anxiety when asking participants to retrospectively evaluate their last use (González et al., 2006). During a recent 10-year period, the California Poison Control System received 37 telephone calls concerning *S. divinorum* exposures with reported neurologic, cardiovascular, and gastrointestinal effects (Vohra et al., 2009). Three cases reported that *S. divinorum* use was associated with an extended psychotic-type reaction, although concurrent other drug use (Singh, 2007), suspected schizophrenic predisposition (Przekop and Lee, 2009), and injuries secondary to medical treatment (Paulzen and Gründer, 2008) have complicated interpretation of these cases. Possession or use of *S. divinorum* is currently illegal in 13 nations and 15 states within the United States, and additional nations and states have implemented lesser forms of control.

Given the wide availability, continued popular use, and legal controversy, information is needed regarding the human psychopharmacology of salvinorin A. In addition to providing information about this novel drug, studying the effects salvinorin A may assist in identifying new opioid receptor modulators that may have therapeutic applications in certain psychiatric disorders (e.g., Alzheimer's disease, schizophrenia, bipolar disorder, cocaine abuse) and in the treatment of pain (Mello and Negus, 2000; Sheffler and Roth, 2003; Kivell and Prisinzano, 2010). This is a report of preliminary findings of basic physiological, behavioral and subjective effects of inhaled salvinorin A across a range of doses, from sub-threshold to high, delivered under comfortable and interpersonally supportive conditions to healthy participants who reported histories of hallucinogen use.

## 2. Methods

### 2.1. Participants

Participants were recruited from the Baltimore, MD area through flyers and ads in local newspapers. After a phone screen confirmed basic inclusion criteria (age, high-school-level education, and prior hallucinogen use), volunteers came to the laboratory for in-person screening. A social worker (who was trained by psychometricians and had a psychiatrist and clinical psychologist available for consultation) conducted a structured clinical interview to exclude individuals with a current or past history of meeting DSM-IV criteria for schizophrenia; psychotic disorder (unless substance-induced or due to a medical condition); bipolar I or II disorder; alcohol or drug dependence (excluding caffeine and nicotine) for the last 5 years; severe major depression; dissociative disorder; and other psychiatric conditions judged to be incompatible with establishment of rapport or safe exposure to hallucinogens. Participants were excluded who reported having a first or second degree relative with schizophrenia, psychotic disorder (unless substance induced or due to a medical condition), or bipolar I or II disorder. Medical evaluation included a physical exam conducted by a nurse practitioner, an ECG evaluated by a physician, and a physician evaluation of blood sample analyses that included a complete blood count with differential and a chemistry panel including electrolytes, glucose, urea, creatinine, uric acid, liver profile, total cholesterol, and triglycerides. Additional screening visits assessed general motivation for participation and established trust and rapport with the study staff. Participants agreed to refrain from using *S. divinorum* or illicit drugs during the course of the study.

Four participants ( $M = 29.5$  years old, range = 23–35 years old; 2 females) passed screening and completed all drug sessions and data collection (Note: one additional individual participated in pilot sessions to develop and refine the inhalation procedure; these data are not included in the reported analyses). Participant bodyweights were 58.5, 74.6, 64.4, and 67.1 kg for the two males and two females, respectively. Participants had at least a high-school level of education ( $M = 15$  years, range = 14–16 years) and reported using *S. divinorum* at least once in the past five years ( $M = 16$  uses, range = 2–40 uses). Participants were compensated \$50 per session (plus a

bonus of \$50 per session upon completion of data collection). Participations were also motivated by their reported interest in spirituality and/or altered states of consciousness. Transportation to and from the study site (via taxi) was provided for all participants. The Institutional Review Board of the Johns Hopkins University School of Medicine approved the study, and all participants gave their informed consent before participation.

### 2.2. Drug preparation and delivery device

Salvinorin A was isolated from *S. divinorum* leaves and shown to be 99.5% pure by HPLC. Because weighing the very small doses of salvinorin A required for this study is difficult, a larger quantity was weighed on an analytical balance and then dissolved in a measured volume of HPLC grade acetone. After filtering through a sterilized, acetone-approved 0.2  $\mu\text{m}$  filter (Millex-LG Filter Unit, Millipore Corporation, Billerica, MA), 1 ml of solution was placed into a 5 ml round bottom chemistry flask and allowed to evaporate, leaving the dose of salvinorin A as a residue on the interior surface of the flask. Before the session, the flask was attached to the bottom of a chemistry vacuum adapter by ground glass tapered joint and secured by a metal Keck clip. A vinyl tube (23 cm long, 6.35 mm inside diameter) was connected to the vacuum line of the adapter for inhalation. The tubing was replaced between participants but was not replaced for different sessions for the same participant. The resulting “pipe” was held stable by a ring stand clamp during administration, and the tube extended through a hole in a room divider toward the participant's sitting area.

### 2.3. Drug administration

Sixteen doses of salvinorin A were administered in an ascending order. Although it is unknown whether salvinorin A effects are bodyweight dependent, doses in this study were adjusted for participant bodyweight based on knowledge that some but not all psychoactive drug effects are bodyweight dependent. The lowest dose in the sequence was 0.375  $\mu\text{g}/\text{kg}$  of bodyweight and subsequent doses were 0.75  $\mu\text{g}/\text{kg}$ , 1.5  $\mu\text{g}/\text{kg}$ , and thereafter increased by an increment of 1.5  $\mu\text{g}/\text{kg}$  until the maximum dose of 21  $\mu\text{g}/\text{kg}$  was reached. Four placebo doses were inserted in the ascending sequence of salvinorin A doses such that each consecutive block of 5 sessions included 1 placebo. The position of the single placebo within each block of 5 sessions was determined randomly for each volunteer. Participants were told that on any session they may receive a dose of salvinorin A or placebo but were not told about the ascending design or frequency of placebos.

For each session the round-bottom flask was heated from underneath with a butane microtorch with approximate flame temperature of 1700 °C (model ST200T, Bernzomatic, Huntersville, NC). Although the boiling point and combustion temperature of salvinorin A have not been empirically determined, the flame temperature was assumed to be sufficient to heat the salvinorin A on the interior of the flask to its boiling point during the decreased air pressure created by inhalation, without substantial combustion of salvinorin A. The microtorch was adjusted so that the flame was approximately 1.5 cm in length, and the tip of the flame was held in contact with the round-bottom flask. Using these procedures, inhalation of unvolatilized drug was unlikely because the salvinorin A residue left upon evaporation of acetone appeared strongly attached to the interior of the flask, and in tests with various rates of mechanical airflow (simulated inhalation) without heat, salvinorin A was observed to remain undisturbed. Tests with mechanical airflow and the application of the microtorch showed the method to result in the volatilization of salvinorin A with little scorching (small black marks presumably resulting from combustion). Seated in a comfortable reclining lounger, the participant inhaled slowly for 40 s while the flask was heated, followed by a verbally cued exhale. For placebo sessions, the same protocol was followed but no salvinorin A was in the flask. The unblinded session monitor who heated the flask was obscured from the participant's view (behind the divider), while the blinded staff member collected drug-strength ratings and all other pre- and post-session data from the participant.

### 2.4. Drug sessions

Each participant completed 20 sessions across several weeks (range = 8–14 weeks). Participants typically completed 1–3 sessions per week with consecutive sessions separated by at least 1 day (range = 1 day to 4.5 weeks).

Each meeting at the study site lasted approximately 2.5 h. Upon arrival, participants provided an expired air sample that was required to indicate a blood alcohol concentration of 0.00% for the session to continue (Alco-Sensor IV, Intoximeters, Inc., Saint Louis, MO). In addition, abstinence from opioids, cocaine, and benzodiazepines was confirmed by urine test before each session (model MUI-PM, Medimpex United Inc., Bensalem, PA). This urine test panel was selected because it can detect opioids such as oxycodone and buprenorphine with kappa opioid effects. Abstinence from hallucinogens (and other drugs not listed above) was not biologically confirmed. However, participants consented to have their urine tested for “various drugs” and were not informed about which drugs were included in the urine test. Female participants were required to provide a negative urine pregnancy test before each session (model HCG-001, Medimpex United Inc., Bensalem, PA). Also before drug administration, participants briefly reviewed experiences from the last session with the study staff. During drug administration, participants were seated in a comfortable

semi-upright or reclined position and wore eyeshades for 3–5 min before and for 10–30 min after drug administration. A relaxing instrumental music track (Steven Halpern, "Awakening", Music for Sound Healing, Inner Peace Music, 1999) was played throughout the session as a continuous loop. Approximately 1 h after drug administration participants completed several questionnaires and computer-based assessments (duration = 45–60 min).

## 2.5. Measures

**2.5.1. Physiology.** Blood pressure (systolic and diastolic using oscillometric method with the blood pressure cuff placed on the arm) and heart rate were monitored using a Non-Invasive Patient Monitor Model 507E (Criticare Systems, Waukesha, WI). Data were collected at baseline (for at least 5 min before drug administration) and every 2 min during the 60 min following drug administration.

**2.5.2. Time course.** Participants indicated overall drug strength using an 11-point scale (0 = definitely no effect; 1 or 2 = possible salvinorin A effects; 3–10 = definite salvinorin A effects with 10 representing "the strongest effect imaginable for salvinorin A"). Participants were verbally cued to provide a rating of drug strength at baseline and every 2 min for 60 min after drug administration. In the case of missing reports (i.e., participant unresponsive during the first few minutes of drug effects), the value of '10' was imputed.

**2.5.3. Safety and tolerability.** Although not reported by users in retrospective analyses (Baggott et al., 2010; González et al., 2006), tremor has been observed in rhesus monkeys at a substantially higher dose (100 µg/kg) than our maximum dose (Butelman, personal communication, 2006). The Fahn–Tolosa–Marin Tremor Rating Scale (TRS; Fahn et al., 1993) was used to classify resting and kinetic tremor severity on a 5-point scale. At baseline and at 15 and 30 min after drug administration, the study staff visually assessed kinetic tremor intensity as the participant bent both of his or her extended arms to touch middle finger to nose. Study staff also rated the magnitude of resting tremor during the time interval leading up to the assessments of kinetic tremor (i.e., 0–15 min, 15–30 min) by closely observing the participant.

To assess psychological effects that might warrant discontinuing future sessions, participants were asked at the end of each session "Would you absolutely refuse to receive the same or higher dose of today's drug in future sessions?" A "no" response was required to continue. In addition, study staff interviewed the participant before and after each session to determine how s/he felt about continuing to participate.

**2.5.4. End-of-session subject-rated effects.** Shortly after the 60-min time point, participants were asked to retrospectively rate the strength of the peak drug effect during the session using the same 11-point scale used to assess the time course of drug effects. Because kappa opioid agonists, including salvinorin A, have been reported to induce dysphoric effects (Walsh et al., 2001; González et al., 2006), participants were asked to complete retrospective ratings of "drug liking" and "drug disliking" (2 questions; 0 = neutral or no effect, 1 = like/dislike but not very much, 2 = like/dislike somewhat, 3 = like/dislike quite a bit, 4 = like/dislike very much), and "good effects" and "bad effects" (2 questions; 0 = no good/bad effects at all, 1 = a little, 2 = moderately, 3 = quite a bit, 4 = very much).

Consistent with case reports and survey studies of *S. divinorum* users (Siebert, 1994; Baggott et al., 2010; Bücheler et al., 2005; González et al., 2006) we hypothesized that salvinorin A would elicit subjective effects with substantial overlap with classic hallucinogens (e.g., psilocybin, LSD). We further hypothesized that, unlike orally administered psilocybin and LSD, volatilized and inhaled salvinorin A would have a time course profile more similar to intravenous dimethyltryptamine (Strassman et al., 1994). In addition, because *S. divinorum* has been used by shamans for divination and "visionary effects" (Ott, 1995), we hypothesized that salvinorin A might elicit subject-rated mystical-type effects. We used two questionnaires to assess these effects. The Hallucinogen Rating Scale (HRS; 99 items) was designed to show sensitivity to dimethyltryptamine (Strassman et al., 1994) and has also been shown sensitive to psilocybin (Griffiths et al., 2006). It consists of six subscales assessing various aspects of hallucinogen effects: Intensity (effects related to the strength of the overall experience), Somaesthesia (interoceptive, visceral and tactile effects), Affect (emotional and affective responses), Perception (visual, auditory, gustatory, and olfactory effects), Cognition (alterations in thought processes or content), and Volition (awareness of the environment and capacity to willfully control one's body). Most items are rated on a 5-point scale (0 = not at all; 4 = extremely). The Mysticism Scale (32 items) was developed to assess primary mystical or spiritual experiences (Hood et al., 2001) and has been shown to be sensitive to the effects of psilocybin (Griffiths et al., 2006). Each item is rated on a 9-point scale (−4 = this description is extremely not true of my own experience; 0 = I cannot decide; +4 = this description is extremely true of my own experience). Approximately 1 h after drug administration, participants completed the HRS and Mysticism Scale with reference to their experiences since receiving the inhaled drug.

## 2.6. Analysis

Subject-rated drug strength ratings collected throughout the time course were used to calculate, for individual participants, area under the curve (AUC) values using

the trapezoidal rule. Repeated measures analysis of variance (ANOVA) with within-subjects factor of dose (17 dose levels including placebo) was used to examine dose-related changes in the subject-rated measures and physiology (peak heart rate and blood pressure). For each participant, drug strength ratings across the 4 placebo sessions were averaged to create a single placebo data point. Tukey's HSD tests were conducted to compare dose levels, with family-wise error rate maintained at  $\alpha = .05$ .

## 3. Results

### 3.1. Time course of acute drug effects

Orderly time- and dose-related effects were observed. Subject-rated drug strength peaked at 2 min (first time point) and then progressively decreased toward pre-inhalation levels. By 20 min after inhalation, mean ratings indicated only a "possible mild" effect (see Fig. 1A). Two participants (1 male, 1 female) provided the maximal rating of 10 at one or more time points during at least one session. Both male participants were unresponsive (scores imputed as 10) on at least one time point for at least one dose. Specifically, one was unresponsive at the 2 min time point in the 15, 16.5, 18, and 21 µg/kg conditions and the 4 min time point in the 21 µg/kg condition. The other male was unresponsive at the 2 min time point in the 18 and 19.5 µg/kg conditions.

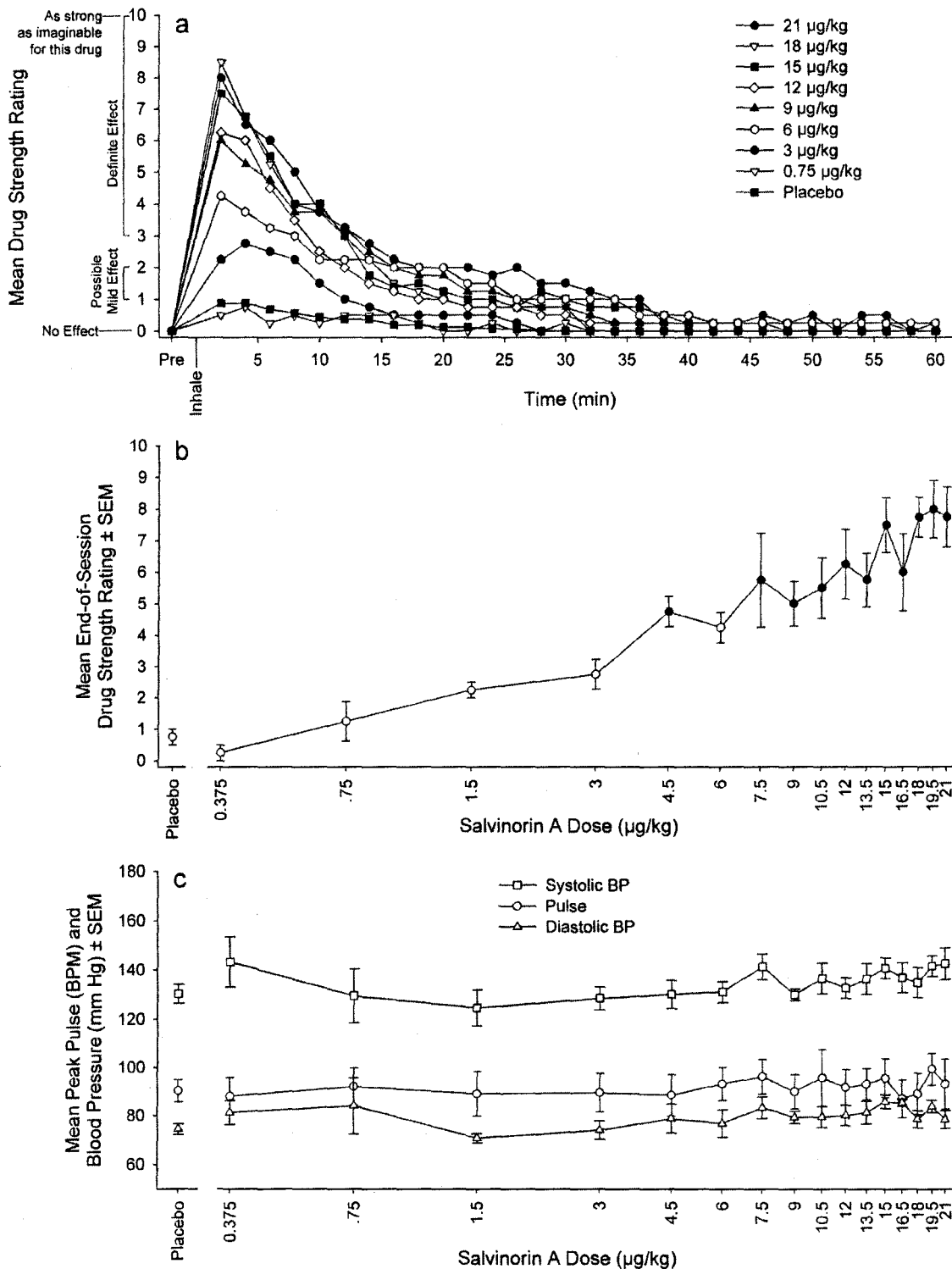
### 3.2. End-of-session retrospective self-reports

The effect of dose on peak drug strength (end-of-session rating) was significant ( $F(16,48) = 12.6, p < .001$ ), and post-hoc tests confirmed that all but one dose in the range 4.5–21 µg/kg were rated significantly stronger than placebo (see Fig. 1B). Results were similar when conducted with AUC values for drug strength ( $F(16,48) = 4.5, p < .001$ ). However, likely due to inter-participant variability in duration of drug effects, post-hoc tests showed only the highest two doses were significantly stronger than placebo. End-of-day ratings of drug liking and good effects followed a similar dose-related pattern as ratings of overall drug strength, and the effect of dose was significant for both liking ( $F(16,48) = 7.5, p < .001$ ) and good effects ( $F(16,48) = 4.4, p < .001$ ). Mean ratings of drug disliking and bad effects were low ( $M_s < 1$ ) across all sessions, and there was no significant effect of dose for either measure ( $p_s > .30$ ). Mean ratings of the highest dose indicated generally positive effects and a lack of dysphoric effects: liking  $M = 3$  (range = 2–4); good effects  $M = 2.25$  (range = 1–4); disliking  $M = .5$  (range = 0–2); and bad effects  $M = .5$  (range = 0–1), with only 1 participant indicating "disliked somewhat". There were significant effects of dose on all subscales of the HRS and on the M Scale ( $p < .05$ ) (Table 1). Post-hoc tests showed significant increases (vs. placebo) on HRS-Intensity beginning at a dose of 4.5 µg/kg, which is consistent with the pattern observed for drug strength (see Fig. 1B). The remaining HRS subscales were significantly greater than placebo only at the highest dose levels (Cognition, Affect, Somaesthesia, and Perception) or not at all (Volition). Scores on the M Scale were significantly greater than placebo at the three highest dose levels (Table 1).

### 3.3. Safety and tolerability

The effect of dose on blood pressure and heart rate were not significant ( $p > .05$ ), indicating no dose-related change in these physiological measures (see Fig. 1C). No resting or kinetic tremors were observed during any session (TRS rating = 0 for all data points). No participant refused to receive the same or higher dose at the end of any session. These results suggest that inhaled salvinorin A was physiologically safe and psychologically well tolerated across the range of doses tested.

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**Fig. 1.** Time- and dose-related changes in drug effects. (a) Subject-rated drug strength (reported at 2-min intervals) as a function of time (pre-drug baseline to 60 min following inhalation). Data points show mean ratings ( $N=4$ ). For graphical clarity, alternating doses in the dose sequence were deleted. (b) Subject-rated peak drug strength from the end-of-session ratings as a function of dose (logarithmic abscissa). Data points show mean ratings ( $N=4$ ); brackets show + and -1 SEM. Filled symbols indicate that the data point was significantly different from placebo (Tukey's HSD test,  $p < .05$ ). (c) Peak heart rate (beats per minute) and blood pressure (mm of Hg) as a function of dose (logarithmic abscissa). Data points show means ( $N=4$ ); brackets show + and -1 SEM.

**4. Discussion**

Consistent with results from nonhuman animal research (Mowry et al., 2003), the present results suggest a safe physiological profile for salvinorin A at the studied doses, under

controlled conditions, and in psychologically and physically healthy hallucinogen-experienced participants. Salvinorin A produced no significant changes in heart rate or blood pressure; no tremor was observed; and no adverse events were reported. Participants tolerated all doses. However, because of the small sample

**Table 1**  
Dose-related subjective effects of salvinorin A on subscales of the Hallucinogen Rating Scale (HRS) and on a Mysticism Scale (M Scale)<sup>a</sup>.

Outcome measure	Salvinorin A dose (µg/kg)																	
	0 <sup>b</sup>	0.375	0.75	1.5	3	4.5	6	7.5	9	10.5	12	13.5	15	16.5	18	19.5	21	
HRS-Intensity	6.88*	0.34	0.12	0.69	1.06	1.37	2.25	1.87	2.19	2.00	2.37	2.50	2.12	2.81	2.44	2.81	2.87	2.31
HRS-Somnathesia	3.65*	0.07	0.00	0.23	0.15	0.21	0.96	0.52	0.90	0.65	0.84	0.67	0.58	1.19	1.03	1.13	1.09	1.21
HRS-Affect	3.00*	0.59	0.71	0.64	0.76	0.80	1.15	0.87	1.46	0.86	1.26	1.29	1.15	1.52	1.33	1.87	1.68	1.48
HRS-Perception	3.76*	0.00	0.06	0.00	0.17	0.48	0.87	0.49	0.97	0.52	0.59	0.56	0.64	0.95	0.89	1.18	1.33	1.15
HRS-Cognition	4.96*	0.00	0.00	0.00	0.12	0.17	0.60	0.33	0.73	0.56	0.79	0.83	0.39	1.31	1.19	1.29	1.27	1.14
HRS-Volition	1.91*	1.20	1.15	1.37	0.94	1.19	1.62	1.22	1.41	1.75	1.28	1.40	1.40	1.69	1.53	1.84	1.59	1.87
Mysticism Scale	4.96*	99	105	95	101	113	129	125	141	125	131	164	157	173	167	191	191	210

<sup>a</sup> All measures were administered at the end of each session (60+ min after drug administration); asterisks indicate  $p < .05$  for  $F$  values in the ANOVA (17 dose levels including placebo;  $df = 16,48$ ); bold typeface indicates significantly different than placebo in post-hoc Tukey's HSD test ( $p < .05$ ).

<sup>b</sup> Mean ratings on four placebo sessions for each of the four participants.

and the healthy, hallucinogen-experienced status of participants, conclusions regarding safety are limited.

Salvinorin A resulted in orderly dose- and time-related participant ratings of drug strength. In psychopharmacology studies with drug experienced volunteers, it is quite unusual for volunteers to report drug strength ratings as high as those observed in the present study, with 2 subjects providing ratings of 10, defined as "as strong as imaginable for this drug." The range of doses examined in this study will be useful for selecting doses for future studies using the same administration procedures (e.g., 3, 7.5, and 21 µg/kg for low, medium, and high doses, respectively). Given the increasing trend and lack of plateau in drug strength ratings (see Fig. 1B) and the lack of adverse effects in this study, future studies may also cautiously explore higher doses of salvinorin A. The relative lack of dysphoric effects ("disliking" and "bad effects") and presence of dose-related positive effects ("liking" and "good effects") contrasts with previous research with kappa agonists (Walsh et al., 2001) and *S. divinorum* (González et al., 2006) showing mainly dysphoric effects. This difference with previous research may relate to participant experience with, expectation of, and preparation for strong altered states of consciousness. In addition, salvinorin A produced dose-related increases on most subscales of the Hallucinogen Rating Scale and on the Mysticism Scale. Although limited by cross-study comparisons, high-dose hallucinogen-type effects as measured by the HRS appeared similar to those produced by intravenous dimethyltryptamine (Strassman et al., 1994) and oral psilocybin (Griffiths et al., 2006), but with qualitative differences (i.e., lower magnitude on perceptual and cognition scales). In addition, the mystical-type effects observed at the highest doses of salvinorin A appeared similar in magnitude to previous results with high-dose oral psilocybin (Griffiths et al., 2006).

The volatilization and inhalation procedures had limitations, such as a lack of quantitative temperature control, which could have possibly resulted in incomplete volatilization or combustion of salvinorin A. In addition, not replacing the tubing between sessions could have theoretically allowed for depositing and re-volatilization of salvinorin A across sessions. However, salvinorin A was observed to virtually completely volatilize with little scorching, and this outcome may be consistent with usual use because combustion also occurs in the smoking of *S. divinorum*, the most common route of use. Also, a post-hoc  $t$ -test comparing peak drug strength between the first and final placebo sessions failed to show a significant difference ( $p = .18$ ), suggesting that depositing and re-volatilization did not likely affect results. Ultimately, the orderly dose-related effects shown in Fig. 1A and B suggest reasonable precision in the administration procedures.

In the comfortable and supportive conditions of the current study (similar to those recommended for human research with classic hallucinogens; Johnson et al., 2008), salvinorin A occasioned a unique profile of subjective effects having similarities to classic hallucinogens, including mystical-type effects. Although participant narratives indicated intense, highly unusual experiences characterized by changes in spatial orientation, feelings of energy or pressure on different parts of the body, and unusual and sometimes recurring themes across sessions such as revisiting childhood memories, cartoon-like imagery and contact with entities, participants were largely behaviorally inactive. In this regard, participant experiences differed notably from some of the more chaotic effects observed in online videos of *S. divinorum* use that have gained notoriety (Lange et al., 2010). In conclusion, these results suggest the feasibility of future research examining the effects of salvinorin A, and potentially other high efficacy kappa agonists, in healthy hallucinogen-experienced participants.

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### Contributors

Drs. Johnson and Griffiths designed the study and wrote the protocol. Drs. Johnson, MacLean, and Reissig conducted experimental sessions and collected data. Dr. Prisinzano provided expertise on the chemistry and pharmacology of salvinorin A. Drs. Johnson, MacLean, and Griffiths contributed to interpretation of results. Dr. Johnson conducted statistical analyses. Drs. Johnson and MacLean wrote the first draft of the manuscript. All authors contributed to and have approved the final manuscript.

### Conflict of interest

All authors declare that they have no conflicts of interest.

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17 Like 105 The hallucinogenic plant *Salvia divinorum* has been used for centuries in shamanistic ceremonies led by spiritual healers in Mexico. But now the drug has gotten so popular among recreational users in America (street names: Magic Mint, Sally D) that the government has taken notice: it's been banned in 15 states and federal legislation has been introduced to regulate the plant as a Schedule 1 drug, like marijuana, heroin and ecstasy.

According to recent surveys, users say burning and inhaling the smoke of dried *Salvia* leaves produces powerful hallucinogenic effects, and helps reduce anxiety, improve mood and increase insight. In one case, a woman with drug-resistant depression claimed significant improvements in mood after experimenting with *Salvia*. (**More on Time.com:** Does Suffering From Withdrawal Really Mean You're Addicted?)

Based on animal studies of salvinorin A, the active ingredient in the *Salvia* plant, some neuropharmacologists believe the drug may have merits beyond getting people high. It could perhaps aid in the medical treatment of serious mental conditions or chronic pain — but some scientists worry that strict federal regulation could undermine its utility.

Matthew Johnson, an instructor in the department of psychiatry and behavioral sciences at Johns Hopkins University, who recently conducted a small, new study of salvinorin A — the first involving human volunteers — testified [PDF] before Congress in 2009:

[T]his compound is completely unique, and there is good reason to think a derivative of the drug could one day provide a breakthrough medication for chronic pain, Alzheimer's disease and other forms of dementia, schizophrenia, bipolar disorder, or cocaine dependence, potentially saving thousands of lives in the long run.

But the first question is, is it safe? In their latest study [PDF], Johnson and colleagues found that it was, at least in the short term. In the experiment, two men and two women who were mentally and physically healthy and free of any drug-abuse problems were each given 16 increasingly larger doses of salvinorin A and four doses of placebo in a lab setting. The participants took the drugs in 20 sessions over two to three months. They were observed for a variety of effects, including motor function, mood, physiology and length of the drug's "high." (**More on Time.com:** What's Langa-Perfume? The Drug From Rio's Bust You've Never Heard Of)

Two of the four participants — all of whom had previously experimented with *Salvia divinorum* and other more common hallucinogens like LSD and mushrooms — reported that salvinorin A resulted in a hallucinogenic effect that was "as strong as imaginable." Researchers noted this was unusual for experienced hallucinogenic-drug users. None of the participants suffered any adverse changes in bodily functions such as blood pressure, heart rate or nerve functioning.

All participants reported that the effect of salvinorin A was markedly different from that of other hallucinogens, stating that previous experiences with LSD or mushrooms had not detached them so completely from their sense of reality. *Salvia* took them into an entirely different realm of

consciousness, they said.

"[P]articipant narratives indicated intense, highly unusual experiences characterized by changes in spatial orientation, feelings of energy or pressure on different parts of the body, and unusual and sometimes recurring themes across sessions such as revisiting childhood memories, cartoon-like imagery and contact with entities," wrote the study's authors. (More on Time.com: 'i-Dosing': Can You Download a Drug High?)

The drug's effects were immediate and lasted between 2 and 20 minutes, depending on the strength of the dose. The users reported liking the drug's effects, though only the two strongest doses used in the study were significantly different from placebo. These preliminary findings bode well for the feasibility of future research on the drug, the authors write.

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February 18, 2009

Dear Senators,

I am a faculty member of Johns Hopkins University School of Medicine in the Department of Psychiatry. My specialty is conducting research on novel drugs of abuse, and understanding the nature of addiction and its treatment.

In my role in representing Johns Hopkins University School of Medicine, I wish to state that if Salvia divinorum is to be made a Schedule I drug, I support amendments which would close the legal loophole for allowing for my currently FDA-approved and Johns Hopkins Institutional Review Board-approved study to conduct human research with salvinorin A, the active constituent of Salvia divinorum. The current mechanism for exemption for Schedule I drugs in Maryland requires Federal legal exemption for research with the Schedule I drug. However, because this drug is not scheduled under Federal law, no such exemption is possible from DEA, which administers such Federal exemptions.

However, speaking beyond my role as a representative of Johns Hopkins, I, as scientist who specializes in drug abuse, addiction and its treatment, along with my research colleague Dr. Roland Griffiths, a Professor and Psychiatry and Neuroscience at Johns Hopkins School of Medicine who has been studying drug abuse for over 30 years, recognize that there is a larger issue here that is not being considered by the Senate. That is, putting the drug into Schedule I will inevitably hamper research, regardless of potential research exemptions. Some legislators have stated that research would continue as normal should a research provision be included in the Schedule I bill. Our experience in the drug abuse research field has shown us that this is a well-intentioned, yet drastic misunderstanding of modern drug development research.

For example, I can guarantee that virtually no pharmaceutical company would invest the millions of dollars, that are required for medications development, into a Schedule I drug, or its derivatives, which would also be considered as Schedule I. There is simply no commercial feasibility for a Scheduled I drug or a derivative of it.

This is alarming considering that this compound is completely unique, and there is good reason to think a derivative of the drug could one day provide a breakthrough medication for chronic pain, Alzheimer's disease and other forms of dementia, schizophrenia, bipolar disorder, or cocaine dependence, potentially saving thousands of lives in the long run. Therefore, scheduling the drug, even if our study is protected, could quite realistically prevent (or delay by decades) potential significant medical advances in the treatment of these life-threatening diseases.

Besides the pharmaceutical industry, large segments of academic research would also be prevented. For example, researchers doing rodent studies on models of Alzheimer's disease are extremely unlikely to be currently working with scheduled drugs, and will not realistically be willing or able to meet the incredibly high thresholds for gaining exemptions for scheduled drugs. Only a small minority of researchers such as myself, who study drugs of abuse have the institutional history and resources to gain these exemptions. For example, we literally have a bank vault for drug storage, 24 hour guarded security at the front desk, etc.

We would encourage legislators to read our included documents. One is a somewhat lengthy synopsis written by Dr. Griffiths and myself, of the known science about Salvia divinorum and its potential areas of danger as well as its promising role as a research tool and its potential for medications development.

However, what may be more useful to legislators is the chart we provide about the wide variety of potential ways of regulating this drug, along with examples of a wide variety of dangerous drugs and how they are regulated. In addition to this, I am providing a 1-page synopsis sheet that distills the known potential dangers of Salvia divinorum across important domains relevant to drug abuse, and compares Salvia divinorum relative to other drugs. We would encourage legislators to review the chart, along with our 1-page comparison sheet, and use these to judge the appropriate way to regulate Salvia divinorum.

We recognize the well-intentioned effort to schedule this drug into Schedule I. We believe a primary reason is the tragic death of the teen in Delaware. We understand the incredible heartache caused by his death. However, from a scientific perspective, there are over 4,000 teen suicides per year, and there is no claim or evidence that the teen was on the drug when he committed suicide. It is scientifically impossible to attribute this death to Salvia divinorum. In contrast, many teens unambiguously die every year from causes directly caused by drugs, including the abuse of solvents (very little regulation) and over the counter medicines (minimally regulated), to alcohol (moderately regulated), and to Scheduled II-V drugs such as cocaine, amphetamine, Oxycontin®, and anabolic steroids, all of which are Scheduled lower than Schedule I.

Considering the greatest good for society, it is worth considering a wide range of legislative options for regulating this drug that fall below Schedule I control.

Sincerely,



Matthew W. Johnson, Ph.D.  
Instructor, Dept. of Psychiatry &  
Behavioral Sciences

s.19(1)



**Fw: Email to Chris Sannerud re: Salvia**  
Stephanie Chandler to: Denis Arsenault

2010-12-13 09:31 AM

Hi Denis,

Please see the letter below which I have drafted to the DEA re: Salvia. I'm uncertain as to what our usual protocol is in terms of communicating with other regulatory authorities, so I am wondering if it would be appropriate to mention the NOI and our proposal to schedule Salvia and salvinorin A despite the fact that neither the MLs or NOI have been DG approved yet?

Stephanie

Dear [REDACTED]

The Office of Controlled Substances (OCS) of Health Canada is currently finalizing its scheduling assessment of the hallucinogenic plant *Salvia divinorum*. At this time, neither *S. divinorum* nor its active ingredient salvinorin A are included in any of the schedules to Canada's *Controlled Drugs and Substances Act (CDSA)*.

According to the National Institute of Drug Abuse (NIDA) website, the Drug Enforcement Administration (DEA) is considering classifying *S. divinorum* as a Schedule I drug. In order to complete our assessment of this plant, I would like to confirm the current regulatory status of *S. divinorum* as well as salvinorin A in the United States. Any additional information regarding the federal control of these substances which you would be able to provide us would also be greatly appreciated.

→ whether this is the case.

Should you have any questions with regard to this request, please do not hesitate to contact me.

Yours Sincerely,

----- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2010-12-13 09:13 AM -----

From: Jocelyn Kula/HC-SC/GC/CA  
To: Stephanie Chandler/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2010-12-10 11:12 AM  
Subject: Re: FYI: Salvia divinorum TIME article

Would suggest that we contact [REDACTED] at the DEA to confirm. Can you pls draft an email and I will send....

JK

Sent by blackberry

Jocelyn Kula  
A/ Director/ Directrice par interim  
Office of Controlled Substances/ Bureau des substances contrôllées  
Stephanie Chandler

----- Original Message -----

**From:** Stephanie Chandler  
**Sent:** 2010-12-10 11:07 AM EST  
**To:** Jocelyn Kula  
**Cc:** Denis Arsenault  
**Subject:** FYI: Salvia divinorum TIME article

FYI

The Time article seems to be a bit misleading as it states "federal legislation has been introduced to regulate the plant as a Schedule I drug". In 2002, a bill was introduced in the US Congress to control Salvia, however that bill subsequently died and it appears that no new legislation has since been introduced. However, as stated in the IAS "According to the National Institute for Drug Abuse, the Drug Enforcement Administration is considering classifying *S. divinorum* and/or salvinorin A as Schedule I drugs."

Stephanie

Jocelyn Kula FYI and can we pls look into reference that Salvi... 2010-12-10 10:11:40 AM

From: Jocelyn Kula/HC-SC/GC/CA  
To: Stephanie Chandler/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2010-12-10 10:11 AM  
Subject: Fw: Salvia divinorum

---

FYI and can we pls look into reference that Salvia is now going to be regulated under the CSA in the US....will be important to have facts right in IYH and NOI etc.  
thx

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224  
---- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2010-12-10 10:11 AM ----

From: Mark Edwards/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC  
Date: 2010-12-10 10:02 AM  
Subject: Fw: Salvia divinorum

---

FYI

---- Forwarded by Mark Edwards/HC-SC/GC/CA on 2010-12-10 10:02 AM ----

From:   
To:   
Date: 2010-12-09 12:53 PM  
Subject: Salvia divinorum

---

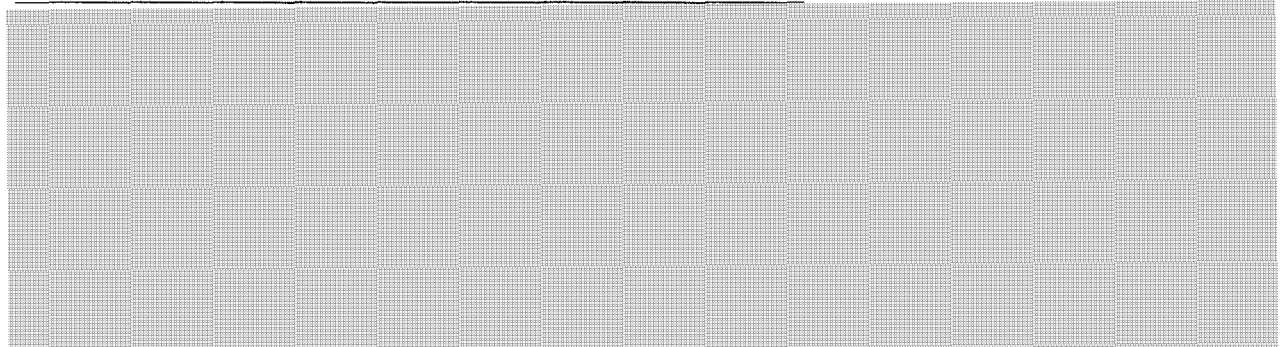
Dear Colleagues and Friends,

I hope this email finds you well. I know that some of you are very interested in the hallucinogenic plant *Salvia divinorum*, as in many places its use is growing. Attached is a new article from Time which may be of interest to you.

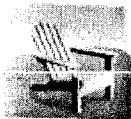
(See attached file: Mexico - *Salvia divinorum* TIME 8 Dec 2010.pdf)

**s.19(1)**

Kind regards,



[www.unodc.org/\[attachment \"Mexico - Salvia divinorum TIME 8 Dec 2010.pdf\" deleted by Stephanie Chandler/HC-SC/GC/CA\]](http://www.unodc.org/[attachment \)



**Re: Fw: Updated Media Lines and Draft Notice of Intent for Salvia** 

Nicole Prentice to: Jocelyn Kula

2010-12-13 03:42 PM

Cc: Stephanie Chandler, Christine Roush

Thanks Jocelyn.

I figured she was busy with other more pressing issues, however, thanks to Miley Cyrus' recent activities there has been some interest in the topic and we expect enquiries. When they come in, we will attempt to respond using previously used messaging and sent your way for review.

Get well soon.

**Nicole Prentice**

Junior Communications Officer | Agente junior des Communications

Regulatory Communications and Media Relations Division | Division des communications réglementaires et des relations avec les médias

Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la consultation et des communications

Health Canada | Santé Canada

Tel: 613.941.3107

Fax: 613.948.8085

Jocelyn Kula

Hi Nicole The docs went to Cathy late last week...

2010-12-13 03:39:15 PM

From: Jocelyn Kula/HC-SC/GC/CA  
To: Nicole Prentice/HC-SC/GC/CA@HWC  
Cc: Stephanie Chandler/HC-SC/GC/CA@HWC, Christine Roush/HC-SC/GC/CA@HWC  
Date: 2010-12-13 03:39 PM  
Subject: Re: Fw: Updated Media Lines and Draft Notice of Intent for Salvia

---

Hi Nicole

The docs went to Cathy late last week but she has not had an opp to review yet as she has been almost completely tied up with meetings and briefings connected to the tobacco-related discussions at HESA and now the forthcoming announcement that I believe has been planned for Thursday.

I am at home sick today but will check in with DGO when I am back in the office tomorrow.

JK

---

Jocelyn Kula

Acting Director/ Directrice par intérim

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs

Health Canada/ Santé Canada

Tel: (613) 952-2177 Fax: (613) 946-4224

Nicole Prentice

Hi again, Have you gotten anything back from...

2010-12-13 03:36:39 PM

From: Nicole Prentice/HC-SC/GC/CA  
To: Stephanie Chandler/HC-SC/GC/CA@HWC

Cc: Christine Roush/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC  
Date: 2010-12-13 03:36 PM  
Subject: Re: Fw: Updated Media Lines and Draft Notice of Intent for Salvia

---

Hi again,

Have you gotten anything back from Cathy on these products by any chance?

**Nicole Prentice**

Junior Communications Officer | Agente junior des Communications  
Regulatory Communications and Media Relations Division | Division des communications réglementaires et des relations avec les médias  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la consultation et des communications  
Health Canada | Santé Canada  
Tel: 613.941.3107  
Fax: 613.948.8085

---

Stephanie Chandler Hi Nicole and Christine, Sorry you weren't cc'e... 2010-12-10 09:07:59 AM

From: Stephanie Chandler/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC, Nicole Prentice/HC-SC/GC/CA@HWC  
Cc: Jocelyn Kula/HC-SC/GC/CA@HWC  
Date: 2010-12-10 09:07 AM  
Subject: Fw: Updated Media Lines and Draft Notice of Intent for Salvia

---

Hi Nicole and Christine,

Sorry you weren't cc'ed on this... but the Salvia MLs and NOI have gone to DGO.

Regards,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca  
---- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2010-12-10 09:04 AM ----

From: Jocelyn Kula/HC-SC/GC/CA  
To: stephanie.szick@hc-sc.gc.ca  
Cc: CSTD-DGO, Stephanie Chandler/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2010-12-09 06:19 PM  
Subject: Updated Media Lines and Draft Notice of Intent for Salvia

---

Hi Stephanie,

Per previous instruction from Cathy and for Cathy's review and approval, please find attached a copy of the revised media lines for Salvia as well as our proposed Notice of Intent. We have worked with Comms

on the media lines, and they are comfortable with us submitting them for Cathy's approval ourselves as we know that Cathy wanted to see both the media lines and the draft NOI at the same time. For this reason, we are not submitting the IYH for approval at this point; our thinking is that we would hold off on issuing that until the NOI was in print. We have already revised the text to be consistent however.

[attachment "Salvia Media Lines\_Dec 9\_OCS + CR.doc" deleted by Nicole Prentice/HC-SC/GC/CA] (with track changes)

[attachment "Salvia Media Lines\_Dec 9\_Clean.doc" deleted by Nicole Prentice/HC-SC/GC/CA] (clean version)

[attachment "DRAFT Salvia NOI\_Dec 8.wpd" deleted by Nicole Prentice/HC-SC/GC/CA]

Jocelyn

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224



## RPD Telephone Enquiry

**Date of Call:** December 13, 2010

**Subject:** Status of *Salvia divinorum* and current media attention

**Language of Correspondence:** English

s.19(1)

**Caller Name:** [REDACTED]

**Caller Organization:** Saskatoon Police Services Drug Unit

**Caller Telephone Number:** (306) 221-9899

### CALL SUMMARY:

[REDACTED] of the Drug Unit of Saskatoon Police Services called to enquire as to whether Health Canada was looking into scheduling this substance under the *Controlled Drugs and Substances Act* (CDSA).

I indicated that Health Canada is currently assessing *S. divinorum* to determine whether it should be scheduled under the CDSA. He asked if this was an active assessment by Health Canada, or if this substance was simply "on our radar". I indicated to [REDACTED] that we are actively assessing *S. divinorum* to determine whether its regulation as a controlled substance would be appropriate.

[REDACTED] indicated that *S. divinorum* has garnered a lot of media attention in Saskatchewan lately. He has received a number of inquiries regarding *S. divinorum* recently, particularly after a recent YouTube video was posted online showing an American celebrity using this substance presumably to achieve a high.

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division  
Office of Controlled Substances

## QUESTION PERIOD NOTE

## NOTE POUR LA PÉRIODE DE QUESTIONS

Date:	December 14, 2010
Classification:	HECS PROTECTED - SESC : PROTÉGÉ

### SUBJECT - SUJET

English:

**DRUGS - SALVIA DIVINORUM**

Français:

**DROGUES - SALVIA DIVINORUM**

### SYNOPSIS - SOMMAIRE

English:

Media interest in Salvia divinorum is recurrent. Questions around this substance generally focus on its legality. Recently, a number of media reports have commented on a YouTube video which reportedly shows the young Hollywood celebrity Miley Cyrus smoking Salvia divinorum. There have also been several reports from scientific and media sources, which indicate that Salvia divinorum has the potential for abuse, and is used by adolescents and young adults for its hallucinogenic properties. ✓

### ANTICIPATED QUESTION - QUESTION PRÉVUE

English:

What is Health Canada doing to protect Canadians from the potential adverse effects associated with the use of Salvia divinorum? ✓

Français:

Quelles mesures Santé Canada prend-il pour protéger les Canadiens contre les effets indésirables possibles liés à l'utilisation de la Salvia divinorum?

*to discuss  
c Stephanie S.*

Key messages = a bit wordy / complex for him to deliver ... need to simplify

is there an alternate / plain language version? - main active ingredient? ingestion? CAN WE JUST SAY SALVIA?

English:

Health Canada has concluded its assessment of *Salvia divinorum* and salvinorin A and is proposing to include both substances in one of the Schedules to the Controlled Drugs and Substances Act (CDSA). It is currently considering whether *Salvia divinorum* be scheduled under the Controlled Drugs and Substances Act.

schedule for BOT of for key messages purposes? ?

The regulation

these substances.

Health Canada through these actions is taking the will take necessary steps to safeguard Canadians against the inclusion of *Salvia divinorum* and salvinorin A in one of the Schedules to the CDSA will reduce the potential health and safety risks associated with the availability and potential abuse of these substances.

them

early next year?

Health Canada will inform stakeholders of its proposal by publishing a Notice to Interested Parties (NOTIP) in Canada Gazette, Part I. The NOTIP will provide stakeholders and other interested parties with the opportunity to provide comments on the proposal to regulate these substances as controlled substances.

our This notice

Français:

BACKGROUND - CONTEXTE

English:

BACKGROUND / CONTEXTE

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, diviner's sage, magic mint, and puff. Certain websites are

also promoting the use of *S. divinorum* as a "legal" alternative to street drugs.

Active

*S. divinorum* is known to have both physical and mental effects which are often described as unpleasant, including:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

Salvinorin A -  
Main active  
ingredient.

International Control of *S. divinorum*

At the present time, *S. divinorum* is not listed under the United Nations Drug Control Conventions which means that it is not required to be regulated as a controlled substance in any of the countries that are signatories to these Conventions. However, some countries have decided to control *S. divinorum* on their own. In Australia, Belgium, Denmark, Sweden, Italy, Finland, and SouthNorth Korea, the possession and sale of *S. divinorum* is illegal. In Spain, its sale is prohibited, but possession or use is not. In Norway, *S. divinorum* cannot be imported without a prescription, and in Japan has recently passed a law that will take effect in April 2007 which totally bans all activities with *S. divinorum* have been banned. In the United States, *S. divinorum* is not regulated as a controlled substance by the US Drug Enforcement Administration; however, although some states such as Missouri, Louisiana, Tennessee and Delaware have implemented laws restricting its use, sale and/or distribution.

Current Situation in Canada

Health Canada considers several factors in determining whether regulation of a substance under is currently completing a review of *Salvia divinorum* against the criteria considered in adding substances to one of the Schedules to the *Controlled Drugs and Substances Act* (CDSA) is warranted, namely:

- International requirements and trends in control and/or scheduling;
- Chemical and pharmacological similarity to other substances already regulated under drugs listed in the CDSA;
- Dependence potential; Legitimate uses of the substance (i.e. therapeutic, scientific, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.
- Likelihood of abuse/misuse;
- Extent of abuse/misuse in Canada;
- Danger to public health and safety; and,
- Legitimate use in Canada

Its main active ingredient is the 1st reference. What is Salvinorin A? - we have much info. here re. Salvinorin A? But need some info. D

Health Canada recently concluded its assessment of *S. divinorum* (and salvinorin A) against the aforementioned factors and now proposes to include both substances in one of the Schedules to the CDSA.

Once this work has been completed, Health Canada will inform stakeholders of its decision. A regulatory proposal will be developed in the coming months.

Presently, because of its hallucinogenic properties, when products containing *S. divinorum* or salvinorin A are

are they? Synonym 001897

marketed for use as hallucinogens they meet the definition of a Natural Health Product (NHP) in accordance with the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act* . It is illegal to sell drugs or NHPs in Canada unless they have been reviewed and approved by Health Canada. As of December/September 2010, no products containing *S. divinorum* or salvinorin A have been authorized for sale by Health Canada.

**ATTACHMENTS / PIÈCE(S)-JOINTE(S)**

Contact/Personne ressource : Denis Arsenault/HC-SC/GC/CA	Tel. no./No de tél. 613-957-6828	Approved by/ Approuvé par Paul Glover, ADM (HECS/SESC)	Tel. no./No. de tél. 946-6701
	Mobile/ Cellulaire: 613-296-4239	Title/ Titre:	Mobile/ Cellulaire:
Alternate/ Secondaire: Jocelyn Kula	Telephone/ Téléphone: 613-952-2177		
	Mobile/ Cellulaire: 613-797-2103		

**Date Prepared/Préparé le :** 2010-09-07

**Prepared by/Préparé par :** Stephanie Chandler **Phone/ No de tél. :** 613-946-0124

**Office/Bureau :** CSTD - Office of Controlled Substances

**Date Contact Signed/  
Signature de la personne  
ressource :**

Contact Signed - Signé

**D.G. Verification/  
Vérification par le D.E. :** Cathy Sabiston

D.G. Approved / Approuvé D.E.

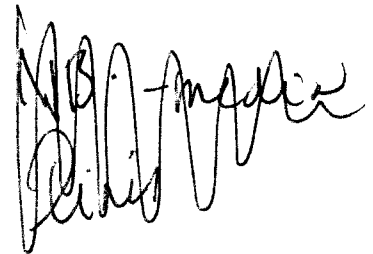
**Date D.G. Verified/  
Date vérifié par le D.E. :**

**Programme :** Controlled Substances and Tobacco Directorate

**ADM Approved/ Approbation  
par le SMA :** Paul Glover  
(946-6701)

**Branch/ Direction générale :** HECS/SESC

**Department/ Ministère :** Health Canada / Santé Canada



**QUESTION PERIOD NOTE**  
**NOTE POUR LA PÉRIODE DE**  
**QUESTIONS**

Date:	December 14, 2010
Classification :	HECS PROTECTED - SESC PROTÉGÉ

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**SUBJECT - SUJET**

English:

**DRUGS - SALVIA DIVINORUM**

Français:

**DROGUES - SALVIA DIVINORUM**

---

**SYNOPSIS - SOMMAIRE**

English:

Media interest in Salvia divinorum is recurrent. Questions around this substance generally focus on its legality. Recently, a number of media reports have commented on a YouTube video which reportedly shows the young Hollywood celebrity Miley Cyrus smoking Salvia divinorum. There have also been several reports from scientific and media sources, which indicate that Salvia divinorum has the potential for abuse, and is used by adolescents and young adults for its hallucinogenic properties.

---

**ANTICIPATED QUESTION - QUESTION PRÉVUE**

English:

What is Health Canada doing to protect Canadians from the potential adverse effects associated with the use of Salvia divinorum?

Français:

Quelles mesures Santé Canada prend-il pour protéger les Canadiens contre les effets indésirables possibles liés à l'utilisation de la Salvia divinorum?

---

English:

- under*
- schedule to s1*
- Health Canada has concluded its assessment of Salvia and its main active ingredient ~~Salvia divinorum~~ and salvinorin A and is proposing to include these substances ~~in one of the Schedules to the Controlled Drugs and Substances Act (CDSA). is currently considering whether Salvia divinorum be scheduled under the Controlled Drugs and Substances Act.~~
  - ~~The inclusion of Salvia divinorum and salvinorin A in one of the Schedules to the CDSA~~ The regulation of these substances will reduce the potential health and safety risks associated with them. ~~availability and potential abuse of this substance.~~
  - Health Canada will ~~inform stakeholders of its proposal by~~ publish a *Notice to Interested Parties* in *Canada Gazette*, Part I early next year. This notice will provide stakeholders and other interested parties with our the opportunity to provide comments on our the proposal to regulate these substances as controlled substances.

Français:

---

## BACKGROUND - CONTEXTE

English:

### BACKGROUND / CONTEXTE

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, diviner's sage, magic mint, and puff. Certain websites are

also promoting the use of *S. divinorum* as a "legal" alternative to street drugs.

*S. divinorum* is known to have both physical and mental effects which are often described as unpleasant, including:

- hallucinations
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- loss of consciousness
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- slurred speech and awkward sentence patterns

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#### Current Situation in Canada

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- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.
- ~~Likelihood of abuse/misuse;~~
- ~~Extent of abuse/misuse in Canada;~~
- ~~Danger to public health and safety; and,~~
- ~~Legitimate use in Canada~~

Health Canada recently concluded its assessment of *S. divinorum* and its main active ingredient salvinorin A against the aforementioned factors and now proposes to include both substances in one of the Schedules to the CDSA.

~~Once this work has been completed, Health Canada will inform stakeholders of its decision. A regulatory proposal will be developed in the coming months.~~



Presently, ~~because of its hallucinogenic properties,~~ when products containing *S. divinorum* or salvinorin A are marketed for use as hallucinogens they meet the definition of a Natural Health Product (NHP) in accordance with the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*. It is illegal to sell drugs or NHPs in Canada unless they have been reviewed and approved by Health Canada. As of December/September 2010, no products containing *S. divinorum* or salvinorin A have been authorized for sale by Health Canada.

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Contact/Personne ressource : Denis Arsenault/HC-SC/GC/CA	Tel. no./No de tél. 613-957-6828	Approved by/ Approuvé par Paul Glover, ADM (HECS/SESC)	Tel. no./No. de tél. 946-6701
	Mobile/ Cellulaire: 613-296-4239	Title/ Titre:	Mobile/ Cellulaire:
Alternate/ Secondaire: Jocelyn Kula	Telephone/ Téléphone: 613-952-2177		
	Mobile/ Cellulaire: 613-797-2103		

**Date Prepared/Préparé le :** 2010-09-07

**Prepared by/Préparé par :** Stephanie Chandler **Phone/ No de tél. :** 613-946-0124

**Office/Bureau :** CSTD - Office of Controlled Substances

**Date Contact Signed/  
Signature de la personne  
ressource :**  Contact Signed - Signé

**D.G. Verification/  
Vérification par le D.E. :** Cathy Sabiston  D.G. Approved / Approuvé D.E.

**Date D.G. Verified/  
Date vérifié par le D.E. :**

**Programme :** Controlled Substances and Tobacco Directorate

**ADM Approved/ Approbation  
par le SMA :** Paul Glover  
(946-6701)

**Branch/ Direction générale :** HECS/SESC

**Department/ Ministère :** Health Canada / Santé Canada

## QUESTION PERIOD NOTE

## NOTE POUR LA PÉRIODE DE QUESTIONS

Date:	December 14, 2010
Classification :	HECS PROTECTED - SESC PROTÉGÉ

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### SUBJECT - SUJET

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Français:

**DROGUES - SALVIA DIVINORUM**

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---

### ANTICIPATED QUESTION - QUESTION PRÉVUE

English:

What is Health Canada doing to protect Canadians from the potential adverse effects associated with the use of Salvia divinorum?

Français:

Quelles mesures Santé Canada prend-il pour protéger les Canadiens contre les effets indésirables possibles liés à l'utilisation de la Salvia divinorum?

---

English:

- Health Canada has concluded its assessment of Salvia and its main active ingredient ~~Salvia divinorum~~ and salvinorin A and is proposing to schedule both substances under ~~in one of the Schedules to the Controlled Drugs and Substances Act (CDSA)~~. ~~is currently considering whether Salvia divinorum be scheduled under the Controlled Drugs and Substances Act.~~
- ~~The inclusion of Salvia divinorum and salvinorin A in one of the Schedules to the CDSA~~ The regulation of these substances will reduce the potential health and safety risks associated with them. ~~availability and potential abuse of thi s substance.~~
- Health Canada will ~~inform stakeholders of its proposal by~~ publish a *Notice to Interested Parties* in *Canada Gazette*, Part I early next year. This notice will provide stakeholders and other interested parties with our the opportunity to provide comments on our the proposal to regulate these substances as controlled substances.

Français:

---

## **BACKGROUND - CONTEXTE**

English:

### **BACKGROUND / CONTEXTE**

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, diviner's sage, magic mint, and puff. Certain websites are

also promoting the use of *S. divinorum* as a "legal" alternative to street drugs.

Both *S. divinorum* and its main active ingredient salvinorin A are known to have both physical and mental effects which are often described as unpleasant, including:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

#### International Control of *S. divinorum*

At the present time, *S. divinorum* is not listed under the United Nations Drug Control Conventions which means that it is not required to be regulated as a controlled substance in any of the countries that are signatories to these Conventions. However, some countries have decided to control *S. divinorum* on their own. In Australia, Belgium, Denmark, Sweden, Italy, Finland, and SouthNorth Korea, the possession and sale of *S. divinorum* is illegal. In Spain, its sale is prohibited, but possession or use is not. In Norway, *S. divinorum* cannot be imported without a prescription, and in Japan ~~has recently passed a law that will take effect in April 2007 which totally bans all activities with *S. divinorum* have been banned.~~ In the United States, *S. divinorum* is not regulated as a controlled substance by the US Drug Enforcement Administration; however, although some states such as Missouri, Louisiana, Tennessee and Delaware have implemented laws restricting its use, sale and/or distribution.

#### Current Situation in Canada

Health Canada considers several factors in determining whether regulation of a substance under ~~is currently completing a review of *Salvia divinorum* against the criteria considered in adding substances to one of the Schedules to the *Controlled Drugs and Substances Act* (CDSA) is warranted, namely:~~

- International requirements and trends in control and/or scheduling;
- Chemical and pharmacological similarity to other substances already regulated under ~~drugs listed in the CDSA;~~
- ~~Dependence potential;~~ Legitimate uses of the substance (i.e. therapeutic, scientific, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.
- ~~Likelihood of abuse/misuse;~~
- ~~Extent of abuse/misuse in Canada;~~
- ~~Danger to public health and safety; and,~~
- ~~Legitimate use in Canada~~

Health Canada recently concluded its assessment of *S. divinorum* and its main active ingredient salvinorin A against the aforementioned factors and now proposes to include both substances in one of the Schedules to the CDSA.

~~Once this work has been completed, Health Canada will inform stakeholders of its decision. A regulatory proposal will be developed in the coming months.~~

Presently, ~~because of its hallucinogenic properties,~~ when products containing *S. divinorum* or salvinorin A are marketed for use as hallucinogens they meet the definition of a Natural Health Product (NHP) in accordance with the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*. It is illegal to sell drugs or NHPs in Canada unless they have been reviewed and approved by Health Canada. As of DecemberSeptember 2010, no products containing *S. divinorum* or salvinorin A have been authorized for sale by Health Canada.

**ATTACHMENTS / PIÈCE(S)-JOINTE(S)**

Contact/Personne ressource : Denis Arsenault/HC-SC/GC/CA	Tel. no./No de tél. 613-957-6828	Approved by/ Approuvé par Paul Glover, ADM (HECS/SESC)	Tel. no./No. de tél. 946-6701
	Mobile/ Cellulaire: 613-296-4239	Title/ Titre:	Mobile/ Cellulaire:
Alternate/ Secondaire: Jocelyn Kula	Telephone/ Téléphone: 613-952-2177		
	Mobile/ Cellulaire: 613-797-2103		

**Date Prepared/Préparé le :** 2010-09-07

**Prepared by/Préparé par :** Stephanie Chandler **Phone/ No de tél. :** 613-946-0124

**Office/Bureau :** CSTD - Office of Controlled Substances

**Date Contact Signed/  
Signature de la personne  
ressource :**  Contact Signed - Signé

**D.G. Verification/  
Vérification par le D.E. :** Cathy Sabiston  D.G. Approved / Approuvé D.E.

**Date D.G. Verified/  
Date vérifié par le D.E. :**

**Programme :** Controlled Substances and Tobacco Directorate

**ADM Approved/ Approbation  
par le SMA :** Paul Glover  
(946-6701)

**Branch/ Direction générale :** HECS/SESC

**Department/ Ministère :** Health Canada / Santé Canada



To: Jocelyn Kula/HC-SC/GC/CA, Denis Arsenault/HC-SC/GC/CA,  
Cc: Carmen Berube/HC-SC/GC/CA@HWC, CSTD-DGO, Denis  
Arsenault/HC-SC/GC/CA@HWC,  
Bcc:  
Subject: Re: Fw: Salvia D QP note update

ATTACHED →

Hi both,

Have put handwritten comments/questions to the note -- have left in Jocelyn's inbox here in DGO for pick up.

Glad to come to your office to chat.

Let me know,

Stephanie Szick  
Director General's Office / Bureau du directeur général  
Controlled Substances & Tobacco Directorate (CSTD) /  
Direction des substances contrôlées et de la lutte au tabagisme (DSCLT)  
Health Canada / Santé Canada  
Tel / Tél: (613) 948-8651

Jocelyn Kula	As requested. I am leaving early for an appt but...	2010-12-14 01:43:30 PM
--------------	---	------------------------

From: Jocelyn Kula/HC-SC/GC/CA  
To: stephanie.szick@hc-sc.gc.ca  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC, CSTD-DGO, Carmen Berube/HC-SC/GC/CA@HWC  
Date: 2010-12-14 01:43 PM  
Subject: Fw: Salvia D QP note update

As requested.

I am leaving early for an appt but Denis is around if you have questions.


Jocelyn

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224  
---- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2010-12-14 01:42 PM ----

From: Stephanie Chandler/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC, CSTD-OCS-DO  
Date: 2010-12-14 01:24 PM  
Subject: Fw: Salvia D QP note update

Hi Jocelyn,

The Salvia QP Note synopsis has been revised as discussed. The document can be found here:   
Denis has reviewed.

Regards,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca  
----- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2010-12-14 01:21 PM -----

From: Denis Arsenault/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: CSTD-OCS-DO, Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2010-12-14 11:27 AM  
Subject: Re: Salvia D QP note update

---

Hi Jocelyn,

The QP note for salvia has been updated for your review in the QP working database.

Denis

---

Denis Arsenault, A/Manager / Gestionnaire p.i.  
Regulatory Policy Division /  
Division des politiques réglementaires,  
Office of Controlled Substances /  
Bureau des substances contrôlées,  
Health Canada / Santé Canada  
Tel/Tél: (613) 957-6828  
Fax / Télécopieur : (613) 946-4224  
E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca

Jocelyn Kula	Will do Stephanie. For action pls Denis.	2010-12-13 12:39:51 PM
--------------	--	------------------------

Stephanie Szick

----- Original Message -----

From: Stephanie Szick  
Sent: 2010-12-13 12:37 PM EST  
To: Jocelyn Kula; CSTD-OCS-DO; Jeannine Ritchot  
Cc: CSTD-DGO  
Subject: Salvia D QP note update

hello all,

Further to the media clip and Cathy's request of this morning per below ---

- I have found in the QP working database a QP note on Salvia revised in Sept. 2010 -- here is the link

to that note --- 

- Given the very recent work on this file, the note should be further fine-tuned and the key messages should line up with the revised media lines. I've attached here the media lines as provided when you sent the NOI last week for Cathy's review/approval. Cathy has seen both but I need to follow up with her on her approvals. Will let you know asap.

[attachment "Salvia Media Lines\_10-12-10.doc" deleted by Jocelyn Kula/HC-SC/GC/CA]

REQUEST -- Can you revise this QP and send to DGO for Cathy's approval by tomorrow COB, Tuesday, Dec. 14/10 ? Please let us know if this time is doable, and if not, what date/time works best?

Sonia - please note for BF list - revised Salvia D QP note.

Thanks very much,  
Stephanie

----- Forwarded by Stephanie Szick/HC-SC/GC/CA on 2010-12-13 12:25 PM -----

From: Cathy A Sabiston/HC-SC/GC/CA  
To: SoniaH Lindblad1/HC-SC/GC/CA@HWC, Stephanie Szick/HC-SC/GC/CA@HWC  
Date: 2010-12-13 09:56 AM  
Subject: Fw: CTV.ca - Hallucinogen salvia popular for its intense high

---

**Make sure the qp card media analysis is up to date.**

Cathy Sabiston  
Director General / Directrice générale  
Controlled Substances & Tobacco Directorate (CSTD)  
Direction des substances contrôlées et de la lutte au tabagisme (DSCLT)  
Health Canada / Santé Canada  
Tel: (613) 941-1977 Fax: (613) 954-2288  
E-mail/courriel: cathy.a.sabiston@hc-sc.gc.ca  
Website/Site web: www.hc-sc.gc.ca

----- Forwarded by Cathy A Sabiston/HC-SC/GC/CA on 2010-12-13 09:56 AM -----

From: HC\_Media\_SC/HC-SC/GC/CA  
To:  
Date: 2010-12-13 09:38 AM  
Subject: CTV.ca - Hallucinogen salvia popular for its intense high  
Sent by: Nicolas Frate

---

Distribution group/Groupe de distribution: Controlled Substances - Substances contrôlées -  
HECSB/DGSESC,

Dec. 13 2010 9:16 AM ET

**Hallucinogen salvia popular for its intense high**

Source: [ctv.ca/health](http://ctv.ca/health)

The once squeaky-clean image of former teen Disney star Miley Cyrus took another hit – so to speak – this weekend, when a video emerged of her purportedly smoking a bong filled with the stuff.

While her father Billy Ray Cyrus is said to be saddened by the video, which appears on the celebrity gossip website TMZ.com, plenty of others are asking: what is salvia and is it legal?



Turns out the hallucinogen -- officially called Salvia divinorum -- is legal in the state of California where Cyrus apparently used it, though it's illegal in 12 other U.S. states. It's also illegal in Canada, although it is openly marketed by some "head shops" in Canada.

Dr. Bryan Roth, a professor of pharmacology at the University of North Carolina explains that the drug is an intense hallucinogenic that's fairly new on the drug scene. He says in the late '90s, recreational drug growers learned how to add the purified active ingredient, salvinorum A, to plants.

"It's only in the last four or five years that it has taken off as a fad," he told CTV's Canada AM from Chapel Hill, N.C.

Yet while its popularity is new, the hallucinogen, with is part of the sage and mint families, has been used for centuries by shamans in Mexico for spiritual healing. In fact, the name salvia means "to heal" and divinorum means "divination." The drug is also known as "diviner's sage" and "magic mint."

What makes salvia so popular is that it gives an intense high that takes just a few seconds to kick in and that lasts only a few minutes.

"Most people describe the effects as nearly instantaneous," Roth explained. "They're basically disassociated from normal reality. The effects of that can range from hilarious laughter, like you see with Miley Cyrus, to stark terror. Then within five to 15 minutes, the effects abate. And within half an hour, people are back to normal."

While research on the drug is scant, a U.S. government-funded study was released just last week in the journal Drug and Alcohol Dependence. In the study, researchers from the Johns Hopkins School of Medicine tested the drug on four subjects with prior experience with hallucinogens.

Two users rated the strength of the effect as "as strong as imaginable" -- considered unusual for people with prior experience with hallucinogens.

The subjects also reported the drug's effects were different from those caused by LSD or "magic mushrooms." While those drugs leave users high but still aware of the world around them, the salvia users said they felt as if they had completely left reality, gone to "other worlds or dimensions," had "contact with entities," and experienced "mystical-type" effects, the researchers reported.

There were no physical effects of the drug, the researchers found: no significant heart rate or blood pressure changes, no tremors or other side effects. And animal studies indicate the drug is not addictive.

Still, Roth points out, because salvia is not well studied yet, the long-term effects on the brain are unknown.

Here in Canada, the popularity of the drug is said to be growing. According to the 2009 Canadian Alcohol and Drug Use Monitoring Survey, about 1.6 per cent of Canadians aged 15 or older have tried salvia. For those aged 15-24, the number rises to 7.3 per cent.

<http://www.ctv.ca/CTVNews/Health/20101213/salvia-cyrus-101213/>

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Thank you.

Media Monitoring Team

**Health Canada**

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**Merci.**

**L'Équipe de surveillance des médias  
Santé Canada**

## QUESTION PERIOD NOTE

## NOTE POUR LA PÉRIODE DE QUESTIONS

Date:	December 14, 2010
Classification :	HECS PROTECTED - SESC PROTÉGÉ

---

### SUBJECT - SUJET

English:

**DRUGS - SALVIA DIVINORUM**

Français:

**DROGUES - SALVIA DIVINORUM**

---

### SYNOPSIS - SOMMAIRE

English:

Media interest in Salvia divinorum is recurrent. Questions around this substance generally focus on its legality. Recently, a number of media reports have commented on a YouTube video which reportedly shows the young Hollywood celebrity Miley Cyrus smoking Salvia divinorum. There have also been several reports from scientific and media sources, which indicate that Salvia divinorum has the potential for abuse, and is used by adolescents and young adults for its hallucinogenic properties.

---

### ANTICIPATED QUESTION - QUESTION PRÉVUE

English:

What is Health Canada doing to protect Canadians from the potential adverse effects associated with the use of Salvia divinorum?

Français:

Quelles mesures Santé Canada prend-il pour protéger les Canadiens contre les effets indésirables possibles liés à l'utilisation de la Salvia divinorum?

---

English:

- Health Canada has concluded its assessment of *Salvia divinorum* and salvinorin A and is proposing to include both substances in one of the Schedules to the *Controlled Drugs and Substances Act* (CDSA). ~~is currently considering whether *Salvia divinorum* be scheduled under the *Controlled Drugs and Substances Act*.~~
- ~~Health Canada through these actions is taking the will take necessary stepsactions to safeguard Canadians against~~ The inclusion of *Salvia divinorum* and salvinorin A in one of the Schedules to the CDSA will reduce the potential health and safety risks associated with the availability and potential abuse of ~~this~~ these substances.
- Health Canada will inform stakeholders of its proposal by publishing a *Notice to Interested Parties* (NOI) in *Canada Gazette*, Part I. The NOI will provide stakeholders and other interested parties with the opportunity to provide comments on the proposal to regulate these substances as controlled substances.

Français:

---

## **BACKGROUND - CONTEXTE**

English:

### **BACKGROUND / CONTEXTE**

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, diviner's sage, magic mint, and puff. Certain websites are

also promoting the use of *S. divinorum* as a "legal" alternative to street drugs.

*S. divinorum* is known to have both physical and mental effects which are often described as unpleasant, including:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

#### International Control of *S. divinorum*

At the present time, *S. divinorum* is not listed under the United Nations Drug Control Conventions which means that it is not required to be regulated as a controlled substance in any of the countries that are signatories to these Conventions. However, some countries have decided to control *S. divinorum* on their own. In Australia, Belgium, Denmark, Sweden, Italy, Finland, and SouthNorth Korea, the possession and sale of *S. divinorum* is illegal. In Spain, its sale is prohibited, but possession or use is not. In Norway, *S. divinorum* cannot be imported without a prescription, and in Japan ~~has recently passed a law that will take effect in April 2007 which totally bans all activities with *S. divinorum* have been banned.~~ In the United States, *S. divinorum* is not regulated as a controlled substance by the US Drug Enforcement Administration; however, although some states such as Missouri, Louisiana, Tennessee and Delaware have implemented laws restricting its use, sale and/or distribution.

#### Current Situation in Canada

Health Canada considers several factors in determining whether regulation of a substance under ~~is currently completing a review of *Salvia divinorum* against the criteria considered in adding substances to one of the Schedules to the *Controlled Drugs and Substances Act* (CDSA) is warranted, namely:~~

- International requirements and trends in control and/or scheduling;
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- Dependence potential; Legitimate uses of the substance (i.e. therapeutic, scientific, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.
- Likelihood of abuse/misuse;
- Extent of abuse/misuse in Canada;
- Danger to public health and safety; and,
- Legitimate use in Canada

Health Canada recently concluded its assessment of *S. divinorum* and salvinorin A against the aforementioned factors and now proposes to include both substances in one of the Schedules to the CDSA.

~~Once this work has been completed, Health Canada will inform stakeholders of its decision. A regulatory proposal will be developed in the coming months.~~

Presently, ~~because of its hallucinogenic properties,~~ when products containing *S. divinorum* or salvinorin A are

marketed for use as hallucinogens they meet the definition of a Natural Health Product (NHP) in accordance with the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*. It is illegal to sell drugs or NHPs in Canada unless they have been reviewed and approved by Health Canada. As of December/September 2010, no products containing *S. divinorum* or salvinorin A have been authorized for sale by Health Canada.

**ATTACHMENTS / PIÈCE(S)-JOINTE(S)**

Contact/Personne ressource : Denis Arsenault/HC-SC/GC/CA	Tel. no./No de tél. 613-957-6828	Approved by/ Approuvé par Paul Glover, ADM (HECS/SESC)	Tel. no./No. de tél. 946-6701
	Mobile/ Cellulaire: 613-296-4239	Title/ Titre:	Mobile/ Cellulaire:
Alternate/ Secondaire: Jocelyn Kula	Telephone/ Téléphone: 613-952-2177		
	Mobile/ Cellulaire: 613-797-2103		

**Date Prepared/Préparé le :** 2010-09-07

**Prepared by/Préparé par :** Stephanie Chandler **Phone/ No de tél. :** 613-946-0124

**Office/Bureau :** CSTD - Office of Controlled Substances

**Date Contact Signed/  
Signature de la personne  
ressource :**

Contact Signed - Signé

**D.G. Verification/  
Vérification par le D.E. :** Cathy Sabiston

D.G. Approved / Approuvé D.E.

**Date D.G. Verified/  
Date vérifié par le D.E. :**

**Programme :** Controlled Substances and Tobacco Directorate

**ADM Approved/ Approbation  
par le SMA :** Paul Glover  
(946-6701)

**Branch/ Direction générale :** HECS/SESC

**Department/ Ministère :** Health Canada / Santé Canada

**QUESTION PERIOD NOTE**  
**NOTE POUR LA PÉRIODE DE**  
**QUESTIONS**

Date:	December 14, 2010
Classification :	HECS PROTECTED - SESC PROTÉGÉ

---

**SUBJECT - SUJET**

English:

**DRUGS - SALVIA DIVINORUM**

Français:

**DROGUES - SALVIA DIVINORUM**

---

**SYNOPSIS - SOMMAIRE**

English:

Media interest in Salvia Divinorum is recurrent but mild. Questions around this substance, to date, have always been about its legality. There have been several reports from scientific and media sources, which indicate that Salvia divinorum has the potential for abuse, and is used by adolescents and young adults for its hallucinogenic properties. Further to an assessment of Salvia divinorum and its main active ingredient salvinorin A, Health Canada is proposing to include both substances in one of the Schedules to the Controlled Drugs and Substances Act (CDSA).

---

**ANTICIPATED QUESTION - QUESTION PRÉVUE**

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	Mobile/ Cellulaire: 613-296-4239	Title/ Titre:	Mobile/ Cellulaire:
Alternate/ Secondaire: Jocelyn Kula	Telephone/ Téléphone: 613-952-2177		
	Mobile/ Cellulaire: 613-797-2103		

**Date Prepared/Préparé le :** 2010-09-07

**Prepared by/Préparé par :** Stephanie Chandler **Phone/ No de tél. :** 613-946-0124

**Office/Bureau :** CSTD - Office of Controlled Substances

**Date Contact Signed/  
Signature de la personne  
ressource :**

**Contact Signed - Signé**

**D.G. Verification/  
Vérification par le D.E. :** Cathy Sabiston

**D.G. Approved / Approuvé D.E.**

**Date D.G. Verified/  
Date vérifié par le D.E. :**

**Programme :** Controlled Substances and Tobacco Directorate

**ADM Approved/ Approbation  
par le SMA :** Paul Glover  
(946-6701)

**Branch/ Direction générale :** HECS/SESC

**Department/ Ministère :** Health Canada / Santé Canada

## QUESTION PERIOD NOTE

## NOTE POUR LA PÉRIODE DE QUESTIONS

Date:	December 14, 2010
Classification :	HECS PROTECTED - SESC PROTÉGÉ

---

### SUBJECT - SUJET

English:

**DRUGS - SALVIA DIVINORUM**

Français:

**DROGUES - SALVIA DIVINORUM**

---

### SYNOPSIS - SOMMAIRE

English:

Media interest in Salvia Divinorum is recurrent but mild. Questions around this substance, to date, have always been about its legality. There have been several reports from scientific and media sources, which indicate that Salvia divinorum has the potential for abuse, and is used by adolescents and young adults for its hallucinogenic properties. Further to an assessment of Salvia divinorum and its main active ingredient salvinorin A, Health Canada is proposing to include both substances in one of the Schedules to the Controlled Drugs and Substances Act (CDSA).

---

### ANTICIPATED QUESTION - QUESTION PRÉVUE

English:

What is Health Canada doing to protect Canadians from the potential adverse effects associated with the use of Salvia divinorum?

Français:

Quelles mesures Santé Canada prend-il pour protéger les Canadiens contre les effets indésirables possibles liés à l'utilisation de la Salvia divinorum?

---

English:

- Health Canada has concluded its assessment of *Salvia divinorum* and salvinorin A and is proposing to include both substances in one of the Schedules to the *Controlled Drugs and Substances Act* (CDSA). ~~is currently considering whether *Salvia divinorum* be scheduled under the *Controlled Drugs and Substances Act*.~~
- ~~Health Canada through these actions is taking the will take necessary steps actions to safeguard Canadians against~~ The inclusion of *Salvia divinorum* and salvinorin A in one of the Schedules to the CDSA will reduce the potential health and safety risks associated with the availability and potential abuse of ~~this~~ these substances.
- Health Canada will inform stakeholders of its proposal by publishing a *Notice to Interested Parties* (NOI) in *Canada Gazette*, Part I. The NOI will provide stakeholders and other interested parties with the opportunity to provide comments on the proposal to regulate these substances as controlled substances.

Français:

---

## **BACKGROUND - CONTEXTE**

English:

### **BACKGROUND / CONTEXTE**

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, diviner's sage, magic mint, and puff. Certain websites are

also promoting the use of *S. divinorum* as a "legal" alternative to street drugs.

*S. divinorum* is known to have both physical and mental effects which are often described as unpleasant, including:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

#### International Control of *S. divinorum*

At the present time, *S. divinorum* is not listed under the United Nations Drug Control Conventions which means that it is not required to be regulated as a controlled substance in any of the countries that are signatories to these Conventions. However, some countries have decided to control *S. divinorum* on their own. In Australia, Belgium, Denmark, Sweden, Italy, Finland, and SouthNorth Korea, the possession and sale of *S. divinorum* is illegal. In Spain, its sale is prohibited, but possession or use is not. In Norway, Salvia divinorum cannot be imported without a prescription, and in Japan ~~has recently passed a law that will take effect in April 2007 which totally bans all activities with *S. divinorum*~~ have been banned. In the United States, *S. divinorum* is not regulated as a controlled substance by the US Drug Enforcement Administration; however, although some states such as Missouri, Louisiana, Tennessee and Delaware have implemented laws restricting its use, sale and/or distribution.

#### Current Situation in Canada

Health Canada considers several factors in determining whether regulation of a substance under ~~is currently completing a review of *Salvia divinorum*~~ against the criteria considered in adding substances to one of the Schedules to the *Controlled Drugs and Substances Act* (CDSA) is warranted, namely:

- International requirements and trends in control and/or scheduling;
- Chemical and pharmacological similarity to other substances already regulated under drugs listed in the CDSA;
- ~~Dependence potential;~~ Legitimate uses of the substance (i.e. therapeutic, scientific, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.
- ~~Likelihood of abuse/misuse;~~
- ~~Extent of abuse/misuse in Canada;~~
- ~~Danger to public health and safety; and;~~
- ~~Legitimate use in Canada~~

Health Canada recently concluded its assessment of *S. divinorum* and salvinorin A against the aforementioned factors and now proposes to include both substances in one of the Schedules to the CDSA.

~~Once this work has been completed, Health Canada will inform stakeholders of its decision. A regulatory proposal will be developed in the coming months.~~

Presently, ~~because of its hallucinogenic properties,~~ when products containing *S. divinorum* or salvinorin A are

marketed for use as hallucinogens, they meet the definition of a Natural Health Product (NHP) in accordance with the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*. It is illegal to sell drugs or NHPs in Canada unless they have been reviewed and approved by Health Canada. As of December/September 2010, no products containing *S. divinorum* or salvinorin A have been authorized for sale by Health Canada.

**ATTACHMENTS / PIÈCE(S)-JOINTE(S)**

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**Date Prepared/Préparé le :** 2010-09-07

**Prepared by/Préparé par :** Stephanie Chandler **Phone/ No de tél. :** 613-946-0124

**Office/Bureau :** CSTD - Office of Controlled Substances

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**Department/ Ministère :** Health Canada / Santé Canada



**Fw: CTV.ca/health - Hallucinogen salvia popular for its intense high**

Jocelyn Kula to: Stephanie Chandler

2010-12-14 11:51 AM

I assume you saw this but just in case.....

---

Jocelyn Kula

Acting Director/ Directrice par intérim

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs

Health Canada/ Santé Canada

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----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2010-12-14 11:51 AM -----

From: HC\_Media\_SC/HC-SC/GC/CA

To:

Date: 2010-12-14 07:33 AM

Subject: CTV.ca/health - Hallucinogen salvia popular for its intense high

Sent by: Hisham Kelati

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Distribution group/Groupe de distribution: Controlled Substances - Substances contrôlées -  
HECSB/DGSESC,

CTV.ca/health

Hallucinogen salvia popular for its intense high

<http://www.ctv.ca/CTVNews/Health/20101213/salvia-cyrus-101213/>

The once squeaky-clean image of former teen Disney star Miley Cyrus took another hit - so to speak - this weekend, when a video emerged of her purportedly smoking a bong filled with salvia.

While her father Billy Ray Cyrus is said to be saddened by the video, which appears on the celebrity gossip website TMZ.com, plenty of others are asking: what is salvia and is it legal?

Turns out the hallucinogen -- officially called Salvia divinorum -- is legal in the state of California where Cyrus apparently used it, though it's illegal in 12 other U.S. states. It's also illegal in Canada, although it is openly marketed by some "head shops" in Canada.

Dr. Bryan Roth, a professor of pharmacology at the University of North Carolina explains that the drug is an intense hallucinogenic that's fairly new on the drug scene. He says in the late '90s, recreational drug growers learned how to add the purified active ingredient, salvinorum A, to plants.

"It's only in the last four or five years that it has taken off as a fad," he told CTV's Canada AM from Chapel Hill, N.C.

Yet while its popularity is new, the hallucinogen, with its part of the sage and mint families, has been used for centuries by shamans in Mexico for spiritual healing. In fact, the name salvia means "to heal" and divinorum means "divination." The drug is also known as "diviner's sage" and "magic mint."

What makes salvia so popular is that it gives an intense high that takes just a few seconds to kick in and that lasts only a few minutes.

"Most people describe the effects as nearly instantaneous," Roth explained. "They're basically disassociated from normal reality. The effects of that can range from hilarious laughter, like you see with Miley Cyrus, to stark terror. Then within five to 15 minutes, the effects abate. And within half an hour,

people are back to normal."

While research on the drug is scant, a U.S. government-funded study was released just last week in the journal *Drug and Alcohol Dependence*. In the study, researchers from the Johns Hopkins School of Medicine tested the drug on four subjects with prior experience with hallucinogens.

Two users rated the strength of the effect as "as strong as imaginable" -- considered unusual for people with prior experience with hallucinogens.

The subjects also reported the drug's effects were different from those caused by LSD or "magic mushrooms." While those drugs leave users high but still aware of the world around them, the salvia users said they felt as if they had completely left reality, gone to "other worlds or dimensions," had "contact with entities," and experienced "mystical-type" effects, the researchers reported.

There were no physical effects of the drug, the researchers found: no significant heart rate or blood pressure changes, no tremors or other side effects. And animal studies indicate the drug is not addictive.

Still, Roth points out, because salvia is not well studied yet, the long-term effects on the brain are unknown.

Here in Canada, the popularity of the drug is said to be growing. According to the 2009 Canadian Alcohol and Drug Use Monitoring Survey, about 1.6 per cent of Canadians aged 15 or older have tried salvia. For those aged 15-24, the number rises to 7.3 per cent.

Products containing salvia divinorum or its active ingredient, salvinorin A, are considered natural health products and, must be authorized by Health Canada in order to be sold. Since Health Canada has not licensed any product containing salvia, sales are illegal.

Health Canada is still reviewing whether salvia should be included in the Controlled Drugs and Substances Act, which bans other hallucinogens, such as peyote, magic mushrooms and LSD.

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Merci.

L'Équipe de surveillance des médias  
Santé Canada



# QUESTION PERIOD NOTE

## NOTE POUR LA PÉRIODE DE QUESTIONS

Date:	December 14, 2010
Classification :	HECS PROTECTED - SESC PROTÉGÉ

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### SUBJECT - SUJET

English:

**DRUGS - SALVIA DIVINORUM**

Français:

**DROGUES - SALVIA DIVINORUM**

---

### SYNOPSIS - SOMMAIRE

English:

Media interest in Salvia divinorum is recurrent. Questions around this substance generally focus on its legality. Recently, a number of media reports have commented on a YouTube video which reportedly shows the young Hollywood celebrity Miley Cyrus smoking Salvia divinorum. There have also been several reports from scientific and media sources, indicating that Salvia divinorum has the potential for abuse, and is used by adolescents and young adults for its hallucinogenic properties.

---

### ANTICIPATED QUESTION - QUESTION PRÉVUE

English:

What is Health Canada doing to protect Canadians from the potential adverse effects associated with the use of Salvia divinorum?

Français:

Quelles mesures Santé Canada prend-il pour protéger les Canadiens contre les effets indésirables possibles liés à l'utilisation de la Salvia divinorum?

English:

- Health Canada has concluded its assessment of Salvia and its main active ingredient ~~Salvia divinorum~~ and salvinorin A and is proposing to schedule both substances under ~~in one of the Schedules to the Controlled Drugs and Substances Act (CDSA)~~ in order to protect the health & safety of Canadians particularly youth.
- ~~The inclusion of Salvia divinorum and salvinorin A in one of the Schedules to the CDSA~~ The regulation of these substances will reduce the potential health and safety risks associated with their use ~~them. availability and potential abuse of this substance.~~
- Health Canada will ~~inform stakeholders of its proposal by~~ publish a *Notice to Interested Parties* in *Canada Gazette*, Part I early next year. This notice will provide stakeholders and other interested parties with ~~our~~ the opportunity to provide comments on ~~our~~ the proposal to regulate these substances as controlled substances.

Français:

---

## BACKGROUND - CONTEXTE

English:

### BACKGROUND / CONTEXTE

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, diviner's sage, magic mint, and puff. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs.

Both the plant *S. divinorum* and its main active ingredient salvinorin A are known to have both physical and

mental effects which are often described as unpleasant, including:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

#### International Control of *S. divinorum*

At the present time, *S. divinorum* and its main active ingredient salvinorin A are not listed under the United Nations Drug Control Conventions which means that they are not required to be regulated as a controlled substances in any of the countries that are signatories to these Conventions. However, some countries have decided to control *S. divinorum* and/or salvinorin A on their own. In Australia, Belgium, Denmark, Sweden, and SouthNorth Korea, the possession and sale of *S. divinorum* is illegal. In Spain, the sale of *S. divinorum* is prohibited, but possession or use is not. In Norway, *S. divinorum* cannot be imported without a prescription, and in Japan has recently passed a law that will take effect in April 2007 which totally bans all activities with salvinorin A have been banned. In the United States, neither *S. divinorum* nor salvinorin A are regulated as controlled substances by the US Drug Enforcement Administration; however, although some states such as Missouri, Louisiana, Tennessee and Delaware have implemented laws restricting the use, sale and/or distribution of one or both substances.

#### Current Situation in Canada

Health Canada considers several factors in determining whether regulation of a substance under is currently completing a review of *Salvia divinorum* against the criteria considered in adding substances to one of the Schedules to the *Controlled Drugs and Substances Act* (CDSA) is warranted, namely:

- International requirements and trends in control and/or scheduling;
- Chemical and pharmacological similarity to other substances already regulated under drugs listed in the CDSA;
- Dependence potential; Legitimate uses of the substance (i.e. therapeutic, scientific, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.
- Likelihood of abuse/misuse;
- Extent of abuse/misuse in Canada;
- Danger to public health and safety; and,
- Legitimate use in Canada

Health Canada recently concluded its assessment of *S. divinorum* and its main active ingredient salvinorin A against the aforementioned factors and now proposes to include both substances in one of the Schedules to the CDSA.

Once this work has been completed, Health Canada will inform stakeholders of its decision. A regulatory proposal will be developed in the coming months.

Presently, because of its hallucinogenic properties, when products containing *S. divinorum* or salvinorin A are marketed for use as hallucinogens they meet the definition of a Natural Health Product (NHP) in accordance with hallucinogenic properties, it meets <sup>as</sup> <sup>is a plant with</sup> under the

*when marketed as a hallucinogen*  
~~the Natural Health Products Regulations and the definition of a drug under the Food and Drugs Act . It is illegal to sell drugs or NHPs in Canada unless they have been reviewed and approved by Health Canada. As of December/September 2010, no products containing S. divinorum or salvinorin A have been authorized for sale by Health Canada.~~ *As of Dec 2010, Health Canada has not licensed for sale any NHPs which contain S. divinorum as an ingredient. The sale of unauthorized NHPs containing S. divinorum and/or salvinorin A may be subject to compliance & enforcement acts by HC under the FDA.*

**ATTACHMENTS / PIÈCE(S)-JOINTE(S)**

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Alternate/ Secondaire: Jocelyn Kula	Telephone/ Téléphone: 613-952-2177		
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**Date Prepared/Préparé le :** 2010-09-07

**Prepared by/Préparé par :** Stephanie Chandler **Phone/ No de tél. :** 613-946-0124

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**QUESTION PERIOD NOTE**  
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**QUESTIONS**

Date:	December 14, 2010
Classification :	<b>HECS PROTECTED - SESC PROTÉGÉ</b>

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**SUBJECT - SUJET**

English:

**DRUGS - SALVIA DIVINORUM**

Français:

**DROGUES - SALVIA DIVINORUM**

---

**SYNOPSIS - SOMMAIRE**

English:

Media interest in Salvia divinorum is recurrent. Questions around this substance generally focus on its legality. Recently, a number of media reports have commented on a YouTube video which reportedly shows the young Hollywood celebrity Miley Cyrus smoking Salvia divinorum. There have also been several reports from scientific and media sources, indicating that Salvia divinorum has the potential for abuse, and is used by adolescents and young adults for its hallucinogenic properties.

---

**ANTICIPATED QUESTION - QUESTION PRÉVUE**

English:

What is Health Canada doing to protect Canadians from the potential adverse effects associated with the use of Salvia divinorum?

Français:

Quelles mesures Santé Canada prend-il pour protéger les Canadiens contre les effets indésirables possibles liés à l'utilisation de la Salvia divinorum?

---

English:

- Health Canada has concluded its assessment of Salvia and its main active ingredient ~~Salvia divinorum~~ salvinorin A and is proposing to schedule both substances under ~~in one of the Schedules to the~~ *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth.
- ~~The inclusion of Salvia divinorum and salvinorin A in one of the Schedules to the CDSA~~ The regulation of these substances will reduce the potential health and safety risks associated with their use ~~them. availability and potential abuse of this substance.~~
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Français:

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## **BACKGROUND - CONTEXTE**

English:

### **BACKGROUND / CONTEXTE**

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, diviner's sage, magic mint, and puff. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs.

Both the plant *S. divinorum* and its main active ingredient salvinorin A are known to have both physical and mental effects which are often described as unpleasant, including:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

#### International Control of *S. divinorum*

At the present time, *S. divinorum* and its main active ingredient salvinorin A are not listed under the United Nations Drug Control Conventions which means that they are not required to be regulated as a controlled substances in any of the countries that are signatories to these Conventions. However, some countries have decided to control *S. divinorum* and/or salvinorin A on their own. In Australia, Belgium, Denmark, Sweden, and SouthNorth Korea, the possession and sale of *S. divinorum* is illegal. In Spain, the sale of *S. divinorum* is prohibited, but possession or use is not. In Norway, *S. divinorum* cannot be imported without a prescription, and in Japan has recently passed a law that will take effect in April 2007 which totally bans all activities with salvinorin A have been banned. In the United States, neither *S. divinorum* nor salvinorin A are regulated as controlled substances by the US Drug Enforcement Administration; however, although some states such as Missouri, Louisiana, Tennessee and Delaware have implemented laws restricting the use, sale and/or distribution of one or both substances.

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English:

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**ANTICIPATED QUESTION - QUESTION PRÉVUE**

English:

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English:

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- The inclusion of ~~Salvia divinorum~~ <sup>as controlled substances</sup> and salvinorin A in one of the Schedules to the CDSA. The regulation of these substances will reduce the potential health and safety risks associated with their use ~~them~~. ~~availability and potential abuse of this substance.~~
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Français:

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## BACKGROUND - CONTEXTE

English:

### BACKGROUND / CONTEXTE

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, diviner's sage, magic mint, and puff. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs.

Both the plant *S. divinorum* and its main active ingredient salvinorin A are known to have both physical and mental effects which are often described as unpleasant, including:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

#### International Control of *S. divinorum*

At the present time, *S. divinorum* and its main active ingredient salvinorin A are not listed under the United Nations Drug Control Conventions which means that they are not required to be regulated as a controlled substances in any of the countries that are signatories to these Conventions. However, some countries have decided to control *S. divinorum* and/or salvinorin A on their own. In Australia, Belgium, Denmark, Sweden, and SouthNorth Korea, the possession and sale of *S. divinorum* is illegal. In Spain, the sale of *S. divinorum* is prohibited, but possession or use is not. In Norway, *S. divinorum* cannot be imported without a prescription, and in Japan ~~has recently passed a law that will take effect in April 2007 which totally bans all activities with salvinorin A have been banned.~~ In the United States, neither *S. divinorum* nor salvinorin A are regulated as controlled substances ~~by the US Drug Enforcement Administration; however,~~ although some states such as Missouri, Louisiana, Tennessee and Delaware have implemented laws restricting the use, sale and/or distribution of one or both substances.

#### Current Situation in Canada

Health Canada considers several factors in determining whether regulation of a substance under ~~is currently completing a review of *Salvia divinorum* against the criteria considered in adding substances to one of the Schedules to the *Controlled Drugs and Substances Act* (CDSA) is warranted,~~ namely:

- International requirements and trends in control and/or scheduling;
- Chemical and pharmacological similarity to other substances already regulated under drugs listed in the CDSA;
- ~~Dependence potential;~~ Legitimate uses of the substance (i.e. therapeutic, scientific, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.
- ~~Likelihood of abuse/misuse;~~
- ~~Extent of abuse/misuse in Canada;~~
- ~~Danger to public health and safety; and,~~
- ~~Legitimate use in Canada~~

Health Canada recently concluded its assessment of *S. divinorum* and its main active ingredient salvinorin A against the aforementioned factors and now proposes to include both substances in Schedule III to the CDSA.

~~Once this work has been completed, Health Canada will inform stakeholders of its decision. A regulatory proposal will be developed in the coming months.~~

~~Presently, because of its hallucinogenic properties, when products containing as *S. divinorum* or salvinorin A is~~

*change per docket*

a plant with hallucinogenic properties, it ~~are marketed for use as hallucinogens~~ they meets the definition of a Natural Health Product (NHP) ~~in accordance with under the Natural Health Products Regulations~~ when marketed as a hallucinogen. ~~and the definition of a drug under the Food and Drugs Act~~ -It is illegal to sell drugs or NHPs in Canada unless they have been reviewed and approved by Health Canada. As of December ~~September~~ 2010, no products containing ~~S. divinorum~~ or salvinorin A have been authorized for sale by Health Canada. Health Canada has not licensed for sale any natural health products which contain *S. divinorum* as an ingredient. The sale of unauthorized natural health products containing *S. divinorum* and/ or salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

**ATTACHMENTS / PIÈCE(S)-JOINTE(S)**

Contact/Personne ressource : Denis Arsenault/HC-SC/GC/CA	Tel. no./No de tél. 613-957-6828	Approved by/ Approuvé par Paul Glover, ADM (HECS/SESC)	Tel. no./No. de tél. 946-6701
	Mobile/ Cellulaire: 613-296-4239	Title/ Titre:	Mobile/ Cellulaire:
Alternate/ Secondaire: Jocelyn Kula	Telephone/ Téléphone: 613-952-2177		
	Mobile/ Cellulaire: 613-797-2103		

**Date Prepared/Préparé le :** 2010-09-07

**Prepared by/Préparé par :** Stephanie Chandler **Phone/ No de tél. :** 613-946-0124

**Office/Bureau :** CSTD - Office of Controlled Substances

**Date Contact Signed/  
Signature de la personne  
ressource :**  Contact Signed - Signé

**D.G. Verification/  
Vérification par le D.E. :** Cathy Sabiston  D.G. Approved / Approuvé D.E.

**Date D.G. Verified/  
Date vérifié par le D.E. :**

**Programme :** Controlled Substances and Tobacco Directorate

**ADM Approved/ Approbation  
par le SMA :** Paul Glover  
(946-6701)

**Branch/ Direction générale :** HECS/SESC

**Department/ Ministère :** Health Canada / Santé Canada

## QUESTION PERIOD NOTE

### NOTE POUR LA PÉRIODE DE QUESTIONS

Date:	December 14, 2010
Classification :	HECS PROTECTED - SESC PROTÉGÉ

---

#### SUBJECT - SUJET

English:

**DRUGS - SALVIA DIVINORUM**

Français:

**DROGUES - SALVIA DIVINORUM**

---

#### SYNOPSIS - SOMMAIRE

English:

Media interest in Salvia divinorum is recurrent. Questions around this substance generally focus on its legality. Recently, a number of media reports have commented on a YouTube video which reportedly shows the young Hollywood celebrity Miley Cyrus smoking Salvia divinorum. There have also been several reports from scientific and media sources, which indicate that Salvia divinorum has the potential for abuse, and is used by adolescents and young adults for its hallucinogenic properties.

---

#### ANTICIPATED QUESTION - QUESTION PRÉVUE

English:

What is Health Canada doing to protect Canadians from the potential adverse effects associated with the use of Salvia divinorum?

Français:

Quelles mesures Santé Canada prend-il pour protéger les Canadiens contre les effets indésirables possibles liés à l'utilisation de la Salvia divinorum?

---

English:

- Health Canada has concluded its assessment of *Salvia* and its main active ingredient ~~*Salvia divinorum*~~ and ~~salvinorin A~~ and is proposing to schedule both substances under ~~in one of the Schedules to the~~ *Controlled Drugs and Substances Act* (CDSA).
- ~~The inclusion of *Salvia divinorum* and salvinorin A in one of the Schedules to the CDSA~~ The regulation of these substances will reduce the potential health and safety risks associated with them. ~~availability and potential abuse of this substance.~~
- Health Canada will ~~inform stakeholders of its proposal by~~ publish a *Notice to Interested Parties* in *Canada Gazette*, Part I early next year. This notice will provide stakeholders and other interested parties with our the opportunity to provide comments on our the proposal to regulate these substances as controlled substances.

Français:

---

## **BACKGROUND - CONTEXTE**

English:

### **BACKGROUND / CONTEXTE**

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, diviner's sage, magic mint, and puff. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs.

Both the plant *S. divinorum* and its main active ingredient salvinorin A are known to have both physical and

mental effects which are often described as unpleasant, including:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

#### International Control of *S. divinorum*

At the present time, *S. divinorum* and its main active ingredient salvinorin A are not listed under the United Nations Drug Control Conventions which means that they are not required to be regulated as a controlled substances in any of the countries that are signatories to these Conventions. However, some countries have decided to control *S. divinorum* and/or salvinorin A on their own. In Australia, Belgium, Denmark, Sweden, and SouthNorth Korea, the possession and sale of *S. divinorum* is illegal. In Spain, the sale of *S. divinorum* is prohibited, but possession or use is not. In Norway, *S. divinorum* cannot be imported without a prescription, and in Japan has recently passed a law that will take effect in April 2007 which totally bans all activities with salvinorin A have been banned. In the United States, neither *S. divinorum* nor salvinorin A are regulated as controlled substances by the US Drug Enforcement Administration; however, although some states such as Missouri, Louisiana, Tennessee and Delaware have implemented laws restricting the use, sale and/or distribution of one or both substances.

#### Current Situation in Canada

Health Canada considers several factors in determining whether regulation of a substance under ~~is currently completing a review of *Salvia divinorum* against the criteria considered in adding substances to one of the Schedules to the Controlled Drugs and Substances Act (CDSA) is warranted, namely:~~

- International requirements and trends in control and/or scheduling;
- Chemical and pharmacological similarity to other substances already regulated under drugs listed in the CDSA;
- Dependence potential; Legitimate uses of the substance (i.e. therapeutic, scientific, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.
- Likelihood of abuse/misuse;
- Extent of abuse/misuse in Canada;
- Danger to public health and safety; and,
- Legitimate use in Canada

Health Canada recently concluded its assessment of *S. divinorum* and its main active ingredient salvinorin A against the aforementioned factors and now proposes to include both substances in one of the Schedules to the CDSA.

~~Once this work has been completed, Health Canada will inform stakeholders of its decision. A regulatory proposal will be developed in the coming months.~~

Presently, ~~because of its hallucinogenic properties, when products containing *S. divinorum* or salvinorin A are marketed for use as hallucinogens they meet the definition of a Natural Health Product (NHP) in accordance with~~

the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*. It is illegal to sell drugs or NHPs in Canada unless they have been reviewed and approved by Health Canada. As of December/September 2010, no products containing *S. divinorum* or salvinorin A have been authorized for sale by Health Canada.

**ATTACHMENTS / PIÈCE(S)-JOINTE(S)**

Contact/Personne ressource : Denis Arsenault/HC-SC/GC/CA	Tel. no./No de tél. 613-957-6828	Approved by/ Approuvé par Paul Glover, ADM (HECS/SESC)	Tel. no./No. de tél. 946-6701
	Mobile/ Cellulaire: 613-296-4239	Title/ Titre:	Mobile/ Cellulaire:
Alternate/ Secondaire: Jocelyn Kula	Telephone/ Téléphone: 613-952-2177		
	Mobile/ Cellulaire: 613-797-2103		

**Date Prepared/Préparé le :** 2010-09-07

**Prepared by/Préparé par :** Stephanie Chandler **Phone/ No de tél. :** 613-946-0124

**Office/Bureau :** CSTD - Office of Controlled Substances

**Date Contact Signed/  
Signature de la personne  
ressource :**  Contact Signed - Signé

**D.G. Verification/  
Vérification par le D.E. :** Cathy Sabiston  D.G. Approved / Approuvé D.E.

**Date D.G. Verified/  
Date vérifié par le D.E. :**

**Programme :** Controlled Substances and Tobacco Directorate

**ADM Approved/ Approbation  
par le SMA :** Paul Glover  
(946-6701)

**Branch/ Direction générale :** HECS/SESC

**Department/ Ministère :** Health Canada / Santé Canada



Approved with one change

**QUESTION PERIOD NOTE**  
**NOTE POUR LA PÉRIODE DE**  
**QUESTIONS**

Date:	December 14, 2010
Classification :	HECS PROTECTED - SESC PROTÉGÉ

**SUBJECT - SUJET**

English:

**DRUGS - SALVIA DIVINORUM**

Français:

**DROGUES - SALVIA DIVINORUM**

**SYNOPSIS - SOMMAIRE**

English:

Media interest in Salvia divinorum is recurrent. Questions around this substance generally focus on its legality. Recently, a number of media reports have commented on a YouTube video which reportedly shows the young Hollywood celebrity Miley Cyrus smoking Salvia divinorum. There have also been several reports from scientific and media sources, indicating that Salvia divinorum has the potential for abuse, and is used by adolescents and young adults for its hallucinogenic properties.

**ANTICIPATED QUESTION - QUESTION PRÉVUE**

English:

What is Health Canada doing to protect Canadians from the potential adverse effects associated with the use of Salvia divinorum?

Français:

Quelles mesures Santé Canada prend-il pour protéger les Canadiens contre les effets indésirables possibles liés à l'utilisation de la Salvia divinorum?

---

**English:**

- Health Canada has concluded its assessment of Salvia and its main active ingredient ~~Salvia divinorum~~ salvinorin A and is proposing to schedule both substances under ~~in one of the Schedules to the~~ *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth.
- ~~The inclusion of Salvia divinorum and salvinorin A in one of the Schedules to the CDSA~~ The regulation of these substances will reduce the potential health and safety risks associated with their use ~~them. availability and potential abuse of this substance.~~
- Health Canada will ~~inform stakeholders of its proposal by~~ publish a *Notice to Interested Parties* in *Canada Gazette*, Part I early next year. This notice will provide stakeholders and other interested parties with ~~our~~ the opportunity to provide comments on ~~our~~ the proposal to regulate these substances as controlled substances.

Français:

---

**BACKGROUND - CONTEXTE**

English:

**BACKGROUND / CONTEXTE**

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, diviner's sage, magic mint, and puff. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs.

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- loss of consciousness
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#### Current Situation in Canada

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- Dependence potential; Legitimate uses of the substance (i.e. therapeutic, scientific, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.
- Likelihood of abuse/misuse;
- Extent of abuse/misuse in Canada;
- Danger to public health and safety; and,
- Legitimate use in Canada

Health Canada recently concluded its assessment of *S. divinorum* and its main active ingredient salvinorin A against the aforementioned factors and now proposes to include both substances in ~~one of the Schedules~~ to the CDSA. III

Once this work has been completed, Health Canada will inform stakeholders of its decision. A regulatory proposal will be developed in the coming months.

Presently, ~~because of its hallucinogenic properties, when products containing~~ as *S. divinorum* or salvinorin A is a plant with hallucinogenic properties, ~~it are marketed for use as hallucinogens they~~ meets the definition of a Natural Health Product (NHP) ~~in accordance with~~ under the *Natural Health Products Regulations* when marketed as a hallucinogen and the definition of a drug under the *Food and Drugs Act*. ~~It is illegal to sell drugs or NHPs in Canada unless they have been reviewed and approved by Health Canada.~~ As of December ~~September~~ 2010, ~~no products containing S. divinorum or salvinorin A have been authorized for sale by Health Canada.~~ Health Canada has not licensed for sale any natural health products which contain *S. divinorum* as an ingredient. The sale of unauthorized natural health products containing *S. divinorum* and/ or salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

**ATTACHMENTS / PIÈCE(S)-JOINTE(S)**

Contact/Personne ressource : Denis Arsenault/HC-SC/GC/CA	Tel. no./No de tél. 613-957-6828	Approved by/ Approuvé par Paul Glover, ADM (HECS/SESC)	Tel. no./No. de tél. 946-6701
	Mobile/ Cellulaire: 613-296-4239	Title/ Titre:	Mobile/ Cellulaire:
Alternate/ Secondaire: Jocelyn Kula	Telephone/ Téléphone: 613-952-2177		
	Mobile/ Cellulaire: 613-797-2103		

**Date Prepared/Préparé le :** 2010-09-07

**Prepared by/Préparé par :** Stephanie Chandler **Phone/ No de tél. :** 613-946-0124

**Office/Bureau :** CSTD - Office of Controlled Substances

**Date Contact Signed/  
Signature de la personne  
ressource :**

Contact Signed - Signé

**D.G. Verification/  
Vérification par le D.E. :**

Cathy Sabiston

D.G. Approved / Approuvé D.E.

**Date D.G. Verified/  
Date vérifié par le D.E. :**


**Programme :** Controlled Substances and Tobacco Directorate

**ADM Approved/ Approbation  
par le SMA :** Paul Glover  
(946-6701)

**Branch/ Direction générale :** HECS/SESC

**Department/ Ministère :** Health Canada / Santé Canada



**Re: Salvia D QP note update**   
Denis Arsenault to: Jocelyn Kula  
Cc: Stephanie Chandler

2010-12-14 05:06 PM

Hi Jocelyn,

No. They have just asked us to simplify the bullets even more, and provide a bit more bumf in the background section regarding salvinorin A (i.e. how is salvinorin A different from salvia divinorum?)

The new version is ready for your review in the database.

Denis

---

Denis Arsenault, A/Manager / Gestionnaire p.i.  
Regulatory Policy Division /  
Division des politiques réglementaires,  
Office of Controlled Substances /  
Bureau des substances contrôlées,  
Health Canada / Santé Canada  
Tel/Tél: (613) 957-6828  
Fax / Télécopieur : (613) 946-4224  
E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca

Jocelyn Kula

Thx- are edits major? Sent by blackberry

2010-12-14 04:42:04 PM

---

From: Jocelyn Kula/HC-SC/GC/CA  
To: Denis Arsenault/HC-SC/GC/CA@HWC  
Cc: Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2010-12-14 04:42 PM  
Subject: Re: Salvia D QP note update

Thx- are edits major?  
Sent by blackberry

Jocelyn Kula  
A/ Director/ Directrice par interim  
Office of Controlled Substances/ Bureau des substances contrôllées

Denis Arsenault

----- Original Message -----

**From:** Denis Arsenault  
**Sent:** 2010-12-14 04:36 PM EST  
**To:** Jocelyn Kula  
**Cc:** Stephanie Chandler  
**Subject:** Fw: Salvia D QP note update

Hi Jocelyn,

Stephanie and I have S. Szick's comments in hand and are revising as suggested. Will let you know the new version is ready for review (and will leave hard copy with S. Szick's comments with your office).

Denis

Denis Arsenault, A/Manager / Gestionnaire p.i.  
Regulatory Policy Division /  
Division des politiques réglementaires,  
Office of Controlled Substances /  
Bureau des substances contrôlées,  
Health Canada / Santé Canada  
Tel/Tél: (613) 957-6828  
Fax / Télécopieur : (613) 946-4224  
E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca

----- Forwarded by Denis Arsenault/HC-SC/GC/CA on 2010-12-14 04:34 PM -----

From: Stephanie Szick/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC  
Cc: Carmen Berube/HC-SC/GC/CA@HWC, CSTD-DGO, Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2010-12-14 03:09 PM  
Subject: Re: Fw: Salvia D QP note update

---

Hi both,

Have put handwritten comments/questions to the note -- have left in Jocelyn's inbox here in DGO for pick up.

Glad to come to your office to chat.

Let me know,

Stephanie Szick  
Director General's Office / Bureau du directeur général  
Controlled Substances & Tobacco Directorate (CSTD) /  
Direction des substances contrôlées et de la lutte au tabagisme (DSCLT)  
Health Canada / Santé Canada  
Tel / Tél: (613) 948-8651

Jocelyn Kula

As requested. I am leaving early for an appt but...

2010-12-14 01:43:30 PM

From: Jocelyn Kula/HC-SC/GC/CA  
To: stephanie.szick@hc-sc.gc.ca  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC, CSTD-DGO, Carmen Berube/HC-SC/GC/CA@HWC  
Date: 2010-12-14 01:43 PM  
Subject: Fw: Salvia D QP note update

---

As requested.

I am leaving early for an appt but Denis is around if you have questions.

Jocelyn

---


Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2010-12-14 01:42 PM -----

From: Stephanie Chandler/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC, CSTD-OCS-DO  
Date: 2010-12-14 01:24 PM  
Subject: Fw: Salvia D QP note update

---

Hi Jocelyn,

The Salvia QP Note synopsis has been revised as discussed. The document can be found here:   
Denis has reviewed.

Regards,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

----- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2010-12-14 01:21 PM -----

From: Denis Arsenault/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: CSTD-OCS-DO, Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2010-12-14 11:27 AM  
Subject: Re: Salvia D QP note update

---

Hi Jocelyn,

The QP note for salvia has been updated for your review in the QP working database.

Denis

---

Denis Arsenault, A/Manager / Gestionnaire p.i.  
Regulatory Policy Division /  
Division des politiques réglementaires,  
Office of Controlled Substances /  
Bureau des substances contrôlées,  
Health Canada / Santé Canada  
Tel/Tél: (613) 957-6828  
Fax / Télécopieur : (613) 946-4224  
E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca

---

Jocelyn Kula Will do Stephanie. For action pls Denis.  
Stephanie Szick

2010-12-13 12:39:51 PM


----- Original Message -----

From: Stephanie Szick

**Sent:** 2010-12-13 12:37 PM EST  
**To:** Jocelyn Kula; CSTD-OCS-DO; Jeannine Ritchot  
**Cc:** CSTD-DGO  
**Subject:** Salvia D QP note update

hello all,

Further to the media clip and Cathy's request of this morning per below ---

- I have found in the QP working database a QP note on Salvia revised in Sept. 2010 -- here is the link to that note --- 
- Given the very recent work on this file, the note should be further fine-tuned and the key messages should line up with the revised media lines. I've attached here the media lines as provided when you sent the NOI last week for Cathy's review/approval. Cathy has seen both but I need to follow up with her on her approvals. Will let you know asap.

[attachment "Salvia Media Lines\_10-12-10.doc" deleted by Jocelyn Kula/HC-SC/GC/CA]

**REQUEST** -- Can you revise this QP and send to DGO for Cathy's approval by tomorrow COB, Tuesday, Dec. 14/10 ? Please let us know if this time is doable, and if not, what date/time works best?

**Sonia** - please note for BF list - revised Salvia D QP note.

Thanks very much,  
Stephanie

----- Forwarded by Stephanie Szick/HC-SC/GC/CA on 2010-12-13 12:25 PM -----

**From:** Cathy A Sabiston/HC-SC/GC/CA  
**To:** SoniaH Lindblad1/HC-SC/GC/CA@HWC, Stephanie Szick/HC-SC/GC/CA@HWC  
**Date:** 2010-12-13 09:56 AM  
**Subject:** Fw: CTV.ca - Hallucinogen salvia popular for its intense high

**Make sure the qp card media analysis is up to date.**

Cathy Sabiston  
Director General / Directrice générale  
Controlled Substances & Tobacco Directorate (CSTD)  
Direction des substances contrôlées et de la lutte au tabagisme (DSCLT)  
Health Canada / Santé Canada  
Tel: (613) 941-1977 Fax: (613) 954-2288  
E-mail/courriel: cathy.a.sabiston@hc-sc.gc.ca  
Website/Site web: www.hc-sc.gc.ca

----- Forwarded by Cathy A Sabiston/HC-SC/GC/CA on 2010-12-13 09:56 AM -----

**From:** HC\_Media\_SC/HC-SC/GC/CA  
**To:**  
**Date:** 2010-12-13 09:38 AM  
**Subject:** CTV.ca - Hallucinogen salvia popular for its intense high  
**Sent by:** Nicolas Frate

Distribution group/Groupe de distribution: Controlled Substances - Substances contrôlées -  
HECSB/DGSESC,



Dec. 13 2010 9:16 AM ET

### **Hallucinogen salvia popular for its intense high**

Source: [ctv.ca/health](http://ctv.ca/health)

The once squeaky-clean image of former teen Disney star Miley Cyrus took another hit – so to speak – this weekend, when a video emerged of her purportedly smoking a bong filled with the stuff.

While her father Billy Ray Cyrus is said to be saddened by the video, which appears on the celebrity gossip website TMZ.com, plenty of others are asking: what is salvia and is it legal?

Turns out the hallucinogen -- officially called Salvia divinorum -- is legal in the state of California where Cyrus apparently used it, though it's illegal in 12 other U.S. states. It's also illegal in Canada, although it is openly marketed by some "head shops" in Canada.

Dr. Bryan Roth, a professor of pharmacology at the University of North Carolina explains that the drug is an intense hallucinogenic that's fairly new on the drug scene. He says in the late '90s, recreational drug growers learned how to add the purified active ingredient, salvinatorum A, to plants.

"It's only in the last four or five years that it has taken off as a fad," he told CTV's Canada AM from Chapel Hill, N.C.

Yet while its popularity is new, the hallucinogen, with is part of the sage and mint families, has been used for centuries by shamans in Mexico for spiritual healing. In fact, the name salvia means "to heal" and divinorum means "divination." The drug is also known as "diviner's sage" and "magic mint."

What makes salvia so popular is that it gives an intense high that takes just a few seconds to kick in and that lasts only a few minutes.

"Most people describe the effects as nearly instantaneous," Roth explained. "They're basically disassociated from normal reality. The effects of that can range from hilarious laughter, like you see with Miley Cyrus, to stark terror. Then within five to 15 minutes, the effects abate. And within half an hour, people are back to normal."

While research on the drug is scant, a U.S. government-funded study was released just last week in the journal Drug and Alcohol Dependence. In the study, researchers from the Johns Hopkins School of Medicine tested the drug on four subjects with prior experience with hallucinogens.

Two users rated the strength of the effect as "as strong as imaginable" -- considered unusual for people with prior experience with hallucinogens.

The subjects also reported the drug's effects were different from those caused by LSD or "magic mushrooms." While those drugs leave users high but still aware of the world around them, the salvia users said they felt as if they had completely left reality, gone to "other worlds or dimensions," had "contact with entities," and experienced "mystical-type" effects, the researchers reported.

There were no physical effects of the drug, the researchers found: no significant heart rate or blood pressure changes, no tremors or other side effects. And animal studies indicate the drug is not addictive.

Still, Roth points out, because salvia is not well studied yet, the long-term effects on the brain are unknown.

Here in Canada, the popularity of the drug is said to be growing. According to the 2009 Canadian Alcohol and Drug Use Monitoring Survey, about 1.6 per cent of Canadians aged 15 or older have tried salvia. For those aged 15-24, the number rises to 7.3 per cent.

<http://www.ctv.ca/CTVNews/Health/20101213/salvia-cyrus-101213/>

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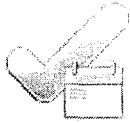
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## Tentative CSS-WG Meeting

2010-12-15 Wed 10:30 AM - 12:00 PM

Attendance is **optional** for Stephanie Chandler

Chair: Tiffany Thornton/HC-SC/GC/CA

Location: 629B, 123 Slater

Required:

Bruna Brands/HC-SC/GC/CA@HWC, Colette Strnad/HC-SC/GC/CA@HWC, Collin Pinto/HC-SC/GC/CA@HWC, Courtney Smith/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, Evelyn Soo/HC-SC/GC/CA@HWC, Hanan Abramovici/HC-SC/GC/CA@HWC, Robin Marles/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC, Tanja Kalajdzic/HC-SC/GC/CA@HWC, Tiana Branch/HC-SC/GC/CA@HWC

Optional:

Isabel Shanahan/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Laura Cooney/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC

### Description

Hi everyone,

Please note that this is a tentative meeting at this time - it might be cancelled if no issues need to be discussed. I will keep you posted.

The ROD from November 16th will be circulated shortly. Please find attached the most recent version of the IAS, however keep in mind that it has not been approved by the Director of OCS and does not include comments from the NOI. If you have further input please send your comments directly to Stephanie Chandler.



Draft Salvia Divinorum IAS\_Oct 29 2010.doc

Thanks very much,  
Tiffany

### Personal Notes

# Issue Analysis Summary

DRAFT

## Scheduling *Salvia Divinorum* under the CDSA

Regulatory Policy Division  
Office of Controlled Substances  
Controlled Substances and Tobacco and Directorate

October 29, 2010

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### 1. APPROVALS

This Issue Analysis Summary is approved.

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Jocelyn Kula, A/Director  
Office of Controlled Substances  
Controlled Substances and Tobacco Directorate

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[DD/MM/2010]

### 2. ISSUE

Health Canada has received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum* (*S. divinorum*,) which is not currently regulated under the *Controlled Drugs and Substances Act* (CDSA). These requests are further to reports from scientific and media sources suggesting that *S. divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has also noted an ongoing media interest regarding the

availability of *S. divinorum* in Canada.

### 3. PURPOSE

To assess *S. divinorum* against the criteria for the addition of a substance to one of the Schedules to the CDSA, and determine whether this substance should be regulated as a controlled substance in Canada.

### 4. CONTEXT

*S. divinorum* is a species of sage which belongs to the mint family, and which is found in the form of dried leaves, extract and plant cuttings. Also called "diviner's sage", the plant is known to induce illusions and hallucinations when chewed or smoked. Salvinorin A, the psychoactive ingredient in *S. divinorum* is a neoclerodane diterpene which is found primarily in the leaves, and to a lesser extent in the stem of the plant.<sup>1</sup>

*S. divinorum* is widely touted as a "legal" hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs among adolescents and young adults.<sup>2</sup> While very little is known about how and where *S. divinorum* is sold in Canada, it is suspected that it is mainly purchased over the Internet and/or bought at head shops or alternative life style stores, etc. *S. divinorum* cuttings are also available from a number of garden supply companies.

*S. divinorum* is a substance not currently scheduled under the CDSA. It can be imported and sold legally in Canada to anyone of any age, anywhere in Canada provided it is not sold as a health product or hallucinogen. In addition, the *S. divinorum* sold in Canada is currently not subject to any specific quality or safety standards.

The use of *S. divinorum* as a psychotropic agent first came to Health Canada's attention in 2002. In 2004, Health Canada received four adverse drug reaction (ADR) reports associated with the use of *S. divinorum* as a hallucinogen, with three being considered non-serious (requiring no medical attention) and the fourth being considered serious (medical intervention was required). The serious ADR report involved the concomitant use of alcohol in a person diagnosed with Attention Deficit Disorder.

Further to the receipt of the aforementioned ADRs, the Marketed Health Products Directorate (MHPD) and the Natural Health Products Directorate (NHPD) of the Health Products and Food Branch (HPFB) prepared an issue analysis summary (IAS) in November 2005, which recommended that *S. divinorum* and its active ingredient salvinorin A be regulated as controlled

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<sup>1</sup> U.S. Department of Justice Drug Enforcement Administration. 2002. Drugs and Chemicals of Concern: Salvia Divinorum (salvinorin A, divinorin A) URL:

[http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm) Nov 2008

<sup>2</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.

substances. This recommendation was maintained when the IAS was updated in November 2006.

Later, in December 2005, MHPD and NHPD prepared a Signal Assessment (SA) (updated in June 2007) that eventually led to the preparation of a Health Risk Assessment (HRA), which concluded that *S. divinorum* or salvinorin A-containing health products would constitute a Type II Health Risk according to the Health Hazard Classification of the Recall Policy of the Health Products and Food Branch Inspectorate (HBFBI). Such a risk is defined as “a situation in which the use of, or exposure to, a product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote”.

Further to a discussion with the Assistant Deputy Minister (ADM) of the Healthy Environments and Consumer Safety Branch (HECSB) in April 2007, the (then) Drug Strategy and Controlled Substances Directorate (DSCSD) (now Controlled Substances and Tobacco Directorate, CSTD) organized a meeting with MHPD, NHPD and HPFBI to discuss *S. divinorum*. HPFBI was to determine appropriate compliance activities regarding *S. divinorum* and consult with the Canada Border Services Agency (CBSA) regarding the movement of products containing *S. divinorum* into and out of Canada.

On September 13, 2007, a further meeting between DSCSD, MHPD, NHPD and HPFBI led to the conclusion that DSCSD would conduct a scheduling assessment of *S. divinorum* in order to explore the possibility of scheduling this substance under the CDSA.

In September 2008, the Director Generals of DSCSD, MHPD, TPD and the HPFBI agreed that media lines and an “It’s Your Health” article on *S. divinorum* would be prepared.

#### **4.1 Relevant Legislative Frameworks in Canada**

##### **4.1.1 Food and Drug Regulations (under the Food and Drugs Act)**

The *Food and Drug Regulations* (F&DR) serve to ensure the safety, efficacy, and quality of health products offered for sale in Canada, including drugs and medical devices. Prior to being given market authorization, a manufacturer must present substantive scientific evidence that their product is safe, efficacious and of high quality. For drugs, Health Canada reviews this information carefully and, if the review is satisfactory, a Notice of Compliance (NOC) is issued and appropriate Drug Identification Numbers (DINs) are assigned.

A “drug” is defined under the F&DR as any substance or mixture of substances manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
- (b) restoration, correction or modification of organic functions in human beings or animals, or

(c) disinfection in premises in which food is manufactured, prepared or kept;

As no products containing *S. divinorum* or its extracts have been reviewed and approved by Health Canada as of October 2010, it is illegal to market *S. divinorum* when it is represented as a drug.

#### 4.1.2 Natural Health Products Regulations (under the Food and Drugs Act)

The *Natural Health Products Regulations* (NHPR) aim to provide Canadians with ready access to natural health products (NHPs) that are safe, effective, and of high quality, while respecting freedom of choice and philosophical and cultural diversity. The NHPR require that all licensed products display a Natural Product Number (NPN), or, in the case of a homeopathic medicine, a Drug Identification Number - Homeopathic Medicine (DIN-HM), on their labels. These numbers are issued once a product is authorized for sale in Canada. A product licence may be obtained pursuant to an application in which the applicant attests to all of the conditions set out in a natural health product monograph prepared and published by the Natural Health Products Directorate. Alternatively, an applicant may submit a product license application that provides evidence of quality, safety and efficacy that is assessed as being sufficient and approved by NHPD by the full submission route. The NHPR also require that all manufacturers, packagers, labelers, and importers have a site license issued on the basis of sufficient evidence of procedures respecting distribution records, product recalls, product handling, storage and delivery, and all other aspects of Good Manufacturing Practices as set out in the NHPR.

The definition of an NHP under the NHPR has both a function and substance component. The function component refers to those substances that are manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
- (b) restoring or correcting organic functions in humans; or
- (c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

The substance component refers to the requirement that all of the medicinal ingredients of an NHP must be substances set out in Schedule 1 (a list of included substances) to the NHPR, a traditional medicine or a homeopathic medicine, and none of the ingredients can be substances set out in Schedule 2, a list of excluded substances which includes any substance listed on Schedules I to V of the CDSA. Section 2(2) of the NHPR excludes those substances (except homeopathic medicines) whose sale is required to be pursuant to a prescription as per Section C.01.043 of the F&DR.

As per section 93(1)(b)(vi) of the NHPR, every natural health product must be labeled with its

authorized recommended use or purpose. In the case of *S. divinorum*, it is generally marketed for its hallucinogenic properties which are considered a modification of an organic function. Therefore products that contain *S. divinorum* and are manufactured, sold or represented for use as a hallucinogen meet the definition of an NHP.

As of October 2010, no products containing *S. divinorum* have been authorized by Health Canada. Therefore no NPNs or DIN-HMs have been issued for such products. Therefore sales of *S. divinorum* are illegal under the NHPR if the product is represented for use as a hallucinogen or if other health claims are made.

#### **4.1.3 Controlled Drugs and Substances Act and its Regulations**

The CDSA provides a legislative framework for the control of substances that can alter mental processes and that may produce harm to the health of an individual or to society when diverted or misused. Except as authorized under its regulations, activities such as possession, possession for the purposes of trafficking, trafficking, importation, exportation, possession for the purposes of exportation and production of controlled substances are prohibited under the CDSA.

The substances regulated under the CDSA are grouped into eight Schedules, and each Schedule is associated with particular offences and penalties as described in Part I of the CDSA.

In determining whether a substance should be regulated as a controlled substance, and into which Schedule of the CDSA it should be placed, Health Canada considers a number of factors including:

- International requirements and trends in the control and/or scheduling;
- Chemical and/or pharmacological similarity to substances listed in the Schedules to the CDSA;
- Legitimate use of the substance, including therapeutic, scientific, industrial or commercial uses;
- Potential for abuse and/or addiction liability;
- Evidence of extent of actual abuse of the substance in Canada and internationally; and
- Risk to personal and public health and safety.

#### **4.2 Assessment of *S. Divinorum* for Scheduling Purposes**

##### **4.2.1 International Requirements and Trends in the Control and/or Scheduling**

At the present time, neither *S. divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and therefore do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

##### ***Australia***



In June 2002, Australia became the first country to prohibit the sale, supply, possession and use of *S. divinorum* and salvinorin A. Both *S. divinorum* and salvinorin A are listed in Schedule 9 of Australia's *Standard for the Uniform Scheduling of Drugs and Poisons* on the basis of "high potential for abuse and risk to public health and safety."<sup>3</sup> Schedule 9 is Australia's most restrictive drug schedule, and includes "substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities."<sup>4</sup>

### **Belgium**

A decree was passed in Belgium on October 22, 2006 which added *S. divinorum* to the list of controlled substances. This list includes substances such as psilocybin mushrooms, khat and peyote cactus.<sup>5</sup>

### **Denmark**

In 2003, Denmark added *S. divinorum* and salvinorin A to their list of "category B" controlled substances, a category which also includes psilocybin mushrooms, cocaine, amphetamine, and several others substances that are only legal for medicinal and scientific purposes. Illegal possession carries a penalty of up to two years in prison.

### **Germany**

*S. divinorum* (plant and plant parts) was added to Appendix I of the *Narcotics Act* in Germany on March 1, 2008, making it illegal to produce, traffic, or possess. The law does not specifically mention salvinorin A.

### **Italy**

On June 25, 2004, the Italian Ministry of Health issued an ordinance prohibiting the sale of *S. divinorum* and its active constituent salvinorin A. On January 11, 2005, the Ministry of Health made possession of *S. divinorum* and salvinorin A illegal by placing them in "Tabella 1" of the *Tabelle Sostanze Stupefacenti o Psicotrope*.

### **Japan**

On November 9, 2006, the Japanese government added a group of thirty-three drugs to its list of controlled substances, including salvinorin A. The drugs are banned under a revised

<sup>3</sup> <http://www.tga.gov.au/ndpsc/record/rr200111.pdf>

<sup>4</sup> [http://www.cognitiveliberty.org/news/salvia\\_australia.htm](http://www.cognitiveliberty.org/news/salvia_australia.htm)

<sup>5</sup>

<http://eldd.emcdda.europa.eu/html.cfm/index5176EN.html?pluginMethod=eldd.shownewsdetails&id=20/12/2006BELGIUM:%20New%20substances%20controlled%20include%20mCPP%20and%20khat>

pharmaceutical law, under which persons involved in their illegal import, production, and sale, i.e. beyond medical treatment or research purposes, will be subject to up to five years imprisonment or a fine of up to five million yen.

### ***Spain***

On January 28, 2004, the Spanish Ministry of Health and Consumption issued an order prohibiting the sale of *S. divinorum*. The regulation went into effect on May 6, 2004 and only prohibits activities related to commerce. Possession and/or use are not considered to be criminal offences.

### ***Other Countries***

It is illegal to possess or sell *S. divinorum* in Croatia, Latvia, Lithuania, Poland, Romania, South Korea and Sweden. In Russia it is illegal to grow or sell *S. divinorum*, but it is legal to possess it. In Estonia, Finland, Iceland and Norway, *S. divinorum* is treated as a medicinal herb and it is illegal to import it without a relevant prescription from a doctor.

### ***United States of America***

*S. divinorum* and salvinorin A are not included in the Schedules to the United States *Controlled Substances Act* although both *S. divinorum* and salvinorin A have been added to a list of chemicals "of concern", but this has no legal implications. According to the National Institute for Drug Abuse, the Drug Enforcement Agency is considering classifying *S. divinorum* and/or salvinorin A as Schedule I drugs. This Schedule includes substances such as LSD and marijuana.

In addition, some individual states have implemented laws restricting its use, sale and/or distribution. As of July 2010, a number of states have enacted legislation placing regulatory controls on *S. divinorum* and/or salvinorin A including Delaware, Georgia, Florida, Hawaii, Illinois, Kansas, Kentucky, Maryland, Mississippi, Missouri, Nebraska, North Dakota, Ohio, Oklahoma, South Dakota, Wisconsin, Virginia, California, Louisiana, Maine, North Carolina, and Tennessee. By way of example, additional details regarding the regulation of *S. divinorum* in these last five states are provided below.

#### ***California***

As of January 1, 2009, the sale or distribution of *S. divinorum* or salvinorin A, or any substance or material containing *S. divinorum* or salvinorin A, to any person under 18 years of age is a misdemeanor punishable by imprisonment in a county jail for not more than six months, a fine of no more than \$1,000, or both.

#### ***Louisiana***

In 2005, Louisiana passed a bill which prohibits the possession, production, manufacture

and distribution of a material, compound, mixture, or preparation intended for human consumption and that contains a hallucinogenic plant. A "hallucinogenic plant" is defined as "any part or portion" of a plant on a list of forty plants, which includes *S. divinorum*.

### ***Maine***

In Maine, *S. divinorum* and salvinorin A are regulated in the same way as tobacco products; adults eighteen years of age or over can legally purchase and use the material, but selling or providing *S. divinorum* or salvinorin A to anyone under the age of eighteen is a criminal offence. Possession by a minor is a civil violation, punishable by a fine, community service, or both.

### ***North Carolina***

On December 1, 2009, the North Carolina State Legislature brought a new law into force which made *S. divinorum* and salvinorin A illegal. The only legal *S. divinorum* activities are the growing for aesthetic, landscaping, or decorative purposes or university-affiliated medical or pharmacological research.

### ***Tennessee***

On July 1, 2006, Tennessee classified the deliberate production, manufacture, distribution, or possession of the active chemical ingredient in the hallucinogenic plant *S. divinorum* as a Class A misdemeanor. It is not, however, a criminal offence to possess, plant, cultivate, grow, or harvest *S. divinorum* for aesthetic, landscaping, or decorative purposes. The law also does not apply to any dosage that is legally obtainable from a retail establishment without a prescription when (and if) it is recognized by the Food and Drug Administration as a homeopathic drug.

## **4.2.2 Chemical and/or Pharmacological Similarity to Substances Listed in the Schedules to the CDSA**

The psychoactive ingredient in *S. divinorum* is the neoclerodane diterpene salvinorin A.<sup>6</sup> Another plant which contains psychotropic terpenoids is *Artemisia absinthium* (wormwood).<sup>7</sup> Salvinorin A is a hallucinogen with a distinct structure and it does not interact with the serotonin type-2A receptor or any other molecular target of classical hallucinogens.<sup>8</sup> Instead, the available research suggests that the psychotropic effects of salvinorin A are mediated by its agonistic actions at the

<sup>6</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage *Salvia divinorum*. *Life Sci.* 2005 Dec 22;78(5):527-31.

<sup>7</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.

$\kappa$ -opioid (KOR) receptor.<sup>9</sup> Its mechanism of action is therefore unique.<sup>10</sup>

The psychoactive effects of *S. divinorum* vary in onset and duration and include perceptual distortions such as the sensation of becoming an object, having visions of various two-dimensional surfaces, films and membranes, revisiting places of the past (particularly childhood), perceived loss of the body and/or identity, various sensations of motion (being pulled or twisted by a force of some kind), uncontrollable hysterical laughter, and overlapping realities (perceptions of being in more than one place).<sup>11</sup> Laughter, happiness, a sense of well-being and dissociative effects were deemed the most positive aspects of *S. divinorum* by users, second only to the "trip" that the drug elicits.<sup>12</sup> Depersonalization, speaking gibberish, widening of consciousness and subjective illusions of rapid movement, flying or hovering have also been reported.<sup>13</sup>

The psychotomimetic effects of *S. divinorum* closely resemble the schizoid symptoms induced by lysergic acid diethylamide (LSD) or phencyclidine (PCP).<sup>14</sup> Yet, it is said to have only a weak influence on the prevailing mood of the user which differentiates it from other hallucinogens such as LSD and psilocybin.<sup>15</sup> Its strong dissociative effects are often compared to those of ketamine.<sup>16</sup> Users have reported that the psychedelic effects of *S. divinorum* were most similar to those caused by psilocybin mushrooms.<sup>17</sup> However, users familiar with the effects of other hallucinogens agree that despite certain similarities to classical hallucinogens, the visions and overall experience are quite unique.<sup>18</sup>

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<sup>9</sup> Roth BL, Baner K, Westkaemper R, Siebert D, Rice KC, Steinberg S, Ernsberger P, Rothman RB. Salvinorin A: a potent naturally occurring nonnitrogenous kappa opioid selective agonist. Proc Natl Acad Sci U S A. 2002 Sep 3;99(18):11934-9.

<sup>10</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>11</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>12</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>13</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5 and Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>14</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5.

<sup>15</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>16</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five Salvia divinorum herbal products. Pharmacotherapy. 2006 Sep;26(9):1268-72.

<sup>17</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>18</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6 and González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

*S. divinorum* causes an unusually high degree of sedation, weakness and fatigue, and the increased de-realization is not commonly reported for classical psychedelics.<sup>19</sup> The combination of these effects seems to correlate with that of other KOR agonists such as pentazocine.<sup>20</sup>

The onset and intensity of the effects of *S. divinorum* appear to be related to the route of administration. Traditional uses generally produce mild effects because the leaves are rolled and chewed or crushed and prepared as a foamy infusion whereby the salvinorin A is degraded in the gastrointestinal system before being absorbed into the bloodstream. Hence, the level of effect relates quite closely to the length of time the material spends in the mouth, with the onset of effect generally taking 5-10 minutes. The effects build over the next hour and last for another hour before they begin to subside.<sup>21</sup>

Routes of administration that avoid the hepatic first-pass effect (i.e. inhalation, intravenous, intramuscular and sublingual use) provide the quickest and most intense effect.<sup>22</sup> Salvinorin A can be isolated from the plant to make a powder which can be vaporized and inhaled. The effects felt from vaporizing salvinorin A are experienced in about 30 seconds, last for about 5-10 minutes, and then subside over the next 30 minutes.<sup>23</sup>

Smoking the dried leaves or a concentrated extract using a pipe or bong is by far the most popular method of administration.<sup>24</sup> Dried leaves may also be fortified with a concentrated extract of salvinorin A. A concentrated extract can also be used sublingually. Neither *S. divinorum* nor salvinorin A can be injected because the powder is insoluble in water.<sup>25</sup>

#### 4.2.3 Legitimate Use of the Substance, including Therapeutic, Scientific, Industrial or Commercial Uses

*S. divinorum* has traditionally been used for spiritual and medicinal purposes by the Mazatec

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<sup>19</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>20</sup> Arasteh K, Poudevida S, Farre M, Roset PN, Cami J. Response patterns of the Spanish version of the 49-item short form of the Addiction Research Center Inventory after the use of sedatives, stimulants, and opioids. *Drug Alcohol Depend.* 1999 Jun 1;55(1-2):117-25.

<sup>21</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>22</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.

<sup>23</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>24</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62 and Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>25</sup> Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs.* 1994 Jul-Sep;26(3):277-83.

Indians in Oaxaca, Mexico.<sup>26</sup> For medicinal purposes (gastrointestinal problems, headaches, rheumatism, anemia and swelling of the stomach) an infusion of the leaves or the leaves themselves are ingested.<sup>27</sup> However, its main use in Mexico today is believed to be for its psychedelic properties in the aid of producing “mystical” or hallucinogenic experiences as part of spiritual rituals.<sup>28</sup>

Although selective KOR agonists have been shown to produce analgesic effects, adverse effects such as psychotomimesis, dysphoria and diuresis have been observed in studies investigating their therapeutic use.<sup>29</sup> In addition, while it has been speculated that KOR agonists may be useful in the treatment of certain psychiatric disorders including Alzheimer’s disease, schizophrenia, dementia and bipolar disorder, but there has been no clinical research to support these hypotheses.<sup>30</sup> That said there are presently no recognized medical uses for *S. divinorum* in Canada.

Similarly, there are no known industrial or commercial uses for *S. divinorum* in Canada. Most websites offering *S. divinorum* cuttings and seeds for sale appear to do so in the context of growing the plant for “recreational” purposes, rather than out of horticultural interest or for its esthetic appeal. However, it should be acknowledged that this does not preclude the possibility of a person growing this plant for purely decorative purposes. *S. divinorum* is also marketed as incense. However, there is no evidence that *S. divinorum* has any fragrant properties that would legitimize such a use. Therefore it is believed that the marketing of this plant as an incense is a means to avoid compliance and enforcement actions by Health Canada.

#### 4.2.4 Potential for Abuse and/or Addiction Liability

Salvinorin A is a potent, KOR-selective agonist and in contrast to the euphoria produced by MOR agonists such as morphine, KOR agonists are negatively reinforcing and aversive.<sup>31</sup> In addition, KOR agonists have analgesic properties, but are not associated with respiratory depression like MOR agonists.<sup>32</sup> Finally, while MOR agonists increase the release of dopamine,

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<sup>26</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>27</sup> Munro, T. The Chemistry of Salvia divinorum. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

<sup>28</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage Salvia divinorum. *Life Sci.* 2005 Dec 22;78(5):527-31.

<sup>29</sup> Barker RL, Fawcett J, Barkin SJ. 2002. Chronic pain management with a focus on the role of newer antidepressants and centrally acting agents. In: *Pain Management: A Practical Guide for Clinicians*, 6th edition, Weiner RS ed. CRC Press, Boca Raton, FL. pp. 415-34 and Tidgewell et al., 2004. A facile method for the preparation of deuterium labelled salvinorin A: *Bioorganic & Medicinal Chemistry Letters*, 14: 5099-5102.

<sup>30</sup> Sheffler DJ & Roth BL. Salvinorin A: the ‘magic mint’ hallucinogen finds a molecular target in the kappa opioid receptor. *Trends Pharmacol Sci.* 2003 Mar;24(3):107-109.

<sup>31</sup> Killinger BA, Peet MM, Baker LE. Salvinorin A fails to substitute for the discriminative stimulus effects of LSD or ketamine in Sprague–Dawley rats. *Pharmacology, Biochemistry & Behaviour.* 2010 May 96; 260-265.

<sup>32</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman’s The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.

the activation of KOR decreases dopamine release in the nucleus accumbens.<sup>33</sup> In the case of MOR agonists, the increase of dopamine acts as a positive reinforcer. This action motivates the user to use the drug again, which could lead to drug abuse and/or addiction. For KOR agonists, this is not the case.

The aversive effects of KOR agonists suggest that the risk of addiction to *S. divinorum* is negligible. Users have reported the negative effects of *S. divinorum* as: the short duration of action, lack of control over the experience, persisting negative effects (most often anxiety),<sup>34</sup> sweating, chills, increased diuresis, impaired vigilance,<sup>35</sup> and negative after-effects including tiredness, feeling head heavy, dizziness, physical exhaustion, and some degree of malaise or 'hangover' as they 'comedown' from the drug.<sup>36</sup> Despite these reports, very few controlled scientific studies of the physical and psychotropic effects of *S. divinorum* on humans have been carried out and the results have been conflicting. For example, one author states: "Many who have used salvinorin A find the experience extremely unnerving, frightening and overly intense and most have no desire to repeat the experience."<sup>37</sup> However, another study suggested that this is not the experience of all recreational users of *S. divinorum*.<sup>38</sup> Over eighty percent of users surveyed on a web-based questionnaire about their *S. divinorum* use said that they would probably or definitely use *S. divinorum* again.<sup>39</sup>

In addition, some users have noted that they require increasing doses of salvinorin A in order to achieve the desired effect and the stimulated cerebral KOR may act as a mechanism of tolerance.<sup>40</sup> Therefore, it is difficult to predict with certainty its potential for addiction and abuse. In studies that have been conducted, there is conflicting information around the addiction liability of *S. divinorum* in both animals and humans. Further studies in this area and on the

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<sup>33</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.

<sup>34</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>35</sup> Bücheler R, Gleiter CH, Schworerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>36</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>37</sup> Turner DM. *Salvinorin - The Psychedelic Essence of Salvia Divinorum*. Panther Press, San Francisco, CA 1996.

<sup>38</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62, Bücheler R, Gleiter CH, Schworerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5, and Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs*. 1994 Jul-Sep;26(3):277-83.

<sup>39</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>40</sup> Bücheler R, Gleiter CH, Schworerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

KOR mediated decrease of dopamine are also required in order to fully understand the addiction potential of this substance.

While concerns for the potential of abuse were initially considered minimal given that 1 kg of dried leaves only yield 3 to 6 human doses of salvinorin A for oral consumption, it was then discovered that vaporizing and inhaling 200-500 micrograms had profound hallucinogenic effects.<sup>41</sup> Given that only small doses of this substance are now necessary to achieve the desired effects through inhalation, the potential for abuse is much higher. Also, the extraction of salvinorin A from the plant is simple, and with care, approximately 1.5 grams of pure salvinorin A per kilogram of dried leaves (8kg of fresh leaves) can be isolated. This is enough for 2000 oral doses.<sup>42</sup>

#### 4.2.5 Evidence of Extent of Actual Abuse of the Substance in Canada and Internationally

In Canada, the prevalence of use of *S. divinorum* has recently been documented. Questions about the use of salvia were included in the 2009 Ontario Student Drug Use and Health Survey, the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey. In some cases it is not clear if responses indicate the use of *S. divinorum* or salvinorin A given the use of the term "salvia".

The results from the 2009 Ontario Student Drug Use and Health Survey were published on November 18, 2009 and indicate that:

- Among all responding students in Ontario, 4.4% reported using *S. divinorum* at least once in the past year. In comparison, 58.2% indicated they had used alcohol, 25.6% indicated they had used cannabis and 5.0% indicated they had used hallucinogens other than LSD and PCP in the past year;
- Males (6.2%) were significantly more likely than females (2.3%) to report using *S. divinorum*;
- There is significant grade variation, with *S. divinorum* use most likely among 11<sup>th</sup> graders (8.6%) and 12<sup>th</sup> graders (8.4%); and

The results of the 2008-2009 Youth Smoking Survey were published on May 31, 2010 and indicate that:

- 4.9% of students stated that they had used salvia in the last twelve months. In comparison, 53.0% indicated they had used alcohol, 27.3% indicated they had used cannabis and 6.9% indicated they had used other hallucinogens in the last twelve months;

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<sup>41</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>42</sup> Valdès LJ 3rd. Salvia divinorum and the unique diterpene hallucinogen, Salvinorin (divinorin) A. J Psychoactive Drugs. 1994 Jul-Sep;26(3):277-83.



- 2.6% of students in Grades 7-9 and 7.0% of students in Grades 10-12 had used salvia in the last twelve months; and
- Males (6.6%) were more likely to have used salvia in the past twelve months compared to females (3.2%).

The Canadian Alcohol and Drug Use Monitoring Survey specifically examined salvia for the first time in 2009. An estimated 1.6% of Canadians, aged 15 years and older, reported that they had used salvia in their lifetime, and 0.2% reported using it in the past-year. In comparison, the prevalence of past-year cannabis use among Canadians 15 years of age and older was 10.6%, while 1.2% of respondents reported using cocaine or crack in the past 12 months, 0.9% ecstasy and 0.7% illicit hallucinogens. Salvia appears however to be a substance that is tried largely by youth with a 7.3% prevalence of lifetime use.

According to the 2009 Monitoring the Future survey, annual prevalence of use of *S. divinorum* among 12th graders in the United States is 5.7%. The American Substance Abuse and Mental Health Services Administration's 2006 National Survey on Drug Use and Health found that, of respondents aged 12 or older, 1.8 million had used *S. divinorum* at least once in their lifetime and 756,000 had used the substance in the past year. Among youth aged 12 to 17, males were more likely than females to have used *S. divinorum* in the past year (0.9% vs. 0.3%).

Health Canada's Drug Analysis Services (DAS) has identified salvinorin A in a number of samples seized by law enforcement, ranging from 9 samples in 2006 to 20 samples in 2009. It is, however, difficult to determine how this data reflects the extent of actual abuse of salvinorin A in Canada, given that it is not an illegal substance and would likely only be seized accidentally or during the seizure of other illicit substances.

The National Forensic Laboratory Information System (NFLIS) and the System to Retrieve Information from Drug Evidence (STRIDE) in the United States are Drug Enforcement Agency (DEA) databases that collect scientifically verified data on analyzed samples in state and local forensic labs as well as samples from DEA labs. While in 2000 no seized samples were found to contain *S. divinorum* or salvinorin A, 70 samples tested positive in 2008. Once again, it is difficult to determine how this data can be used to reflect the actual extent of abuse of *S. divinorum* and salvinorin A in the United States as both these substances are not listed in the *Controlled Substances Act*.

The increase in both the number of enquiries to Health Canada from various municipalities and members of the public and the amount of media interest regarding the availability of *S. divinorum* in Canada may be an indication that the recreational use of *S. divinorum* as a hallucinogen is on the rise. However, it may only reflect an increased awareness of the phenomenon.

#### **4.2.6 Risk to Personal and Public Health and Safety**

The potential for harm to the user and/or other individuals is primarily related to the hallucinogenic properties of the substance. As this substance is typically smoked, there is no risk of infectious disease transmission as is the case when a drug is injected. Users may get up and

walk around without apparent awareness of their movements, behaviour or surroundings, and distinction between self and surroundings is often lost. At doses greater than 1mg of salvinorin A, out of body experiences are frequent and loss of consciousness has been reported.<sup>43</sup> There is little information regarding the social behaviours of persons under the influence of *S. divinorum* products, and what risks their activities such as operating a motorized vehicle may pose to the general public. There is also very little data regarding the toxicity, teratogenicity or other long-term effects of *S. divinorum* use.<sup>44</sup>

As far as law enforcement is concerned, the Department has only received a limited number of communications indicating concern with respect to *S. divinorum*. The Royal Canadian Mounted Police (RCMP) has stated that while *S. divinorum* is readily available, it has not become a popular drug in Canada, probably due to its aversive effects such as anxiety and introversion.

A handful of case reports regarding physiological and psychotropic effects of *S. divinorum* use have been published in the scientific/medical literature. For example, an international case report described the perceptions of a 19 year-old man after inhaling *S. divinorum* smoke. The peak psychotropic effects, including prickling of the skin, fever-like hot flashes, muscular tremor, and depersonalization, were reached in less than five minutes after inhalation of an unknown amount of smoke from burning dried leaves.<sup>45</sup> Another report involved a 15-year-old male who presented to psychiatric emergency services with acute onset of paranoia, déjà vu, blunted affect, difficulties in thought processing and slowed speech after smoking *S. divinorum* over an unknown period of time. During his hospitalization all symptoms improved significantly except the feeling of déjà vu. Based on this case presentation, the author suggested that the feelings of déjà vu may be a long-term effect of *S. divinorum* use.<sup>46</sup> However, given that this is the only case report in which déjà vu was associated with the use of *S. divinorum*, more reports are needed to substantiate this finding.

In addition to the above-mentioned reports, in 2006, a case was reported in the U.S. in which a 17-year-old boy committed suicide after smoking *S. divinorum* for an unknown period of time.<sup>47</sup> It should be noted that alcohol and general depression were the main confounders in this case. After this case was reported, the state of Delaware passed a law which classified *S. divinorum* as a Schedule I controlled substance along with other hallucinogenic substances.

Like many drugs of abuse, users are often unaware of the potency and adulterants in the product they purchase. A study by Wolowich *et al.* (2006), showed that the salvinorin A content in five out of five *S. divinorum* products was falsely indicated on the label and 4 out of 5 products contained unidentified adulterants (i.e. vitamin E, caffeine).<sup>48</sup>

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<sup>43</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>44</sup> Grundmann O, Phipps SM, Zadezensky I, Butterweck V. *Salvia divinorum* and Salvinorin A: An Update on Pharmacology and Analytical Methodology. *Planta Med* 2007 Jun;73:1039-1046.

<sup>46</sup> Singh S. (2007) Adolescent salvia substance abuse. *Addiction.* 102, 823-824.

<sup>47</sup> <http://www.kvbc.com/Global/story.asp?S=4893692>

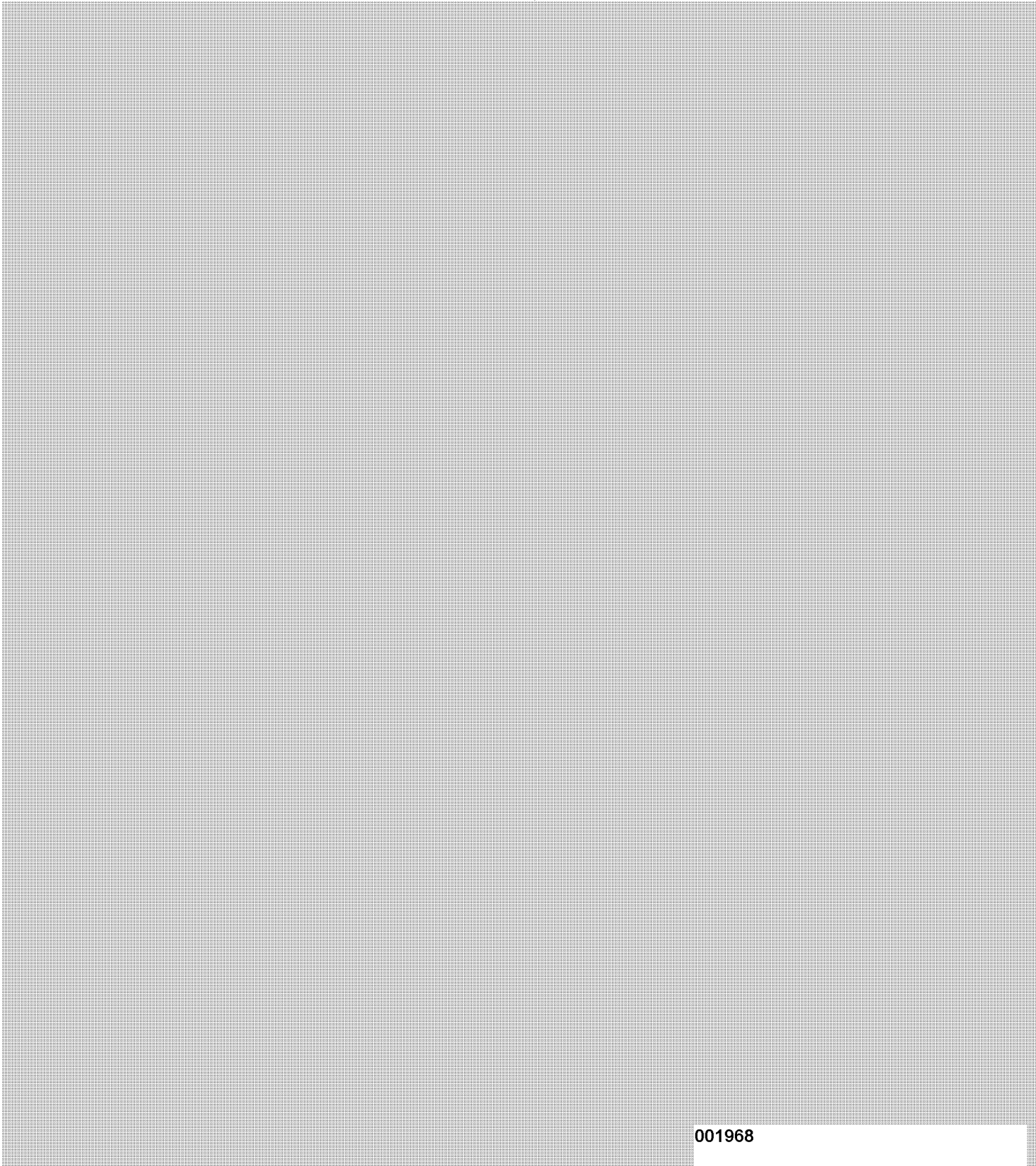
<sup>48</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.

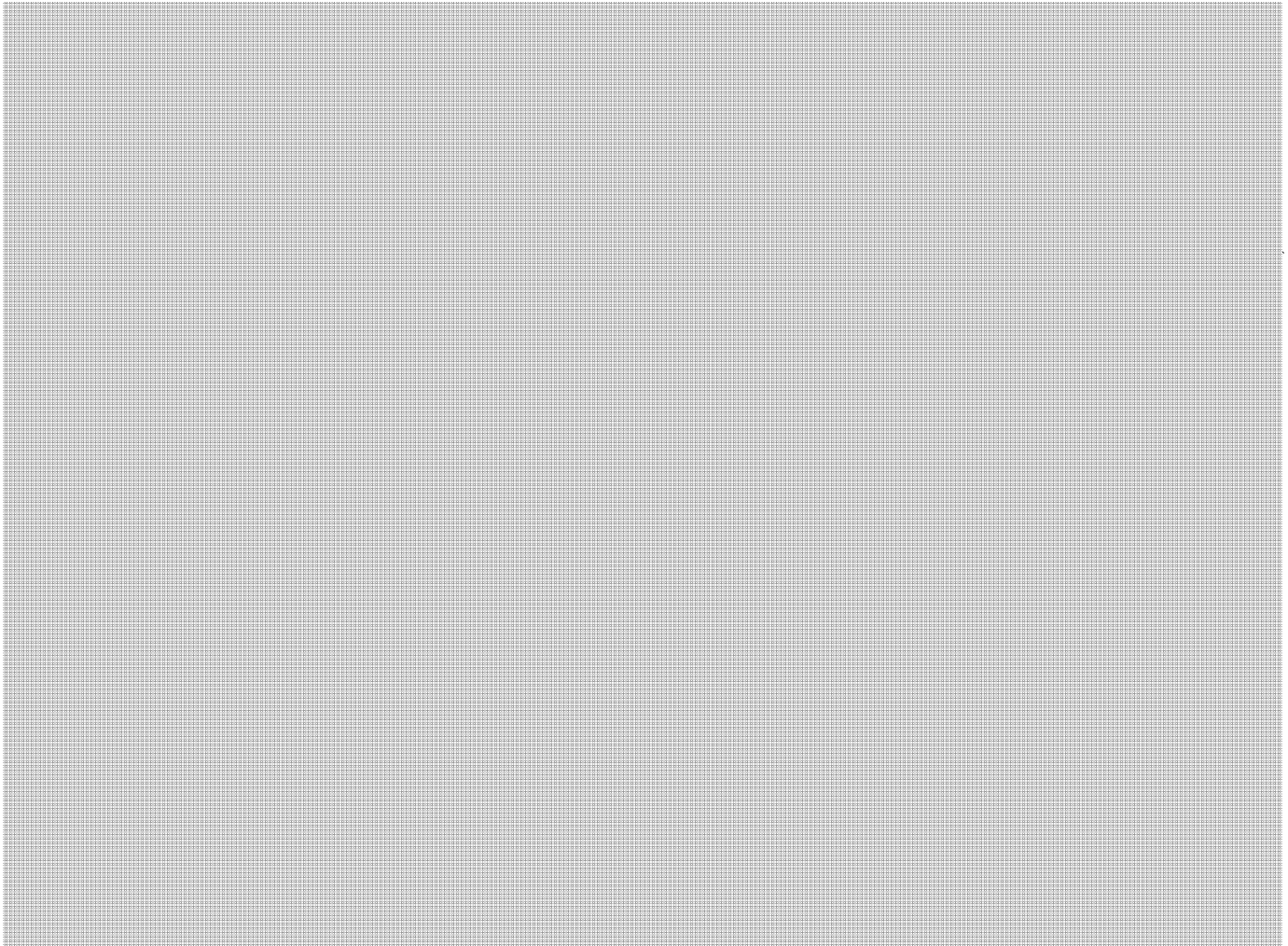
**s.21(1)(a)**

**s.21(1)(b)**

There are also several reports of domestic adverse reactions related to the use of *S. divinorum* that have been received through the Canada Vigilance database. However, this does not reflect true incidence due to under-reporting.

**5. ASSESSMENT OF RISKS AND BENEFITS**





## 7. CONSIDERATIONS

The NHPR are limited in their capacity to control the availability of *S. divinorum* in that *S. divinorum* products are often declared as incense and therefore cannot be considered unapproved natural health products. In addition, compliance and enforcement actions such as voluntary stop-sales, forfeiture, destruction, and administrative seizure, cannot be implemented unless the marketing of the product indicates that it is to be sold for human consumption in order to modify an organic function. Unlicensed natural health products are also permitted to be imported provided they are for personal use only.

Non-regulatory options for the control of *S. divinorum*, such as the development of an educational campaign to highlight the risks associated with using this plant, were also considered. However, the risks associated with this substance, as well as the confusion concerning its enforcement as a natural health product only when it is sold for use with a health claim, do not make this option viable.

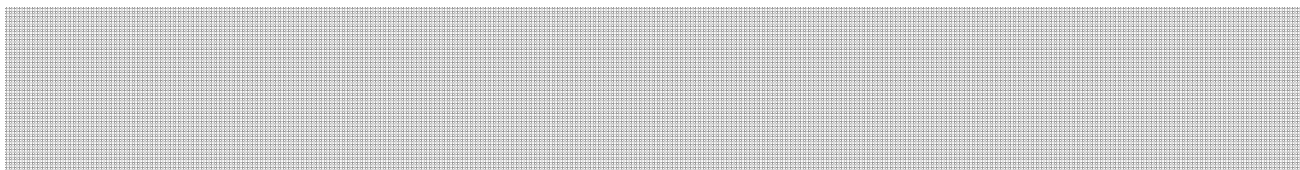
*S. divinorum* meets the criteria for scheduling a substance under the CDSA. While neither the plant nor its main active component salvinorin A are scheduled under any of the UN Drug Control Conventions, a number of countries and American states have taken steps to control the distribution and use of these substances. *S. divinorum* and salvinorin A are pharmacologically similar to other substances included in Schedule III to the CDSA, such as LSD and psilocybin.

There are also currently no legitimate therapeutic, commercial or industrial uses for *S. divinorum*. While the addiction potential of *S. divinorum* appears to be low, there is a significant potential for its abuse as a 'legal' hallucinogen. There is very little information with regards to the long-term effects of *S. divinorum* use. There is also evidence of abuse, particularly by Canadian youth and potential for individual health risks as well as risks to public health and safety.

In light of a recommendation to include *S. divinorum* under Schedule III to the CDSA, it is also recommended that the main psychoactive ingredient of this plant, salvinorin A, be scheduled. Salvinorin A can easily be extracted from *S. divinorum* and this substance gives the plant its hallucinogenic properties. Therefore salvinorin A results in the same risks as *S. divinorum* and should also be controlled under the CDSA in the same manner as *S. divinorum*.

s.21(1)(a)  
s.21(1)(b)

## 8. RECOMMENDATIONS



## 9. CONSULTATIONS

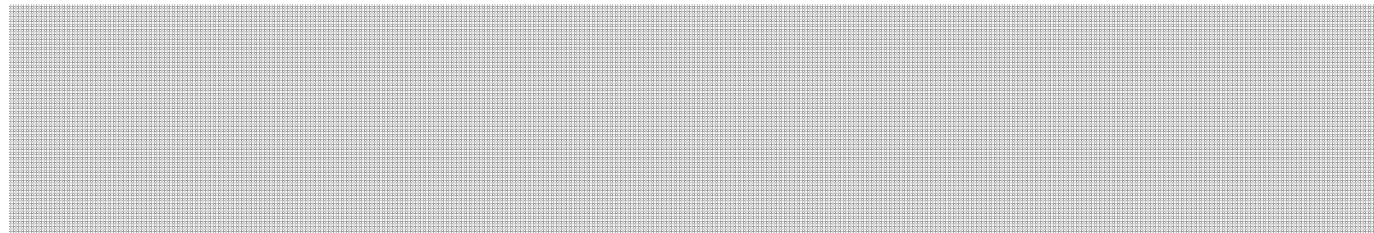
The Drug Analysis Services (DAS) was contacted in order to provide any data available regarding the identification of salvinorin A in samples submitted by law enforcement.

The Royal Canadian Mounted Police (RCMP) was contacted in order to establish their views with respect to *S. divinorum* use in Canada. The RCMP advised that *S. divinorum* is readily available and law enforcement agencies have no legal means to prevent its sale.

OCS has received a number of correspondences from Canada Border Services Agency (CBSA) officers concerning a lack of information regarding the status of *S. divinorum* and how the plant should be treated at the border. CBSA officers have also expressed concern regarding the plant's hallucinogenic properties. At present, only shipments of *S. divinorum* that are represented for sale as health products that modify organic functions can be refused for import under the NHPR.

OCS brought *S. divinorum* to the Controlled Substances Scheduling Working Group (CSS-WG) in August 2010 to discuss the possibility of regulatory control of this substance. After assessing the available information against the six criteria listed in the Context section of this Issue Analysis Summary, the CSS-WG recommended that *S. divinorum* be included under Schedule III to the CDSA.

## 10. IMPLEMENTATION AND EVALUATION

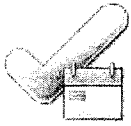


**Page(s) 001971 to\à 001971**

**Is(Are) exempted pursuant to section(s)  
est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**



**Salvia D**

**2010-12-15 Wed 2:30 PM - 3:00  
PM**

Attendance is **required** for Denis Arsenault

Chair: Cathy A Sabiston/HC-SC/GC/CA

Sent By: Cyndi Vaughan/HC-SC/GC/CA

Location: Cathy's Office

Required:

Denis Arsenault/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Stephanie  
Szick/HC-SC/GC/CA@HWC

**Description**

Please bring Media Lines, NOI and QP note.

Thank you

**Personal Notes**



**Re: Fw: Media Summary/Sommaire des médias December 15 2010** 

Jocelyn Kula to: Robin Marles

2010-12-15 11:43 AM

Robert Leitch, Allison Lui, David Cunningham, Helene Lacourciere,  
Cc: Kevin Bernardo, Laura Francis-Lamb, Lisa MacKay, Mano Murty,  
Melinda Lee Choon, Sarah Chippure, Scott Jordan, Shahid Perwaiz,  
Stephanie Jack, Denis Arseneault, Stephanie Chandler

From: Jocelyn Kula/HC-SC/GC/CA

To: Robin Marles/HC-SC/GC/CA@HWC

Cc: Robert Leitch/HC-SC/GC/CA@HWC, Allison Lui/HC-SC/GC/CA@HWC, David  
Cunningham/HC-SC/GC/CA@HWC, Helene Lacourciere/HC-SC/GC/CA@HWC, Kevin  
Bernardo/HC-SC/GC/CA@HWC, Laura Francis-Lamb/HC-SC/GC/CA@HWC, Lisa  
MacKay/HC-SC/GC/CA@HWC, Mano Murty/HC-SC/GC/CA@HWC, Melinda Lee  
Choon/HC-SC/GC/CA@HWC, Sarah Chippure/HC-SC/GC/CA@HWC, Scott  
Jordan/HC-SC/GC/CA@HWC, Shahid Perwaiz/HC-SC/GC/CA@HWC, Stephanie  
Jack/HC-SC/GC/CA@HWC, Denis Arseneault/HC-SC/GC/CA@HWC, Stephanie  
Chandler/HC-SC/GC/CA@HWC

Thanks Robin,

For everyone's information, OCS has recently completed its scheduling assessment on Salvia and Salvinorin A, and a final decision as to recommended next steps is with our DG right now. I should be able to provide more info in the coming weeks.

Jocelyn

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Jocelyn Kula

Acting Director/ Directrice par intérim

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs

Health Canada/ Santé Canada

Tel: (613) 952-2177 Fax: (613) 946-4224

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Robin Marles

At this time, Salvia divinorum is classified as an...

2010-12-15 09:33:25 AM

From: Robin Marles/HC-SC/GC/CA

To: Robert Leitch/HC-SC/GC/CA@HWC

Cc: Allison Lui/HC-SC/GC/CA@HWC, David Cunningham/HC-SC/GC/CA@HWC, Helene  
Lacourciere/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Kevin  
Bernardo/HC-SC/GC/CA@HWC, Laura Francis-Lamb/HC-SC/GC/CA@HWC, Lisa  
MacKay/HC-SC/GC/CA@HWC, Mano Murty/HC-SC/GC/CA@HWC, Melinda Lee  
Choon/HC-SC/GC/CA@HWC, Robert Leitch/HC-SC/GC/CA@HWC, Sarah  
Chippure/HC-SC/GC/CA@HWC, Scott Jordan/HC-SC/GC/CA@HWC, Shahid  
Perwaiz/HC-SC/GC/CA@HWC, Stephanie Jack/HC-SC/GC/CA@HWC

Date: 2010-12-15 09:33 AM

Subject: Re: Fw: Media Summary/Sommaire des médias December 15 2010

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At this time, Salvia divinorum is classified as an NHP when manufactured, sold or represented for use for modifying organic functions, e.g. as a hallucinogen. The Office of Controlled Substances will provide further input as they deem appropriate.

Robin



Robert Leitch

Salvia, made popular by Miley Cyrus video, sold...

2010-12-15 09:27:05 AM

From: Robert Leitch/HC-SC/GC/CA  
To: Allison Lui/HC-SC/GC/CA@HWC, Kevin Bernardo/HC-SC/GC/CA@HWC, Melinda Lee Choon/HC-SC/GC/CA@HWC, Robert Leitch/HC-SC/GC/CA@HWC, Sarah Chippure/HC-SC/GC/CA@HWC, Scott Jordan/HC-SC/GC/CA@HWC, Shahid Perwaiz/HC-SC/GC/CA@HWC, Stephanie Jack/HC-SC/GC/CA@HWC, David Cunningham/HC-SC/GC/CA@HWC, Helene Lacourciere/HC-SC/GC/CA@HWC, Mano Murty/HC-SC/GC/CA@HWC, Laura Francis-Lamb/HC-SC/GC/CA@HWC, Robin Marles/HC-SC/GC/CA@HWC, Lisa MacKay/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC  
Date: 2010-12-15 09:27 AM  
Subject: Fw: Media Summary/Sommaire des médias December 15 2010

- Salvia, made popular by Miley Cyrus video, sold legally in Vancouver; Hallucinogenic plant legal in Canada; 15 U.S. states have banned it
- Nutmeg can be more than a spice in your cupboard; Abuse on rise! Some people use nutmeg to get high
- Flat Stomach Concept Extra recalled; MAY POSE SERIOUS HEALTH RISK: HEALTH CANADA

Any progress on the Salvia file?

Robert Leitch, M.Sc., M.Eng.

Associate Director / Directeur Associé  
Marketed Biologicals, Biotechnology and Natural Health Products Bureau (MBBNHPB) /  
Bureau des Produits Biologiques, Biotechnologiques et de Santé Naturels Commercialisés  
Marketed Health Products Directorate - (MHPD) / Direction des produits de santé commercialisés -  
(DPSC)  
Rm 2203, HPB, 200 Tunney's Pasture Driveway / Pièce 2203, 200 promenade Tunney's Pasture  
Ottawa, Ontario K1A 0K9 AL 0702A

Tel: 613.960.9759 Fax: 613.954.2354

----- Forwarded by Robert Leitch/HC-SC/GC/CA on 2010-12-15 09:22 AM -----

From: Bernice Wayboda/HC-SC/GC/CA  
To:  
Cc: Bernice Wayboda/HC-SC/GC/CA@HWC, ECD Personnel DCHG  
Date: 2010-12-15 08:24 AM  
Subject: Media Summary/Sommaire des médias December 15 2010

## Wednesday, December 15, 2010

- ONTARIO TOLD TO PAY FOR U.S. SURGERY; Three-day wait in Toronto; 'urgent' care in Buffalo
- Province won't fund drug for man with rare form of kidney cancer
- 'We are taking a stand'



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**IDNUMBER:** 201012150018  
**DOCID:** 100313884  
**PUBLICATION:** Vancouver Sun  
**PAGE:** A9  
**DATE:** 2010.12.15  
**SECTION:** Westcoast News  
**EDITION:** Final  
**BYLINE:** Randy Shore  
**SOURCE:** Vancouver Sun  
 Colour Photo: Mark Van Manen, Vancouver Sun /  
**ILLUSTRATION:** Rebecca Ambrose with several Salvia plants at the Seed Bank in east Vancouver.;  
**WORD COUNT:** 353  
**CIRCULATION:** 169307

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## Salvia, made popular by Miley Cyrus video, sold legally in Vancouver; Hallucinogenic plant legal in Canada; 15 U.S. states have banned it

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The drug Salvia divinorum, made famous in the viral You-Tube video in which pop star Miley Cyrus smokes a bong, has been sold quietly for at least the past 10 years in Vancouver.

Fox News and other agencies are reporting that sales of the drug have tripled in some U.S. states, such as California, where people are specifically asking for "the stuff Miley was **smoking.**"

But Vancouver Seed Bank owner Rebecca Ambrose says Salvia has long had a following of perhaps a few hundred people locally.

"People come in fairly steadily asking about it and the effects from it, but we haven't seen a big influx," Ambrose said. The East Hastings shop sells live cuttings and a concentrated form. "We sell out of it quite regularly."

"A wide range of people are interested in its psychedelic effects and don't want to be out of it for a long time," she said. "It's not like mushrooms or LSD where you are in for an eight-hour journey. In its extract form, Salvia causes an intense hallucinogenic effect for about 15 minutes."

The drug is widely available on the Internet in both Canada and the United States as a dried leaf, a tobacco-like form fortified to enhance its potency, an alcohol-based tincture and a nearly pure crystalline form, used mainly for research purposes.

Salvia, made popular by Miley Cyrus video, sold legally in Vancouver; Hallucinogenic pl... Page 2 of 2

The leaves of the plant have been used for centuries by Mazatec Indians in Oaxaca, Mexico, mainly by shamans seeking to induce visions.

A powerful hallucinogen in its concentrated form, the plant and its derivatives are completely legal in Canada, according to the RCMP. Fifteen U.S. states have banned it.

Cyrus was videotaped **smoking** the herb from a glass pipe known as a bong on her 18th birthday. She begins to laugh hysterically and is heard to say: "Omigod, I'm having a bit of a bad trip."

"I always recommend that people do it with someone who won't be **smoking** it so you have someone there to make you feel secure," said Ambrose. "You do for 15 minutes lose all sense of time and space."

rshore@vancouver.sun.com Blog:  
vancouver.sun.com/randyshoretwitter.com/thegreenmanblog

Updated: 2002-08-15

▲ This site hosted by  
Densan Consultants Ltd/Ltée.



**Re: Urgent - Media Inquiry - Salvia (RCMP)** 

Christine Roush to: Jocelyn Kula

2010-12-15 10:37 AM

Cc: Stephanie Chandler, Nicole Prentice

History: This message has been replied to and forwarded.

Jocelyn,

Below is an email I just received from the Comms shop at the RCMP who have received a media inquiry about Salvia. Could you please take a look at their suggested response and let me know as soon as possible if you are OK with it. As well, we really need to get our new Salvia media lines approved as quickly as possible, as Salvia has been in the news quite a bit in the last week. I believe they are currently with Cathy. Is there anything you can do to facilitate her approval so we can keep these moving and have them fully approved before Christmas?

\*\*\*\*\*

Hi Christine...as I suspected, we've received a media query about our stance on Salvia out in H Division (Halifax). I drafted the following brief holding lines, but would appreciate if you could advise if they're ok...I'm just learning about this substance myself. For most info, I would refer them to HC...

Many thanks,

Robin Percival

Communications Strategist/ Conseillère en stratégies de communications  
RCMP/GRC

Tel./tél. (613) 949-0574; Fax/télé. (613) 993-5454

robin.percival@rcmp-grc.gc.ca

1 attachment



Salvia - Media Lines .wpd

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
Health Canada/Santé Canada  
Tel/Tél : (613) 954-0712/Cell: (613) 219-7194  
Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca

Nicole Prentice

Thanks Jocelyn. I figured she was busy with oth...

2010-12-13 03:42:31 PM

From: Nicole Prentice/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Stephanie Chandler/HC-SC/GC/CA@HWC, Christine Roush/HC-SC/GC/CA@HWC  
Date: 2010-12-13 03:42 PM

Subject: Re: Fw: Updated Media Lines and Draft Notice of Intent for Salvia

---

Thanks Jocelyn.

I figured she was busy with other more pressing issues, however, thanks to Miley Cyrus' recent activities there has been some interest in the topic and we expect enquiries. When they come in, we will attempt to respond using previously used messaging and sent your way for review.

Get well soon.

**Nicole Prentice**

Junior Communications Officer | Agente junior des Communications  
Regulatory Communications and Media Relations Division | Division des communications réglementaires et des relations avec les médias  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la consultation et des communications  
Health Canada | Santé Canada  
Tel: 613.941.3107  
Fax: 613.948.8085

Jocelyn Kula	Hi Nicole The docs went to Cathy late last week...	2010-12-13 03:39:15 PM
Nicole Prentice	Hi again, Have you gotten anything back from...	2010-12-13 03:36:39 PM
Stephanie Chandler	Hi Nicole and Christine, Sorry you weren't cc'e...	2010-12-10 09:07:59 AM

**RCMP Media Lines - DRAFT**  
**Not for distribution**

---

**Date: December, 2010**

**Re: Salvia Divinorum**

---

**Issue:** *Salvia divinorum* is a plant with psychoactive properties which when smoked or chewed can cause a number of physical and mental effects including hallucinations and/or triggering a “high”. *Salvia divinorum* is available online and in head shops and its popularity is growing: According to the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS), about 1.6 per cent of Canadians aged 15 or older have tried salvia. For those aged 15-24, the number rises to 7.3 per cent. While several countries have placed controls on the import and/or sale of this substance, it is not currently regulated in Canada under the *Controlled Drugs and Substances Act* (CDSA) and its Regulations. Health Canada is currently assessing whether the control of *Salvia divinorum* under the CDSA is warranted. However, when products containing *Salvia divinorum* are marketed for the purposes of modifying an organic function (such as for their hallucinogenic effects) they meet the definition of a natural health product and, as such, must be authorized by Health Canada before they can be sold.

**Media Lines**

- The RCMP is aware of the presence of this substance in Canada; however, to date, it hasn't surfaced as a significant problem.
- As with any substance whose long-term effects haven't been fully documented, the RCMP is concerned about the use (and potential abuse) of *Salvia divinorum*.
- As products containing *Salvia divinorum* that are marketed for use as hallucinogens are considered natural health products, it is in contravention of the *Natural Health Products Regulations* to sell them without approval from Health Canada.

**ONLY IF ASKED:**

Q: If it's illegal to sell Salvia in Canada, why aren't the RCMP charging stores or (people) for selling (using) it here?

A: It is currently only illegal to sell Salvia products that are marketed for use as hallucinogens. Such unauthorized products may be subject to compliance and enforcement by Health Canada. Most of the products that the RCMP and Health Canada are aware of are not sold in this way. Law enforcement cannot seize *Salvia divinorum* unless it is regulated as a controlled substance under the

*Controlled Drugs and Substances Act (CDSA).*

Q: Will you be moving to make it illegal under the CDSA?

A: (Refer to Health Canada).

**Please refer all other questions on Salvia (effects, legal status, etc.) to Health Canada.**

**Updated by:** Robin Percival, Communications Strategist, Drugs and Organized Crime

**Approved by:** Supt. Eric Slinn, Dir., Drug Branch

National Communications Services  
(613)993-2999

**RCMP Media Lines - DRAFT**  
**Not for distribution**

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**Date: December, 2010**

**Re: Salvia Divinorum**

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also in  
our  
media



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**Approved by:** Supt. Eric Slinn, Dir., Drug Branch

National Communications Services  
(613)993-2999

**RCMP Media Lines - DRAFT**  
**Not for distribution**

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**Date: December, 2010**

**Re: Salvia Divinorum**

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~~It's popularity is growing. According to the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS), about 1.6 per cent of Canadians aged 15 or older have tried salvia. For those aged 15-24, the number rises to 7.3 per cent.~~

~~Products containing *salvia divinorum* are considered natural health products and, as such, must be authorized by Health Canada before they can be sold.~~

**Media Lines**

- The RCMP is aware of the presence of this substance in Canada. ~~however, to date, it hasn't surfaced as a significant problem.~~
- As with any substance whose long-term effects haven't been fully documented, the RCMP is concerned about the use (and potential abuse) of *Salvia divinorum*.
- As products containing *Salvia divinorum* ~~products~~ that are marketed for use as hallucinogens are considered natural health products, it is in contravention of the *Natural Health Products Regulations* ~~is illegal to sell them without approval from Health Canada's authorization.~~

~~As with any substance whose long-term effects haven't been fully documented, the RCMP is concerned about the use (or abuse) of Salvia.~~

**ONLY IF ASKED:**

**Q:** If it's illegal to sell Salvia in Canada, why aren't the RCMP charging stores or (people) for selling (using) it here?

**A:** It is currently only illegal to sell Salvia products that are marketed for use as hallucinogens. Such unauthorized products may be subject to compliance and enforcement by Health Canada. Most of the products that the RCMP and Health Canada are aware of are not sold in this way. Law enforcement cannot seize *Salvia divinorum* unless it is regulated as a controlled substance under the *Controlled Drugs and Substances Act* (CDSA). ~~considered natural health products which can't be sold without Health Canada's authorization. However, Salvia isn't regulated under the *Controlled Drugs and Substances Act*, which is what we enforce.~~

**Q:** Will you be moving to make it illegal under the CDSA?

**A:** (Refer to Health Canada).

**Please refer all other questions on Salvia (effects, legal status, etc.) to Health Canada.**

**Updated by:** Robin Percival, Communications Strategist, Drugs and Organized Crime

**Approved by:** Supt. Eric Slinn, Dir., Drug Branch

National Communications Services  
(613)993-2999



**Re: Urgent - Media Inquiry - Salvia (RCMP)** 

Christine Roush to: Stephanie Chandler

2010-12-15 11:04 AM

Cc: Jocelyn Kula, Nicole Prentice, Denis Arsenault

History: This message has been forwarded.

---

Thanks Stephanie - I will await your comments.

Christine Roush  
Senior Communications Advisor/

Stephanie Chandler Hi Christine, We do have some revisions to ma... 2010-12-15 11:01:07 AM

From: Stephanie Chandler/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Cc: Jocelyn Kula/HC-SC/GC/CA@HWC, Nicole Prentice/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2010-12-15 11:01 AM  
Subject: Re: Urgent - Media Inquiry - Salvia (RCMP)

---

Hi Christine,

We do have some revisions to make to the RCMP media lines that we will send to you.

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

Christine Roush Jocelyn, Below is an email I just received from t... 2010-12-15 10:37:02 AM  
1 attachment  
[attachment "Salvia - Media Lines .wpd" deleted by Christine Roush/HC-SC/GC/CA]

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
Health Canada/Santé Canada  
Tel/Tél : (613) 954-0712/Cell: (613) 219-7194  
Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca

Nicole Prentice	Thanks Jocelyn. I figured she was busy with oth...	2010-12-13 03:42:31 PM
Jocelyn Kula	Hi Nicole The docs went to Cathy late last week...	2010-12-13 03:39:15 PM
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**Fw: Urgent - Media Inquiry - Salvia (RCMP)**

Denis Arsenault to: Jocelyn Kula

Cc: Stephanie Chandler

2010-12-15 11:21 AM

---

History: This message has been replied to and forwarded.

---

Hi Jocelyn,

Attached is a revised version of the RCMP media lines with our suggested changes.

Denis

---

Denis Arsenault, A/Manager / Gestionnaire p.i.

Regulatory Policy Division /

Division des politiques réglementaires,

Office of Controlled Substances /

Bureau des substances contrôlées,

Health Canada / Santé Canada

Tel/Tél: (613) 957-6828

Fax / Télécopieur : (613) 946-4224

E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca

----- Forwarded by Denis Arsenault/HC-SC/GC/CA on 2010-12-15 11:19 AM -----

From: Stephanie Chandler/HC-SC/GC/CA  
To: Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2010-12-15 11:12 AM  
Subject: Fw: Urgent - Media Inquiry - Salvia (RCMP)

---

Hi Denis,

For your review.



Salvia - Media Lines RCMP\_SC.wpd

Stephanie Chandler

Junior Regulatory Project Officer

Regulatory Policy Division/ Division de la politique réglementaire

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs

Health Canada/ Santé Canada

Tel: (613) 946-0124, Fax: (613) 946-4224

E-Mail: stephanie.chandler@hc-sc.gc.ca

----- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2010-12-15 11:11 AM -----

From: Christine Roush/HC-SC/GC/CA  
To: Stephanie Chandler/HC-SC/GC/CA@HWC  
Cc: Jocelyn Kula/HC-SC/GC/CA@HWC, Nicole Prentice/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2010-12-15 11:04 AM  
Subject: Re: Urgent - Media Inquiry - Salvia (RCMP)

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001987

Christine Roush  
Senior Communications Advisor/

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**RCMP Media Lines - DRAFT**  
**Not for distribution**

---

**Date: December, 2010**

**Re: Salvia Divinorum**

---

**Issue:** *Salvia divinorum* is a plant with psychoactive properties which when smoked or chewed can cause a number of physical and mental effects including hallucinations and/or triggering a “high”. *Salvia divinorum* is available online and in head shops and its popularity is growing: According to the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS), about 1.6 per cent of Canadians aged 15 or older have tried salvia. For those aged 15-24, the number rises to 7.3 per cent. While several countries have placed controls on the import and/or sale of this substance, it is not currently regulated in Canada under the *Controlled Drugs and Substances Act* (CDSA) and its Regulations. Health Canada is currently assessing whether the control of *Salvia divinorum* under the CDSA is warranted. However, when products containing *Salvia divinorum* are marketed for the purposes of modifying an organic function (such as for their hallucinogenic effects) they meet the definition of a natural health product and, as such, must be authorized by Health Canada before they can be sold.

**Media Lines**

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Q: Will you be moving to make it illegal under the CDSA?

A: (Refer to Health Canada).

**Please refer all other questions on Salvia (effects, legal status, etc.) to Health Canada.**

**Updated by:** Robin Percival, Communications Strategist, Drugs and Organized Crime

**Approved by:** Supt. Eric Slinn, Dir., Drug Branch

National Communications Services  
(613)993-2999

**RCMP Media Lines - DRAFT**  
**Not for distribution**

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**Date: December, 2010**

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**Updated by:** Robin Percival, Communications Strategist, Drugs and Organized Crime

**Approved by:** Supt. Eric Slinn, Dir., Drug Branch

National Communications Services  
(613)993-2999

**RCMP Media Lines - DRAFT**  
**Not for distribution**

**Date: December, 2010**

**Re: Salvia Divinorum**

④

① **Issue:** *Salvia divinorum* is a plant with psychoactive properties which when smoked or chewed can cause a number of physical and mental effects including hallucinations and/or triggering an intense "high" and hallucinations. It is available online and in head shops, and while several countries have placed controls on the import and/or sale of this substance, now banned it, to date it is not currently regulated in Canada under the *Controlled Drugs and Substances Act* (CDSA) and its Regulations in Canada. Health Canada is currently assessing whether the control of *Salvia divinorum* under the CDSA is warranted.

② *Salvia divinorum* is available online and in head shops. However, when products containing *Salvia divinorum* are marketed for the purposes of modifying an organic function (such as for their hallucinogenic effects) they meet the definition of a natural health product and, as such, must be authorized by Health Canada before they can be sold.

⑤

③ **and** its popularity is growing: According to the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS), about 1.6 per cent of Canadians aged 15 or older have tried salvia. For those aged 15-24, the number rises to 7.3 per cent.

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- The RCMP is aware of the presence of this substance in Canada; however, to date, it hasn't surfaced as a significant problem.
- As with any substance whose long-term effects haven't been fully documented, the RCMP is concerned about the use (and potential abuse) of *Salvia divinorum*.
- As products containing *Salvia divinorum* products that are marketed for use as hallucinogens are considered natural health products, it is in contravention of the *Natural Health Products Regulations* is illegal to sell them without approval from Health Canada's authorization.
- ~~• As with any substance whose long-term effects haven't been fully documented, the RCMP is concerned about the use (or abuse) of Salvia.~~

**ONLY IF ASKED:**

**Q:** If it's illegal to sell Salvia in Canada, why aren't the RCMP charging stores or (people) for selling (using) it here?

**A:** It is currently only illegal to sell Salvia products that are marketed for use as hallucinogens. Such unauthorized products may be subject to compliance and enforcement by Health Canada. Most of the products that the RCMP and Health Canada are aware of are not sold in this way. Law enforcement cannot seize *Salvia divinorum* unless it is regulated as a controlled substance under the *Controlled Drugs and Substances Act* (CDSA). ~~considered natural health products which can't be sold without Health Canada's authorization.~~ However, Salvia isn't regulated under the *Controlled Drugs and Substances Act*, which is what we enforce.

**Q:** Will you be moving to make it illegal under the CDSA?

**A:** (Refer to Health Canada).

**Please refer all other questions on Salvia (effects, legal status, etc.) to Health Canada.**

**Updated by:** Robin Percival, Communications Strategist, Drugs and Organized Crime

**Approved by:** Supt. Eric Slinn, Dir., Drug Branch

National Communications Services  
(613)993-2999

**RCMP Media Lines - DRAFT**  
**Not for distribution**

**Date: December, 2010**

**Re: Salvia Divinorum**

**Issue:** *Salvia divinorum* is a plant with psychoactive properties which when smoked or chewed can cause a number of physical and mental effects including ~~triggering an intense high and/or hallucinations. It is available online and in head shops, and while several countries have placed controls on the import and/or sale of this substance, now banned it, to date it is not currently regulated in Canada under the Controlled Drugs and Substances Act (CDSA) and its Regulations in Canada.~~ Health Canada is currently assessing whether the control of *Salvia divinorum* under the CDSA is warranted.

and/or triggering "high"

*Salvia divinorum* is available online and in head shops. However, when products containing *Salvia divinorum* are marketed for the purposes of modifying an organic function (such as for their hallucinogenic effects) they meet the definition of a natural health product and, as such, must be authorized by Health Canada before they can be sold.

It's popularity is growing: According to the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS), about 1.6 per cent of Canadians aged 15 or older have tried salvia. For those aged 15-24, the number rises to 7.3 per cent.

~~Products containing salvia divinorum are considered natural health products and, as such, must be authorized by Health Canada before they can be sold.~~

**Media Lines**

- The RCMP is aware of the presence of this substance in Canada; however, to date, it hasn't surfaced as a significant problem.
- As with any substance whose long-term effects haven't been fully documented, the RCMP is concerned about the use (and potential abuse) of *Salvia divinorum*.
- As products containing *Salvia divinorum* ~~products~~ that are marketed for use as hallucinogens are considered natural health products, it is in contravention of the *Natural Health Products Regulations* ~~is illegal~~ to sell them without approval from Health Canada's authorization.
- ~~• As with any substance whose long-term effects haven't been fully documented, the RCMP is concerned about the use (or abuse) of Salvia.~~

**ONLY IF ASKED:**

Q: If it's illegal to sell Salvia in Canada, why aren't the RCMP charging stores or (people) for selling (using) it here?

A: It is currently only illegal to sell Salvia products that are marketed for use as hallucinogens. Such unauthorized products may be subject to compliance and enforcement by Health Canada. Most of the products that the RCMP and Health Canada are aware of are not sold in this way. Law enforcement cannot seize *Salvia divinorum* unless it is regulated as a controlled substance under the *Controlled Drugs and Substances Act* (CDSA). ~~considered natural health products which can't be sold without Health Canada's authorization. However, Salvia isn't regulated under the *Controlled Drugs and Substances Act*, which is what we enforce.~~

Q: Will you be moving to make it illegal under the CDSA?

A: (Refer to Health Canada).

**Please refer all other questions on Salvia (effects, legal status, etc.) to Health Canada.**

**Updated by:** Robin Percival, Communications Strategist, Drugs and Organized Crime

**Approved by:** Supt. Eric Slinn, Dir., Drug Branch

National Communications Services  
(613)993-2999

RCMP Media Lines - DRAFT  
Not for distribution

Date: December, 2010

Re: Salvia Divinorum

is this consistent with our lines  
didn't think we used

Issue: *Salvia divinorum* is a plant with psychoactive properties which when smoked or chewed can trigger an intense high and hallucinations. It is available online and in head shops, and while several countries have now banned it, to date it is not regulated in Canada under the *Controlled Drugs and Substances Act* and its Regulations in Canada.

also  
that  
about  
and/or  
ie. some  
people  
don't  
halluci-  
rate

It's popularity is growing: According to the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS), about 1.6 per cent of Canadians aged 15 or older have tried salvia. For those aged 15-24, the number rises to 7.3 per cent.

When products containing *Salvia divinorum* are marketed for the purposes of modifying an organic function (such as, for their hallucinogenic effects) they meet the definition of a considered natural health products and, as such, must be authorized by Health Canada before they can be sold.

Media Lines

1. The RCMP is aware of the presence of this substance in Canada; however, to date, it hasn't surfaced as a significant problem.

3. As *Salvia divinorum* products that are marketed for use as hallucinogens are considered natural health products, it in contravention of the *Natural Health Products Regulations* is illegal to sell them without ~~Health Canada's authorization~~ approval from Health Canada.

2. As with any substance whose long-term effects haven't been fully documented, the RCMP is concerned about the use (or abuse) of *Salvia divinorum*.

and potential

ONLY IF ASKED:

Q: If it's illegal to sell Salvia in Canada, why aren't the RCMP charging stores or (people) for selling (using) it here?

A: ~~When Salvia products are marketed for use as hallucinogens, they are considered natural health products which can't be lawfully sold without Health Canada's authorization. However, Salvia isn't controlled/regulated under the Controlled Drugs and Substances Act, which is what we enforce.~~  
that  
it is currently only illegal to sell and most of the products that the RCMP is aware of are not sold in this way.

Q: Will you be moving to make it illegal under the CDSA?

Law enforcement  
cannot seize it  
is it?

appears  
very  
critical  
of HC  
can we  
soften?



A: (Refer to Health Canada).

*legal status*  
**Please refer all other questions on Salvia (effects, etc.) to Health Canada.**

**Updated by:** Robin Percival, Communications Strategist, Drugs and Organized Crime

**Approved by:** Supt. Eric Slinn, Dir., Drug Branch

National Communications Services  
(613)993-2999

**RCMP Media Lines - DRAFT**  
**Not for distribution**

**Date: December, 2010**

**Re: Salvia Divinorum**

**Issue:** Salvia Divinorum is a plant with psychoactive properties which when smoked or chewed can trigger an intense high and hallucinations. It is available online and in head shops, and while several countries have now banned it, to date it is not regulated under the Controlled Drugs and Substances Act ~~in Canada.~~ *and its Regulations.* ~~Substance~~ *Act* → *in Canada*

It's popularity is growing: According to the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS), about 1.6 per cent of Canadians aged 15 or older have tried salvia. For those aged 15-24, the number rises to 7.3 per cent. ✓

Products containing salvia divinorum are considered natural health products and, as such, must be authorized by Health Canada before they can be sold. *modify*

**Media Lines**

- The RCMP is aware of the presence of this substance in Canada; however, to date, it hasn't surfaced as a significant problem.
- As Salvia products are considered natural health products, it is illegal to sell them without Health Canada's authorization. *modify*
- As with any substance whose long-term effects haven't been fully documented, the RCMP is concerned about the use (or abuse) of Salvia. *divinorum*

**ONLY IF ASKED:**

Q: If it's illegal to sell Salvia in Canada, why aren't the RCMP charging stores or (people) for selling (using) it here?

A: Salvia products are considered natural health products which can't be sold without Health Canada's authorization. However, Salvia isn't regulated under the Controlled Drugs and Substances Act, which is what we enforce. *divinorum* ~~substance~~ *controlled*

Q: Will you be moving to make it illegal under the CDSA?

A: (Refer to Health Canada). ~~Result~~

**Please refer all other questions on Salvia (effects, etc.) to Health Canada.**

**Updated by:** Robin Percival, Communications Strategist, Drugs and Organized Crime

**Approved by:** Supt. Eric Slinn, Dir., Drug Branch

National Communications Services  
(613)993-2999



**Fw: Salvia QP Link**

Jocelyn Kula to: stephanie.szick  
Cc: Denis Arsenault, Stephanie Chandler

2010-12-15 11:46 AM

revised per comments from yesterday. guess we will be discussing this afternoon.  
FYI- urgent advice on RCMP lines on salvia will be coming to Cathy for approval this afternoon; also, all  
the media attention has made the IYH Salvia team ask about the status of the doc. I have responded and  
said that our scheduling recommendation is with Cathy for approval.....

JK

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224  
---- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2010-12-15 11:44 AM ----

---

From: Carmen Berube/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Date: 2010-12-15 11:26 AM  
Subject: Salvia QP Link

---





**Re: Fw: Media Summary/Sommaire des médias December 15 2010** 

Lisa MacKay to: Jocelyn Kula

2010-12-15 01:44 PM

Robin Marles, Robert Leitch, Allison Lui, David Cunningham, Helene Lacourciere, Kevin Bernardo, Laura Francis-Lamb, Mano Murty,  
Cc: Melinda Lee Choon, Sarah Chippure, Scott Jordan, Shahid Perwaiz, Stephanie Jack, Denis Arsenault, Stephanie Chandler, Christine Roush, Nicole Prentice

Thanks Jocelyn!

Lisa

Jocelyn Kula

Not exactly, we just want the IYH to reflect the r...

2010-12-15 01:41:10 PM

From: Jocelyn Kula/HC-SC/GC/CA  
To: Lisa MacKay/HC-SC/GC/CA@HWC  
Cc: Robin Marles/HC-SC/GC/CA@HWC, Robert Leitch/HC-SC/GC/CA@HWC, Allison Lui/HC-SC/GC/CA@HWC, David Cunningham/HC-SC/GC/CA@HWC, Helene Lacourciere/HC-SC/GC/CA@HWC, Kevin Bernardo/HC-SC/GC/CA@HWC, Laura Francis-Lamb/HC-SC/GC/CA@HWC, Mano Murty/HC-SC/GC/CA@HWC, Melinda Lee Choon/HC-SC/GC/CA@HWC, Sarah Chippure/HC-SC/GC/CA@HWC, Scott Jordan/HC-SC/GC/CA@HWC, Shahid Perwaiz/HC-SC/GC/CA@HWC, Stephanie Jack/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC, Christine Roush/HC-SC/GC/CA@HWC, Nicole Prentice/HC-SC/GC/CA@HWC  
Date: 2010-12-15 01:41 PM  
Subject: Re: Fw: Media Summary/Sommaire des médias December 15 2010

Not exactly, we just want the IYH to reflect the recommendation to schedule (which is still with our DG for approval) and we can't publish the IYH until we publish an NOI stating our intent to schedule in the *Canada Gazette*. So, the scheduling process does not need to be completed per se, but just out of the cabinet confidence "zone".

We will keep you posted as we move along. For now, we are concentrating on getting media lines and the NOI approved, and helping the RCMP with its media lines (they seem to be getting the brunt of enquiries apparently).....

JK

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

Lisa MacKay

Hi Jocelyn, I just want to confirm that the plan is...

2010-12-15 01:35:31 PM

From: Lisa MacKay/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Robin Marles/HC-SC/GC/CA@HWC, Robert Leitch/HC-SC/GC/CA@HWC, Allison Lui/HC-SC/GC/CA@HWC, David Cunningham/HC-SC/GC/CA@HWC, Helene Lacourciere/HC-SC/GC/CA@HWC, Kevin Bernardo/HC-SC/GC/CA@HWC, Laura Francis-Lamb/HC-SC/GC/CA@HWC, Mano Murty/HC-SC/GC/CA@HWC, Melinda Lee Choon/HC-SC/GC/CA@HWC, Sarah Chippure/HC-SC/GC/CA@HWC, Scott

Jordan/HC-SC/GC/CA@HWC, Shahid Perwaiz/HC-SC/GC/CA@HWC, Stephanie Jack/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC, Christine Roush/HC-SC/GC/CA@HWC, Nicole Prentice/HC-SC/GC/CA@HWC

Date: 2010-12-15 01:35 PM  
Subject: Re: Fw: Media Summary/Sommaire des médias December 15 2010

---

Hi Jocelyn,

I just want to confirm that the plan is to have nothing released until Salvia is scheduled?

Thanks

Lisa Mackay

It's Your Health Project Manager/Gestionnaire du projet Votre santé et vous

Consumer Information Bureau / Bureau d'information aux consommateurs

Marketing and Communications Services Directorate/Direction des services de marketing et de communications

Public Affairs, Consultation and Communications Branch/ Direction générale des affaires publiques, de la consultation et des communications

Health Canada | Santé Canada

Tel 613.954.0105

Lisa\_Mackay@hc-sc.gc.caa

Jocelyn Kula

Thanks Robin, For everyone's information, OCS...

2010-12-15 11:43:22 AM

From: Jocelyn Kula/HC-SC/GC/CA  
To: Robin Marles/HC-SC/GC/CA@HWC  
Cc: Robert Leitch/HC-SC/GC/CA@HWC, Allison Lui/HC-SC/GC/CA@HWC, David Cunningham/HC-SC/GC/CA@HWC, Helene Lacourciere/HC-SC/GC/CA@HWC, Kevin Bernardo/HC-SC/GC/CA@HWC, Laura Francis-Lamb/HC-SC/GC/CA@HWC, Lisa Mackay/HC-SC/GC/CA@HWC, Mano Murty/HC-SC/GC/CA@HWC, Melinda Lee Choon/HC-SC/GC/CA@HWC, Sarah Chippure/HC-SC/GC/CA@HWC, Scott Jordan/HC-SC/GC/CA@HWC, Shahid Perwaiz/HC-SC/GC/CA@HWC, Stephanie Jack/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2010-12-15 11:43 AM  
Subject: Re: Fw: Media Summary/Sommaire des médias December 15 2010

---

Thanks Robin,

For everyone's information, OCS has recently completed its scheduling assessment on Salvia and Salvinorin A, and a final decision as to recommended next steps is with our DG right now. I should be able to provide more info in the coming weeks.

Jocelyn

---

Jocelyn Kula

Acting Director/ Directrice par intérim

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs

Health Canada/ Santé Canada

Tel: (613) 952-2177 Fax: (613) 946-4224

Robin Marles

At this time, Salvia divinorum is classified as an...

2010-12-15 09:33:25 AM



**Re: Fw: Media Summary/Sommaire des médias December 15 2010**

Christine Roush to: Jocelyn Kula

2010-12-15 01:56 PM

Cc: Denis Arsenault, Stephanie Chandler

You spoke too soon. We just received a media inquiry on Salvia from Global that will be coming your way soon.

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
Health Canada/Santé Canada  
Tel/Tél : (613) 954-0712/Cell: (613) 219-7194  
Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca

Jocelyn Kula

Not exactly, we just want the IYH to reflect the r...

2010-12-15 01:41:12 PM

From: Jocelyn Kula/HC-SC/GC/CA  
To: Lisa MacKay/HC-SC/GC/CA@HWC  
Cc: Robin Marles/HC-SC/GC/CA@HWC, Robert Leitch/HC-SC/GC/CA@HWC, Allison Lui/HC-SC/GC/CA@HWC, David Cunningham/HC-SC/GC/CA@HWC, Helene Lacourciere/HC-SC/GC/CA@HWC, Kevin Bernardo/HC-SC/GC/CA@HWC, Laura Francis-Lamb/HC-SC/GC/CA@HWC, Mano Murty/HC-SC/GC/CA@HWC, Melinda Lee Choon/HC-SC/GC/CA@HWC, Sarah Chippure/HC-SC/GC/CA@HWC, Scott Jordan/HC-SC/GC/CA@HWC, Shahid Perwaiz/HC-SC/GC/CA@HWC, Stephanie Jack/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC, Christine Roush/HC-SC/GC/CA@HWC, Nicole Prentice/HC-SC/GC/CA@HWC  
Date: 2010-12-15 01:41 PM  
Subject: Re: Fw: Media Summary/Sommaire des médias December 15 2010

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We will keep you posted as we move along. For now, we are concentrating on getting media lines and the NOI approved, and helping the RCMP with its media lines (they seem to be getting the brunt of enquiries apparently).....

JK

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
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Tel: (613) 952-2177 Fax: (613) 946-4224

Lisa MacKay

Hi Jocelyn, I just want to confirm that the plan is...

2010-12-15 01:35:31 PM



**Re: Fw: Salvia QP Link**

Stephanie Szick to: Jocelyn Kula, Cyndi Vaughan  
Cc: Denis Arsenault, Stephanie Chandler

2010-12-15 11:50 AM

Thanks Jocelyn

Can you bring for this meeting also the RCMP salvia lines you mention or are these coming through Christine R on a separate track?

Cyndi -- can you print this QP and add to the other docs for Cathy's file for this meeting (please make a meeting file for me also -- thanks!)

Stephanie Szick  
Director General's Office / Bureau du directeur général  
Controlled Substances & Tobacco Directorate (CSTD) /  
Direction des substances contrôlées et de la lutte au tabagisme (DSCLT)  
Health Canada / Santé Canada  
Tel / Tél: (613) 948-8651

Jocelyn Kula revised per comments from yesterday. guess w... 2010-12-15 11:46:39 AM

From: Jocelyn Kula/HC-SC/GC/CA  
To: stephanie.szick@hc-sc.gc.ca  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2010-12-15 11:46 AM  
Subject: Fw: Salvia QP Link

revised per comments from yesterday. guess we will be discussing this afternoon.  
FYI- urgent advice on RCMP lines on salvia will be coming to Cathy for approval this afternoon; also, all the media attention has made the IYH Salvia team ask about the status of the doc. I have responded and said that our scheduling recommendation is with Cathy for approval.....

JK

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224  
----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2010-12-15 11:44 AM -----

From: Carmen Berube/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Date: 2010-12-15 11:26 AM  
Subject: Salvia QP Link





**Re: Urgent - Media Inquiry - Salvia (RCMP)**

Jocelyn Kula to: Christine Roush

2010-12-15 04:23 PM

Cc: Stephanie Chandler, Nicole Prentice, Denis Arsenault

Here are our comments on the RCMP lines. As you can see, we are suggesting major edits. We are still working on two enquiries further to discussion with Cathy this afternoon.



Salvia - Media Lines RCMP OSC v.4.wpd

Jocelyn Kula

Acting Director/ Directrice par intérim

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs

Health Canada/ Santé Canada

Tel: (613) 952-2177 Fax: (613) 946-4224

Christine Roush

Jocelyn, Below is an email I just received from t...

2010-12-15 10:37:02 AM

From: Christine Roush/HC-SC/GC/CA  
 To: Jocelyn Kula/HC-SC/GC/CA@HWC  
 Cc: Stephanie Chandler/HC-SC/GC/CA@HWC, Nicole Prentice/HC-SC/GC/CA@HWC  
 Date: 2010-12-15 10:37 AM  
 Subject: Re: Urgent - Media Inquiry - Salvia (RCMP)

Jocelyn,

Below is an email I just received from the Comms shop at the RCMP who have received a media inquiry about Salvia. Could you please take a look at their suggested response and let me know as soon as possible if you are OK with it. As well, we really need to get our new Salvia media lines approved as quickly as possible, as Salvia has been in the news quite a bit in the last week. I believe they are currently with Cathy. Is there anything you can do to facilitate her approval so we can keep these moving and have them fully approved before Christmas?

\*\*\*\*\*

Hi Christine...as I suspected, we've received a media query about our stance on Salvia out in H Division (Halifax). I drafted the following brief holding lines, but would appreciate if you could advise if they're ok...I'm just learning about this substance myself. For most info, I would refer them to HC...

Many thanks,

Robin Percival

Communications Strategist/ Conseillère en stratégies de communications

RCMP/GRC

Tel./tél. (613) 949-0574; Fax/télé. (613) 993-5454

robin.percival@rcmp-grc.gc.ca

1 attachment

[attachment "Salvia - Media Lines .wpd" deleted by Jocelyn Kula/HC-SC/GC/CA]

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
Health Canada/Santé Canada  
Tel/Tél : (613) 954-0712/Cell: (613) 219-7194  
Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca

Nicole Prentice	Thanks Jocelyn. I figured she was busy with oth...	2010-12-13 03:42:31 PM
Jocelyn Kula	Hi Nicole The docs went to Cathy late last week...	2010-12-13 03:39:15 PM
Nicole Prentice	Hi again, Have you gotten anything back from...	2010-12-13 03:36:39 PM
Stephanie Chandler	Hi Nicole and Christine, Sorry you weren't cc'e...	2010-12-10 09:07:59 AM

**RCMP Media Lines - DRAFT**  
**Not for distribution**

---

**Date: December, 2010**

**Re: Salvia Divinorum**

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**Issue:** *Salvia divinorum* is a plant with psychoactive properties which when smoked or chewed can cause a number of physical and mental effects including hallucinations and/or triggering an intense "high". *Salvia divinorum* is available online and in head shops and its popularity is growing: According to the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS), about 1.6 per cent of Canadians aged 15 or older have tried salvia. For those aged 15-24, the number rises to 7.3 per cent. and hallucinations. It is available online and in head shops, and

When products containing *Salvia divinorum* are marketed for the purposes of modifying an organic function (such as for their hallucinogenic effects) they meet the definition of a natural health product and, as such, must be authorized by Health Canada before they can be sold.

While several countries have placed controls on the import and/or sale of this substance, now banned it, to date it is not currently regulated in Canada under the *Controlled Drugs and Substances Act* (CDSA) and its Regulations in Canada. Health Canada is currently assessing whether regulation the control of *Salvia divinorum* under the CDSA is warranted.

However, when products containing *Salvia divinorum* are marketed for the purposes of modifying an organic function (such as for their hallucinogenic effects) they meet the definition of a natural health product and, as such, must be authorized by Health Canada before they can be sold.

It's popularity is growing: According to the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS), about 1.6 per cent of Canadians aged 15 or older have tried salvia. For those aged 15-24, the number rises to 7.3 per cent.

Products containing *salvia divinorum* are considered natural health products and, as such, must be authorized by Health Canada before they can be sold.

**Media Lines**

- The RCMP is aware of the presence of this substance in Canada, however, to date, it hasn't surfaced as a significant problem.
- As with any substance whose long-term effects haven't been fully documented, the RCMP is concerned about the use (and potential abuse) of *Salvia divinorum*.
- As products containing *Salvia divinorum* products that are marketed for use as hallucinogens are considered natural health products, it is in contravention of the *Natural Health Products Regulations* is illegal to sell them without approval from Health Canada's authorization.

~~As with any substance whose long-term effects haven't been fully documented, the RCMP is concerned about the use (or abuse) of Salvia.~~

**ONLY IF ASKED:**

Q: If it's illegal to sell Salvia in Canada, why aren't the RCMP charging stores or (people) for selling (using) it here?

A: It is currently only illegal to sell Salvia products that are marketed for use as hallucinogens. Such unauthorized products may be subject to compliance and enforcement by Health Canada. Most of the products that the RCMP and Health Canada are aware of are not sold in this way. Law enforcement cannot seize *Salvia divinorum* unless it is regulated as a controlled substance under the *Controlled Drugs and Substances Act* (CDSA). ~~considered natural health products which can't be sold without Health Canada's authorization. However, Salvia isn't regulated under the *Controlled Drugs and Substances Act*, which is what we enforce.~~

Q: Will you be moving to make it illegal under the CDSA?

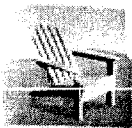
A: (Refer to Health Canada).

**Please refer all other questions on Salvia (effects, legal status, etc.) to Health Canada.**

**Updated by:** Robin Percival, Communications Strategist, Drugs and Organized Crime

**Approved by:** Supt. Eric Slinn, Dir., Drug Branch

National Communications Services  
(613)993-2999



**Fw: Media enquiry - Global National - Salvia**

Nicole Prentice to: Jocelyn Kula

2010-12-15 02:20 PM

Cc: Christine Roush, CSTD-OCS-DO, Stephanie Chandler, Denis Arsenault

Hi Jocelyn and team,

Here is the first of two salvia enquiries for your input/approval by 3pm today, if possible as this is due at 4. Proposed responses have been drafted from previous enquiries.

Thanks in advance.

Nicole

**Q1) is it legal?**

A1) Health Canada does not recommend the use of products containing *S. divinorum* and/or salvinorin A because very little is known about these substances and their potential effects on the brain and/or body, and their impact on physical and mental functions.

To date, Health Canada has not licensed for sale any drug or Natural Health Product which contains salvia as an ingredient.

It is a contravention of the *Food and Drugs Act* and the *Natural Health Products Regulations* to sell Natural Health Products in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN) on the label. The sale of unauthorized natural health products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

Complaints about the sale of unauthorized products containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate by calling 1-800-267-9675.

Health Canada is currently assessing whether the regulation of *Salvia divinorum* and/or Salvinorin A under the *Controlled Drugs and Substances Act* is warranted.

**Q2) Is it a concern for HC?**

A2) Health Canada is aware of salvia and has noted media interest regarding the availability of *Salvia divinorum* in Canada.

Health Canada will continue to collect and study information about *S. divinorum* as it becomes available and is currently assessing whether the regulation of *Salvia divinorum* and/or Salvinorin A under the *Controlled Drugs and Substances Act* is warranted.

**Q3) Is it considered a drug?**

A3) *Salvia divinorum* is a species of sage which belongs to the mint family. It is found in the form of dried leaves, extract and plant cuttings. *Salvia divinorum*, also known as "diviner's sage", is chewed or smoked in order to induce its psychotropic effects, which means it affects the mind and mental processes.

Health Canada is currently assessing whether the regulation of *Salvia divinorum* and/or Salvinorin A under the *Controlled Drugs and Substances Act* is warranted.

Health Canada considers several factors in determining whether regulation of a substance under the

*Controlled Drugs and Substances Act (CDSA)* is warranted.

These include:

- Overall risk to public health and safety posed by the substance.
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- International requirements and trends in international control.

**Nicole Prentice**

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Regulatory Communications and Media Relations Division | Division des communications  
réglementaires et des relations avec les médias  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires  
publiques, de la consultation et des communications  
Health Canada | Santé Canada  
Tel: 613.941.3107  
Fax: 613.948.8085

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To: Christine Roush/HC-SC/GC/CA@HWC, Paul Spendlove/HC-SC/GC/CA@HWC  
Cc: Dave Stephens/HC-SC/GC/CA@HWC, Nicole Prentice/HC-SC/GC/CA@HWC  
Date: 2010-12-15 01:39 PM  
Subject: Media enquiry - Global National - Salvia

---

Good afternoon,

Dust off the canned lines - salvia call!

Salvia

- Q1) is it legal?
- Q2) Is it a concern for HC?
- Q3) Is it considered a drug?

Deadline: today 4pm

Thanks

Dave

David Thomas  
Media Relations Officer | Agent des relations avec les médias  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la  
consultation et des communications  
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david.thomas@hc-sc.gc.ca  
Government of Canada | Gouvernement du Canada



To:  
Cc:  
Bcc:  
Subject: Fw: Media enquiry - Global National - Salvia

----- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2010-12-15 02:30 PM -----

From: Nicole Prentice/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Christine Roush/HC-SC/GC/CA@HWC, CSTD-OCS-DO, Stephanie  
Chandler/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2010-12-15 02:20 PM  
Subject: Fw: Media enquiry - Global National - Salvia

Hi Jocelyn and team,

Here is the first of two salvia enquiries for your input/approval by 3pm today, if possible as this is due at 4. Proposed responses have been drafted from previous enquiries.

Thanks in advance.

Nicole

**Q1) is it legal?**

A1)

The plant *Salvia divinorum* is not regulated under the *Controlled Drugs and Substances Act* (CDSA) and therefore activities with it are not considered illegal in Canada. Health Canada is currently assessing whether the regulation of *Salvia divinorum* and/or salvinorin A under the CDSA is warranted. However, because *Salvia divinorum* is a plant with hallucinogenic properties, it meets the definition of a natural health product (NHP) under the *Natural Health Products Regulations* when marketed as such. The sale of unauthorized natural health products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

~~Health Canada does not recommend the use of products containing *S. divinorum* and/or salvinorin A because very little is known about these substances and their potential effects on the brain and/or body, and their impact on physical and mental functions.~~

~~To date, Health Canada has not licensed for sale any drug or Natural Health Product which contains salvia as an ingredient.~~

~~It is a contravention of the *Food and Drugs Act* and the *Natural Health Products Regulations* to sell Natural Health Products in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN) on the label. The sale of unauthorized natural health products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.~~

~~Complaints about the sale of unauthorized products containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate by calling 1-800-267-9675.~~

~~Health Canada is currently assessing whether the regulation of *Salvia divinorum* and/or salvinorin A under the *Controlled Drugs and Substances Act* is warranted.~~

**Q2) Is it a concern for HC?**



appeal  
Monsieur  
in use  
particularly  
in youth

A2) Health Canada is concerned about the increased use, abuse potential and unknown effects of *Salvia divinorum*. ~~As a result, Health Canada is currently assessing whether the regulation of *Salvia divinorum* and/or salvinorin A under the *Controlled Drugs and Substances Act* is warranted.~~

Health Canada does not recommend the use of products containing *S. divinorum* and/or salvinorin A because very little is known about these substances and their potential effects on the brain and/or body, and their impact on physical and mental functions.

**Q3) Is it considered a drug?**

A3) Products containing *Salvia divinorum* meet the definition of a Natural Health Product when they are marketed for use for their hallucinogenic properties. Natural Health Products are a category of health products which are regulated under the *Food and Drugs Act*. ~~However, unless *Salvia divinorum* is marketed with a health claim it would not necessarily be considered a drug per se as defined in the *Food and Drugs Act*.~~ *not, however*

~~*Salvia divinorum* is a species of sage which belongs to the mint family. It is found in the form of dried leaves, extract and plant cuttings. *Salvia divinorum*, also known as "diviner's sage", is chewed or smoked in order to induce its psychotropic effects, which means it affects the mind and mental processes.~~

~~Health Canada is currently assessing whether the regulation of *Salvia divinorum* and/or salvinorin A under the *Controlled Drugs and Substances Act* is warranted.~~

~~Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted.~~

~~These include:-~~

- ~~— Overall risk to public health and safety posed by the substance.~~
- ~~— Chemical and pharmacological similarity to other substances already regulated under the CDSA;~~
- ~~— Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);~~
- ~~— Potential for abuse and risk of addiction associated with the substance;~~
- ~~— Extent of actual abuse of the substance in Canada and internationally; and~~
- ~~— International requirements and trends in international control.~~

**Nicole Prentice**

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Date: 2010-12-15 01:39 PM  
Subject: Media enquiry - Global National - Salvia

Good afternoon,

Dust off the canned lines - salvia call!

Salvia

Q1) is it legal?

Q2) Is it a concern for HC?

Q3) Is it considered a drug?

Deadline: today 4pm

Thanks

Dave

David Thomas

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**Fw: Media enquiry - Global National - Salvia**

Stephanie Chandler to: Jocelyn Kula  
Cc: Denis Arsenault, CSTD-OCS-DO

2010-12-15 03:22 PM

Hi Jocelyn,

For your review. Denis has approved. Deadline is 3:30pm. Media request #2 is also on its way.

Stephanie

----- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2010-12-15 02:30 PM -----

From: Nicole Prentice/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Christine Roush/HC-SC/GC/CA@HWC, CSTD-OCS-DO, Stephanie Chandler/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2010-12-15 02:20 PM  
Subject: Fw: Media enquiry - Global National - Salvia

Hi Jocelyn and team,

Here is the first of two salvia enquiries for your input/approval by 3pm today, if possible as this is due at 4. Proposed responses have been drafted from previous enquiries.

Thanks in advance.  
Nicole

**Q1) is it legal?**

~~A1) Health Canada does not recommend the use of products containing *S. divinorum* and/or salvinorin A because very little is known about these substances and their potential effects on the brain and/or body, and their impact on physical and mental functions.~~

~~To date, Health Canada has not licensed for sale any drug or Natural Health Product which contains salvia as an ingredient.~~

When products containing *Salvia divinorum* and/or its main active ingredient salvinorin A are sold for the purposes of modifying brain function (such as for their hallucinogenic effect), they meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*. It is a contravention of the *Food and Drugs Act* and the *Natural Health Products Regulations* to sell Natural Health Products in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN) on the label. To date, Health Canada has not licensed for sale any drug or Natural Health Product which contains salvia as an ingredient. The sale of unauthorized natural health products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

Complaints about the sale of unauthorized products containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate by calling 1-800-267-9675.

Health Canada is currently assessing whether the regulation of *Salvia divinorum* and/or salvinorin A under the *Controlled Drugs and Substances Act* is warranted.

**Q2) Is it a concern for HC?**

~~A2) Health Canada is aware of *Salvia divinorum* and has noted media interest regarding the availability of~~

concerned about . . . .  
per discuss 002016

this plant ~~Salvia divinorum~~ in Canada.

Health Canada ~~will continue to collect and study information about Salvia divinorum as it becomes available~~ and is currently assessing whether the regulation of *Salvia divinorum* and/or salvinorin A under the *Controlled Drugs and Substances Act* is warranted.

Health Canada does not recommend the use of products containing *S. divinorum* and/or salvinorin A because very little is known about these substances and their potential effects on the brain and/or body, and their impact on physical and mental functions.

**Q3) Is it considered a drug?**

A3) (See A1)

~~Salvia divinorum is a species of sage which belongs to the mint family. It is found in the form of dried leaves, extract and plant cuttings. Salvia divinorum, also known as "diviner's sage", is chewed or smoked in order to induce its psychotropic effects, which means it affects the mind and mental processes.~~

Health Canada is currently assessing whether the regulation of *Salvia divinorum* and/or salvinorin A under the *Controlled Drugs and Substances Act* is warranted.

~~Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted.~~

~~These include:-~~

- ~~• Overall risk to public health and safety posed by the substance.~~
- ~~• Chemical and pharmacological similarity to other substances already regulated under the CDSA.~~
- ~~• Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);~~
- ~~• Potential for abuse and risk of addiction associated with the substance;~~
- ~~• Extent of actual abuse of the substance in Canada and internationally; and~~
- ~~• International requirements and trends in international control.~~

• meets definition of an NHP, which is a category of health products regulated under the Food and Drugs Act but ~~not~~ ~~which~~ it ~~is~~ ~~already~~ is ~~not~~ a ~~drug~~ ~~per se~~ as defined in the Food and Drugs Act per se.

**Nicole Prentice**

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 Regulatory Communications and Media Relations Division | Division des communications réglementaires et des relations avec les médias  
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Q2) Is it a concern for HC?

Q3) Is it considered a drug?

Deadline: today 4pm

Thanks

Dave

David Thomas

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**Re: Fw: Media enquiry - Global National - Salvia**

Jocelyn Kula to: Nicole Prentice

2010-12-15 03:44 PM

Cc: Christine Roush, CSTD-DGO, CSTD-OCS-DO, Denis Arsenault,  
Stephanie Chandler

Nicole,

I have been in back to back meetings all afternoon and Carmen is just printing stuff now.

Jocelyn

---

Jocelyn Kula

Acting Director/ Directrice par intérim

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs

Health Canada/ Santé Canada

Tel: (613) 952-2177 Fax: (613) 946-4224

---

Nicole Prentice

Hi again, Media relations is already checking in...

2010-12-15 03:42:44 PM

From: Nicole Prentice/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Christine Roush/HC-SC/GC/CA@HWC, CSTD-OCS-DO, Stephanie  
Chandler/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, CSTD-DGO  
Date: 2010-12-15 03:42 PM  
Subject: Fw: Media enquiry - Global National - Salvia

---

Hi again,

Media relations is already checking in on this enquiry. Will we be able to get it soon?

**Nicole Prentice**

Junior Communications Officer | Agente junior des Communications

Regulatory Communications and Media Relations Division | Division des communications  
réglementaires et des relations avec les médias

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Hi Jocelyn and team,

Here is the first of two salvia enquiries for your input/approval by 3pm today, if possible as this is due at 4. Proposed responses have been drafted from previous enquiries.

Thanks in advance.  
Nicole

**Q1) is it legal?**

A1) Health Canada does not recommend the use of products containing *S. divinorum* and/or salvinorin A because very little is known about these substances and their potential effects on the brain and/or body, and their impact on physical and mental functions.

To date, Health Canada has not licensed for sale any drug or Natural Health Product which contains salvia as an ingredient.

It is a contravention of the *Food and Drugs Act* and the *Natural Health Products Regulations* to sell Natural Health Products in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN) on the label. The sale of unauthorized natural health products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

Complaints about the sale of unauthorized products containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate by calling 1-800-267-9675.

Health Canada is currently assessing whether the regulation of *Salvia divinorum* and/or Salvinorin A under the *Controlled Drugs and Substances Act* is warranted.

**Q2) Is it a concern for HC?**

A2) Health Canada is aware of salvia and has noted media interest regarding the availability of *Salvia divinorum* in Canada.

Health Canada will continue to collect and study information about *S. divinorum* as it becomes available and is currently assessing whether the regulation of *Salvia divinorum* and/or Salvinorin A under the *Controlled Drugs and Substances Act* is warranted.

**Q3) Is it considered a drug?**

A3) *Salvia divinorum* is a species of sage which belongs to the mint family. It is found in the form of dried leaves, extract and plant cuttings. *Salvia divinorum*, also known as "diviner's sage", is chewed or smoked in order to induce its psychotropic effects, which means it affects the mind and mental processes.

Health Canada is currently assessing whether the regulation of *Salvia divinorum* and/or Salvinorin A under the *Controlled Drugs and Substances Act* is warranted.

Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted.

These include:

- Overall risk to public health and safety posed by the substance.
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;

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Dust off the canned lines - salvia call!

Salvia

- Q1) is it legal?
- Q2) Is it a concern for HC?
- Q3) Is it considered a drug?

Deadline: today 4pm

Thanks

Dave

David Thomas  
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**Fw: Media enquiry - Global National - Salvia**

Stephanie Chandler to: Jocelyn Kula

Cc: Denis Arsenault, CSTD-OCS-DO

2010-12-15 05:25 PM

Hi Jocelyn,

A2 and A3 have been revised as discussed, for your review. Also to be forwarded to Comms upon your approval.

Thanks,

Stephanie

----- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2010-12-15 02:30 PM -----

From: Nicole Prentice/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
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Thanks in advance.

Nicole

**Q1) is it legal?**

A1)

The plant *Salvia divinorum* is not regulated under the *Controlled Drugs and Substances Act* (CDSA) and therefore activities with it are not considered illegal in Canada. Health Canada is currently assessing whether the regulation of *Salvia divinorum* and/or salvinorin A under the CDSA is warranted. However, because *Salvia divinorum* is a plant with hallucinogenic properties, it meets the definition of a natural health product (NHP) under the *Natural Health Products Regulations* when marketed as such. The sale of unauthorized natural health products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

~~Health Canada does not recommend the use of products containing *S. divinorum* and/or salvinorin A because very little is known about these substances and their potential effects on the brain and/or body, and their impact on physical and mental functions.~~

~~To date, Health Canada has not licensed for sale any drug or Natural Health Product which contains salvia as an ingredient.~~

~~It is a contravention of the *Food and Drugs Act* and the *Natural Health Products Regulations* to sell Natural Health Products in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN) on the label. The sale of unauthorized natural health products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.~~

~~Complaints about the sale of unauthorized products containing *S. divinorum* and/or salvinorin A can be~~

~~referred to the Health Products and Food Branch Inspectorate by calling 1-800-267-9675.~~

~~Health Canada is currently assessing whether the regulation of *Salvia divinorum* and/or salvinorin A under the *Controlled Drugs and Substances Act* is warranted.~~

**Q2) Is it a concern for HC?**

A2) Health Canada is concerned about the apparent increased use of *Salvia divinorum*, particularly by youth.

Health Canada does not recommend the use of products containing *S. divinorum* and/or salvinorin A because very little is known about these substances and their potential effects on the brain and/or body, and their impact on physical and mental functions.

**Q3) Is it considered a drug?**

A3) Products containing *Salvia divinorum* meet the definition of a Natural Health Product when they are marketed for use for their hallucinogenic properties. Natural Health Products are a category of health products which are regulated under the *Food and Drugs Act*. *Salvia divinorum* is not, however, considered a drug per se as defined in the *Food and Drugs Act*.

~~*Salvia divinorum* is a species of sage which belongs to the mint family. It is found in the form of dried leaves, extract and plant cuttings. *Salvia divinorum*, also known as "diviner's sage", is chewed or smoked in order to induce its psychotropic effects, which means it affects the mind and mental processes.~~

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Q2) Is it a concern for HC?

Q3) Is it considered a drug?

Deadline: today 4pm

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Health Canada | Santé Canada  
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david.thomas@hc-sc.gc.ca  
Government of Canada | Gouvernement du Canada



**Re: Fw: Media enquiry - Global National - Salvia**

Christine Roush to: Jocelyn Kula

2010-12-15 04:06 PM

Cc: Nicole Prentice, CSTD-DGO, CSTD-OCS-DO, Denis Arsenault,  
Stephanie Chandler

Jocelyn - I know you are working on the Salvia responses, but any chance we can get the RCMP response back asap - from CBC Halifax. It is already 5pm in Halifax so the RCMP may have to ask for an extension and let this one go.

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
Health Canada/Santé Canada  
Tel/Tél : (613) 954-0712/Cell: (613) 219-7194  
Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca

Jocelyn Kula

Nicole, I have been in back to back meetings all...

2010-12-15 03:44:12 PM

From: Jocelyn Kula/HC-SC/GC/CA  
To: Nicole Prentice/HC-SC/GC/CA@HWC  
Cc: Christine Roush/HC-SC/GC/CA@HWC, CSTD-DGO, CSTD-OCS-DO, Denis  
Arsenault/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2010-12-15 03:44 PM  
Subject: Re: Fw: Media enquiry - Global National - Salvia

Nicole,

I have been in back to back meetings all afternoon and Carmen is just printing stuff now.

Jocelyn

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

Nicole Prentice

Hi again, Media relations is already checking in...

2010-12-15 03:42:44 PM



To:  
Cc:  
Bcc:  
Subject: Re: URGENT: Media enquiry - CTV - salvia

Hi Jocelyn,

Q1) Is it approved by HC or not? Is it legal? Banned?

A1) The plant *Salvia divinorum* is not controlled under the *Controlled Drugs and Substances Act* (CDSA) and therefore is not considered illegal in Canada. However, as *Salvia divinorum* is a plant with hallucinogenic properties when consumed by humans, it meets the definition of a natural health product (NHP) under the *Natural Health Products Regulations* when marketed as a hallucinogen. To date, Health Canada has not licensed for sale any Natural Health Product which contains *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products containing *S. divinorum* and/or salvininorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

Health Canada is currently assessing whether the regulation of *Salvia divinorum* and/or salvininorin A under the *Controlled Drugs and Substances Act* is warranted.

Nicole Prentice      Hi Jocelyn, Please see another request below fr...      2010-12-15 04:41:31 PM

From: Nicole Prentice/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Christine Roush/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, CSTD-DGO, CSTD-OCS-DO  
Date: 2010-12-15 04:41 PM  
Subject: URGENT: Media enquiry - CTV - salvia

Hi Jocelyn,

Please see another request below from CTV with a deadline of one hour. Can we use one of the responses you are preparing for the other enquiries to close this off asap?

Thanks.

**Nicole Prentice**

Junior Communications Officer | Agente junior des Communications  
Regulatory Communications and Media Relations Division | Division des communications réglementaires et des relations avec les médias  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la consultation et des communications  
Health Canada | Santé Canada  
Tel: 613.941.3107  
Fax: 613.948.8085

----- Forwarded by Nicole Prentice/HC-SC/GC/CA on 2010-12-15 04:39 PM -----

From: David Thomas/HC-SC/GC/CA  
To: Nicole Prentice/HC-SC/GC/CA@HWC, Christine Roush/HC-SC/GC/CA@HWC, Paul Spendlove/HC-SC/GC/CA@HWC  
Cc: Dave Stephens/HC-SC/GC/CA@HWC  
Date: 2010-12-15 04:37 PM  
Subject: Media enquiry - CTV - salvia

Hi,

Salvia

Q1) Is it approved by HC or not? Is it legal? Banned?


Deadline: 1 hour

Thanks

Dave

David Thomas  
Media Relations Officer | Agent des relations avec les médias  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la  
consultation et des communications  
Health Canada | Santé Canada  
613.946.4250  
david.thomas@hc-sc.gc.ca  
Government of Canada | Gouvernement du Canada



**Re: URGENT: Media enquiry - CTV - salvia**   
Stephanie Chandler to: Jocelyn Kula  
Cc: Denis Arsenault, CSTD-OCS-DO

2010-12-15 05:08 PM

Hi Jocelyn,

Salvia media request # 3 for your review.

Q1) Is it approved by HC or not? Is it legal? Banned?

A1) The plant *Salvia divinorum* is not regulated under the *Controlled Drugs and Substances Act* (CDSA) and therefore activities with it are not considered illegal in Canada. Health Canada is currently assessing whether the regulation of *Salvia divinorum* and/or salvinorin A under the CDSA is warranted. However, because *Salvia divinorum* is a plant with hallucinogenic properties, it meets the definition of a natural health product (NHP) under the *Natural Health Products Regulations* when marketed as such. The sale of unauthorized natural health products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

Nicole Prentice

Hi Jocelyn, Please see another request below fr...

2010-12-15 04:41:31 PM

From: Nicole Prentice/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Christine Roush/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, CSTD-DGO, CSTD-OCS-DO  
Date: 2010-12-15 04:41 PM  
Subject: URGENT: Media enquiry - CTV - salvia

---

Hi Jocelyn,

Please see another request below from CTV with a deadline of one hour. Can we use one of the responses you are preparing for the other enquiries to close this off asap?

Thanks.

**Nicole Prentice**

Junior Communications Officer | Agente junior des Communications  
Regulatory Communications and Media Relations Division | Division des communications réglementaires et des relations avec les médias  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la consultation et des communications  
Health Canada | Santé Canada  
Tel: 613.941.3107  
Fax: 613.948.8085

----- Forwarded by Nicole Prentice/HC-SC/GC/CA on 2010-12-15 04:39 PM -----

From: David Thomas/HC-SC/GC/CA  
To: Nicole Prentice/HC-SC/GC/CA@HWC, Christine Roush/HC-SC/GC/CA@HWC, Paul Spendlove/HC-SC/GC/CA@HWC  
Cc: Dave Stephens/HC-SC/GC/CA@HWC  
Date: 2010-12-15 04:37 PM  
Subject: Media enquiry - CTV - salvia

---

Hi,



**Fw: Media enquiry - Global National - Salvia**  
Stephanie Chandler to: Denis Arsenault

2010-12-15 02:53 PM

For your review. Still waiting for Nicole to send me request #2.

Stephanie

----- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2010-12-15 02:30 PM -----

From: Nicole Prentice/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Christine Roush/HC-SC/GC/CA@HWC, CSTD-OCS-DO, Stephanie  
Chandler/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2010-12-15 02:20 PM  
Subject: Fw: Media enquiry - Global National - Salvia

---

Hi Jocelyn and team,

Here is the first of two salvia enquiries for your input/approval by 3pm today, if possible as this is due at 4. Proposed responses have been drafted from previous enquiries.

Thanks in advance.  
Nicole

**Q1) is it legal?**

~~A1) Health Canada does not recommend the use of products containing *S. divinorum* and/or salvinorin A because very little is known about these substances and their potential effects on the brain and/or body, and their impact on physical and mental functions.~~

~~To date, Health Canada has not licensed for sale any drug or Natural Health Product which contains salvia as an ingredient.~~

When products containing *Salvia divinorum* and/or its main active ingredient salvinorin A are sold for the purposes of modifying brain function (such as for their hallucinogenic effect), they meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*. It is a contravention of the *Food and Drugs Act* and the *Natural Health Products Regulations* to sell Natural Health Products in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN) on the label. To date, Health Canada has not licensed for sale any drug or Natural Health Product which contains salvia as an ingredient. The sale of unauthorized natural health products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

Complaints about the sale of unauthorized products containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate by calling 1-800-267-9675.

Health Canada is currently assessing whether the regulation of *Salvia divinorum* and/or salvinorin A under the *Controlled Drugs and Substances Act* is warranted.

**Q2) Is it a concern for HC?**

A2) Health Canada is aware of *Salvia divinorum* and has noted media interest regarding the availability of this plant ~~Salvia divinorum~~ in Canada.

Health Canada will continue to collect and study information about *Salvia divinorum* as it becomes



available and is currently assessing whether the regulation of *Salvia divinorum* and/or salvinorin A under the *Controlled Drugs and Substances Act* is warranted.

Health Canada does not recommend the use of products containing *S. divinorum* and/or salvinorin A because very little is known about these substances and their potential effects on the brain and/or body, and their impact on physical and mental functions.

**Q3) Is it considered a drug?**

A3) (See A1) ~~NS~~

~~When salvia products are sold for the purposes of modifying organic function (such as, for their hallucinogenic effect), they meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*.~~

~~*Salvia divinorum* is a species of sage which belongs to the mint family. It is found in the form of dried leaves, extract and plant cuttings. *Salvia divinorum*, also known as "diviner's sage", is chewed or smoked in order to induce its psychotropic effects, which means it affects the mind and mental processes.~~

Health Canada is currently assessing whether the regulation of *Salvia divinorum* and/or salvinorin A under the *Controlled Drugs and Substances Act* is warranted.

~~Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted.~~

~~These include:-~~

- ~~• Overall risk to public health and safety posed by the substance.~~
- ~~• Chemical and pharmacological similarity to other substances already regulated under the CDSA;~~
- ~~• Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);~~
- ~~• Potential for abuse and risk of addiction associated with the substance;~~
- ~~• Extent of actual abuse of the substance in Canada and internationally; and~~
- ~~• International requirements and trends in international control.~~

**Nicole Prentice**

Junior Communications Officer | Agente junior des Communications  
Regulatory Communications and Media Relations Division | Division des communications réglementaires et des relations avec les médias  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la consultation et des communications  
Health Canada | Santé Canada  
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Fax: 613.948.8085

----- Forwarded by Nicole Prentice/HC-SC/GC/CA on 2010-12-15 02:16 PM -----

From: David Thomas/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC, Paul Spendlove/HC-SC/GC/CA@HWC  
Cc: Dave Stephens/HC-SC/GC/CA@HWC, Nicole Prentice/HC-SC/GC/CA@HWC  
Date: 2010-12-15 01:39 PM  
Subject: Media enquiry - Global National - Salvia

Good afternoon,

Dust off the canned lines - salvia call!

Salvia

Q1) is it legal?

Q2) Is it a concern for HC?

Q3) Is it considered a drug?

Deadline: today 4pm

Thanks

Dave

David Thomas

Media Relations Officer | Agent des relations avec les médias

Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la  
consultation et des communications

Health Canada | Santé Canada

613.946.4250

david.thomas@hc-sc.gc.ca

Government of Canada | Gouvernement du Canada



**Fw: URGENT: Media enquiry - CTV - salvia**

Stephanie Chandler to: Nicole Prentice

2010-12-15 05:21 PM

Cc: Christine Roush, Jocelyn Kula, Denis Arsenault, CSTD-OCS-DO

Hi Nicole,

The following has been approved by Jocelyn. However I believe you have an extension on these requests in order for you to consult with HPFB tomorrow.

Regards,

Stephanie

Stephanie Chandler

Junior Regulatory Project Officer

Regulatory Policy Division/ Division de la politique réglementaire

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs

Health Canada/ Santé Canada

Tel: (613) 946-0124, Fax: (613) 946-4224

E-Mail: stephanie.chandler@hc-sc.gc.ca

----- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2010-12-15 05:19 PM -----

From: Stephanie Chandler/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC, CSTD-OCS-DO  
Date: 2010-12-15 05:08 PM  
Subject: Re: URGENT: Media enquiry - CTV - salvia

Hi Jocelyn,

Salvia media request # 3 for your review.

Q1) Is it approved by HC or not? Is it legal? Banned?

A1) The plant *Salvia divinorum* is not regulated under the *Controlled Drugs and Substances Act* (CDSA) and therefore activities with it are not considered illegal in Canada. Health Canada is currently assessing whether the regulation of *Salvia divinorum* and/or salvinorin A under the CDSA is warranted. However, because *Salvia divinorum* is a plant with hallucinogenic properties, it meets the definition of a natural health product (NHP) under the *Natural Health Products Regulations* when marketed as such. The sale of unauthorized natural health products containing *Salvia divinorum* and/or salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

Nicole Prentice

Hi Jocelyn, Please see another request below fr...

2010-12-15 04:41:31 PM

From: Nicole Prentice/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Christine Roush/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, CSTD-DGO, CSTD-OCS-DO  
Date: 2010-12-15 04:41 PM  
Subject: URGENT: Media enquiry - CTV - salvia

Hi Jocelyn,



**Fw: For input/approval: Media enquiry - Vancouver Sun - Salvia**

Stephanie Chandler to: Jocelyn Kula  
Cc: Denis Arsenault, CSTD-OCS-DO

2010-12-15 04:34 PM

Hi Jocelyn,

Revised as per discussion. Denis has reviewed.

Stephanie

----- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2010-12-15 03:02 PM -----

From: Nicole Prentice/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Christine Roush/HC-SC/GC/CA@HWC, CSTD-OCS-DO, Denis Arsenault/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2010-12-15 03:00 PM  
Subject: For input/approval: Media enquiry - Vancouver Sun - Salvia

Hi again,

Here is the second media enquiry for your input/approval, hopefully by 3:30pm today. This is due asap. Again, proposed responses have been taken from previous enquiries.

Thanks in advance.  
Nicole

**Q1) What has HC learned about how Salvia is used by Canadians?**

A1)

Recently there have been reports suggesting that Canadian teens and young adults are using *Salvia divinorum* for its ability to produce hallucinations. Certain websites are also promoting the use of *Salvia divinorum* as a "legal" alternative to street drugs.

Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, less than 2% of Canadians age 15 and older reported having used *Salvia divinorum* at least once in their lifetime. Youth, ages 15-24 were much more likely to have used it than adults. The results from the *Canadian 2008-2009 Youth Smoking Survey* show that 5% of 15 year olds have used *Salvia divinorum* in the past year.

Health Canada does not recommend the use of products containing *S. divinorum* and/or its main active ingredient salvinorin A because very little is known about these substances and their potential effects on the brain and/or body, and their impact on physical and mental functions.

~~Health Canada is aware of salvia and has noted media interest regarding the availability of *Salvia divinorum* in Canada.~~

~~To date, Health Canada has not licensed for sale any drug or Natural Health Product which contains salvia as an ingredient.~~

~~It is a contravention of the *Food and Drugs Act* and the *Natural Health Products Regulations* to sell Natural Health Products in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN) on the label. The sale of unauthorized natural health~~

~~products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.~~

~~Complaints about the sale of unauthorized products containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate by calling 1-800-267-9675.~~

Q2) How does HC classify Salvia?

- ① A2) The plant *Salvia divinorum* is not controlled under the *Controlled Drugs and Substances Act* (CDSA) and therefore ~~is~~ not considered illegal in Canada. ~~However, *Salvia divinorum* is a plant with hallucinogenic properties when consumed by humans, it meets the definition of a natural health product (NHP) under the *Natural Health Products Regulations* when marketed as a hallucinogen. To date, Health Canada has not licensed for sale any Natural Health Product which contains *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.~~
- ② Health Canada is currently assessing whether the regulation of ~~*Salvia divinorum* and/or salvinorin A~~ under the CDSA is warranted.

~~Health Canada is currently reviewing all the available information regarding *Salvia divinorum*, including the prevalence of its use in Canada, to determine whether regulation of *Salvia divinorum* under the *Controlled Drugs and Substances Act* (CDSA) is warranted.~~

~~A controlled substance is any type of drug that the federal government has categorized as having a higher than average potential for abuse or addiction. Such drugs are divided into categories based on their potential for abuse or addiction. Controlled substances range from illegal street drugs to prescription medications.~~

~~Health Canada considers several factors in determining whether regulation of a substance under the CDSA is warranted.~~

~~These include:-~~

- ~~• Overall risk to public health and safety posed by the substance.~~
- ~~• Chemical and pharmacological similarity to other substances already regulated under the CDSA;~~
- ~~• Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);~~
- ~~• Potential for abuse and risk of addiction associated with the substance;~~
- ~~• Extent of actual abuse of the substance in Canada and internationally; and~~
- ~~• International requirements and trends in international control.~~

**Nicole Prentice**

Junior Communications Officer | Agente junior des Communications  
Regulatory Communications and Media Relations Division | Division des communications réglementaires et des relations avec les médias  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la consultation et des communications  
Health Canada | Santé Canada  
Tel: 613.941.3107  
Fax: 613.948.8085



**Fw: For input/approval: Media enquiry - Vancouver Sun - Salvia**

Stephanie Chandler to: Jocelyn Kula  
Cc: Denis Arsenault, CSTD-OCS-DO

2010-12-15 03:25 PM

Hi Jocelyn,

Media request #2 for your review. Denis has already reviewed. Please note that the NHP-related lines come from a previous media request which HPFB reviewed. Nicole also does not seem to think that HPFB needs to review these, however we would like to confirm that you agree.

Thanks,

Stephanie

----- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2010-12-15 03:02 PM -----

From: Nicole Prentice/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Christine Roush/HC-SC/GC/CA@HWC, CSTD-OCS-DO, Denis Arsenault/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2010-12-15 03:00 PM  
Subject: For input/approval: Media enquiry - Vancouver Sun - Salvia

Hi again,

Here is the second media enquiry for your input/approval, hopefully by 3:30pm today. This is due asap. Again, proposed responses have been taken from previous enquiries.

Thanks in advance.

Nicole

**Q1) What has HC learned about how Salvia is used by Canadians?**

A1)

Recently there have been reports suggesting that Canadian teens and young adults are using *Salvia divinorum* for its ability to produce hallucinations. Certain websites are also promoting the use of *Salvia divinorum* as a "legal" alternative to street drugs.

Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, less than 2% of Canadians age 15 and older reported having used *Salvia divinorum* at least once in their lifetime. Youth, ages 15-24 were much more likely to have used it than adults. The results from the *Canadian 2008-2009 Youth Smoking Survey* show that 5% of 15 year olds have used *Salvia divinorum* in the past year.

Health Canada does not recommend the use of products containing *S. divinorum* and/or its main active ingredient salvinorin A because very little is known about these substances and their potential effects on the brain and/or body, and their impact on physical and mental functions.

~~Health Canada is aware of salvia and has noted media interest regarding the availability of *Salvia divinorum* in Canada.~~

~~To date, Health Canada has not licensed for sale any drug or Natural Health Product which contains salvia as an ingredient.~~

It is a contravention of the *Food and Drugs Act* and the *Natural Health Products Regulations* to sell Natural Health Products in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN) on the label. The sale of unauthorized natural health products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

Complaints about the sale of unauthorized products containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate by calling 1-800-267-9675.

## Q2) How does HC classify Salvia?

*revise discussion per Cathy*  
A2) When products containing *Salvia divinorum* and/or its main active ingredient salvinorin A are sold for the purposes of modifying brain function (such as for their hallucinogenic effect), they meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*. It is a contravention of the *Food and Drugs Act* and the *Natural Health Products Regulations* to sell Natural Health Products in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN) on the label. To date, Health Canada has not licensed for sale any drug or Natural Health Product which contains salvia as an ingredient. The sale of unauthorized natural health products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

Complaints about the sale of unauthorized products containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate by calling 1-800-267-9675.

~~Neither *Salvia divinorum* nor salvinorin A are currently <sup>regulated</sup> controlled under the *Controlled Drugs and Substances Act* (CDSA). However, Health Canada is currently assessing whether ~~the~~ regulation of *Salvia divinorum* and/or salvinorin A under the CDSA is warranted.~~ *He*

~~Health Canada is currently reviewing all the available information regarding *Salvia divinorum*, including the prevalence of its use in Canada, to determine whether regulation of *Salvia divinorum* under the *Controlled Drugs and Substances Act* (CDSA) is warranted.~~

~~A controlled substance is any type of drug that the federal government has categorized as having a higher than average potential for abuse or addiction. Such drugs are divided into categories based on their potential for abuse or addiction. Controlled substances range from illegal street drugs to prescription medications.~~

~~Health Canada considers several factors in determining whether regulation of a substance under the CDSA is warranted.~~

~~These include:-~~

- ~~• Overall risk to public health and safety posed by the substance.~~
- ~~• Chemical and pharmacological similarity to other substances already regulated under the CDSA;~~
- ~~• Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);~~
- ~~• Potential for abuse and risk of addiction associated with the substance;~~
- ~~• Extent of actual abuse of the substance in Canada and internationally; and~~
- ~~• International requirements and trends in international control.~~

**Nicole Prentice**

Junior Communications Officer | Agente junior des Communications  
Regulatory Communications and Media Relations Division | Division des communications  
réglementaires et des relations avec les médias  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires  
publiques, de la consultation et des communications  
Health Canada | Santé Canada  
Tel: 613.941.3107  
Fax: 613.948.8085

----- Forwarded by Nicole Prentice/HC-SC/GC/CA on 2010-12-15 02:58 PM -----

From: David Thomas/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC, Paul Spendlove/HC-SC/GC/CA@HWC  
Cc: Nicole Prentice/HC-SC/GC/CA@HWC, Dave Stephens/HC-SC/GC/CA@HWC  
Date: 2010-12-15 02:00 PM  
Subject: Media enquiry - Vancouver Sun - Salvia

---

Good afternoon,

- Q1) What has HC learned about how Salvia is used by Canadians?
- Q2) How does HC classify Salvia?
- Q3) Wants copy of statement we sent to CP

Deadline: Today ASAP

Thanks

Dave

David Thomas  
Media Relations Officer | Agent des relations avec les médias  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la  
consultation et des communications  
Health Canada | Santé Canada  
613.946.4250  
david.thomas@hc-sc.gc.ca  
Government of Canada | Gouvernement du Canada





**Fw: For input/approval: Media enquiry - Vancouver Sun - Salvia**  
Stephanie Chandler to: Denis Arsenault

2010-12-15 03:16 PM

Hi Denis,

For your review. Please note that the NHP-related lines come from a previous media request which HPFB reviewed. Nicole also does not seem to think that HPFB needs to review these, however it should be confirmed with JK.

Stephanie

----- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2010-12-15 03:02 PM -----

From: Nicole Prentice/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Christine Roush/HC-SC/GC/CA@HWC, CSTD-OCS-DO, Denis Arsenault/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2010-12-15 03:00 PM  
Subject: For input/approval: Media enquiry - Vancouver Sun - Salvia

Hi again,

Here is the second media enquiry for your input/approval, hopefully by 3:30pm today. This is due asap. Again, proposed responses have been taken from previous enquiries.

Thanks in advance.  
Nicole

**Q1) What has HC learned about how Salvia is used by Canadians?**

A1)

Recently there have been reports suggesting that Canadian teens and young adults are using *Salvia divinorum* for its ability to produce hallucinations. Certain websites are also promoting the use of *Salvia divinorum* as a "legal" alternative to street drugs. ~~As of December 2010 Health Canada has not authorized for sale any products containing *Salvia divinorum*.~~

Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, less than 2% of Canadians age 15 and older reported having used *Salvia divinorum* at least once in their lifetime. Youth, ages 15-24 were much more likely to have used it than adults. The results from the *Canadian 2008-2009 Youth Smoking Survey* show that 5% of 15<sup>yr</sup>olds have used *Salvia divinorum* in the past year. <sup>spell</sup>

Health Canada does not recommend the use of products containing *S. divinorum* and/or its main active ingredient salvinorin A because very little is known about these substances and their potential effects on the brain and/or body, and their impact on physical and mental functions.

~~Health Canada is aware of salvia and has noted media interest regarding the availability of *Salvia divinorum* in Canada.~~

~~To date, Health Canada has not licensed for sale any drug or Natural Health Product which contains salvia as an ingredient.~~

~~It is a contravention of the *Food and Drugs Act* and the *Natural Health Products Regulations* to sell Natural Health Products in Canada unless they have been reviewed by Health Canada and authorized for~~

~~sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN) on the label. The sale of unauthorized natural health products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.~~

~~Complaints about the sale of unauthorized products containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate by calling 1-800-267-9675.~~

## Q2) How does HC classify Salvia?

A2) When products containing *Salvia divinorum* and/or its main active ingredient salvinorin A are sold for the purposes of modifying brain function (such as, for their hallucinogenic effect), they meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*. It is a contravention of the *Food and Drugs Act* and the *Natural Health Products Regulations* to sell Natural Health Products in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN) on the label. To date, Health Canada has not licensed for sale any drug or Natural Health Product which contains salvia as an ingredient. The sale of unauthorized natural health products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

~~Complaints about the sale of unauthorized products containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate by calling 1-800-267-9675.~~

~~Neither *Salvia divinorum* nor salvinorin A are currently controlled under the *Controlled Drugs and Substances Act* (CDSA). However, Health Canada is currently assessing whether the regulation of *Salvia divinorum* and/or salvinorin A under the CDSA is warranted.~~

~~Health Canada is currently reviewing all the available information regarding *Salvia divinorum*, including the prevalence of its use in Canada, to determine whether regulation of *Salvia divinorum* under the *Controlled Drugs and Substances Act* (CDSA) is warranted.~~

~~A controlled substance is any type of drug that the federal government has categorized as having a higher than average potential for abuse or addiction. Such drugs are divided into categories based on their potential for abuse or addiction. Controlled substances range from illegal street drugs to prescription medications.~~

~~Health Canada considers several factors in determining whether regulation of a substance under the CDSA is warranted.~~

~~These include:-~~

- ~~• Overall risk to public health and safety posed by the substance.~~
- ~~• Chemical and pharmacological similarity to other substances already regulated under the CDSA;~~
- ~~• Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);~~
- ~~• Potential for abuse and risk of addiction associated with the substance;~~
- ~~• Extent of actual abuse of the substance in Canada and internationally; and~~
- ~~• International requirements and trends in international control.~~

**Nicole Prentice**

Junior Communications Officer | Agente junior des Communications  
Regulatory Communications and Media Relations Division | Division des communications  
réglementaires et des relations avec les médias  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires  
publiques, de la consultation et des communications  
Health Canada | Santé Canada  
Tel: 613.941.3107  
Fax: 613.948.8085

----- Forwarded by Nicole Prentice/HC-SC/GC/CA on 2010-12-15 02:58 PM -----

From: David Thomas/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC, Paul Spendlove/HC-SC/GC/CA@HWC  
Cc: Nicole Prentice/HC-SC/GC/CA@HWC, Dave Stephens/HC-SC/GC/CA@HWC  
Date: 2010-12-15 02:00 PM  
Subject: Media enquiry - Vancouver Sun - Salvia

---

Good afternoon,

- Q1) What has HC learned about how Salvia is used by Canadians?
- Q2) How does HC classify Salvia?
- Q3) Wants copy of statement we sent to CP

Deadline: Today ASAP

Thanks

Dave

David Thomas  
Media Relations Officer | Agent des relations avec les médias  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la  
consultation et des communications  
Health Canada | Santé Canada  
613.946.4250  
david.thomas@hc-sc.gc.ca  
Government of Canada | Gouvernement du Canada



**Fw: For input/approval: Media enquiry - Vancouver Sun - Salvia**

Stephanie Chandler to: Nicole Prentice

2010-12-15 05:06 PM

Cc: Christine Roush, Jocelyn Kula, Denis Arsenault, CSTD-OCS-DO

Hi Nicole,

Sorry for the delay. Please see our revisions below. Has been reviewed by Jocelyn. The Global and CTV requests are on their way.

Stephanie

----- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2010-12-15 03:02 PM -----

From: Nicole Prentice/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Christine Roush/HC-SC/GC/CA@HWC, CSTD-OCS-DO, Denis Arsenault/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2010-12-15 03:00 PM  
Subject: For input/approval: Media enquiry - Vancouver Sun - Salvia

Hi again,

Here is the second media enquiry for your input/approval, hopefully by 3:30pm today. This is due asap. Again, proposed responses have been taken from previous enquiries.

Thanks in advance.

Nicole

**Q1) What has HC learned about how Salvia is used by Canadians?**

A1)

Recently there have been reports suggesting that Canadian teens and young adults are using *Salvia divinorum* for its hallucinogenic properties. Certain websites are also promoting the use of *Salvia divinorum* as a "legal" alternative to street drugs.

Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, less than 2% of Canadians age 15 and older reported having used *Salvia divinorum* at least once in their lifetime. Youth, ages 15-24 were much more likely to have used it than adults. The results from the *Canadian 2008-2009 Youth Smoking Survey* show that 5% of 15 year olds have used *Salvia divinorum* in the past year.

Health Canada does not recommend the use of products containing *S. divinorum* and/or its main active ingredient salvinorin A because very little is known about these substances and their potential effects on the brain and/or body, and their impact on physical and mental functions.

~~Health Canada is aware of salvia and has noted media interest regarding the availability of *Salvia divinorum* in Canada.~~

~~To date, Health Canada has not licensed for sale any drug or Natural Health Product which contains salvia as an ingredient.~~

~~It is a contravention of the *Food and Drugs Act* and the *Natural Health Products Regulations* to sell Natural Health Products in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN) on the label. The sale of unauthorized natural health products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement~~

~~action by Health Canada under the *Food and Drugs Act*.~~

~~Complaints about the sale of unauthorized products containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate by calling 1-800-267-9675.~~

**Q2) How does HC classify Salvia?**

A2) The plant *Salvia divinorum* is not regulated under the *Controlled Drugs and Substances Act* (CDSA) and therefore activities with it are not considered illegal in Canada. Health Canada is currently assessing whether the regulation of *Salvia divinorum* and/or salvinorin A under the CDSA is warranted. However, because *Salvia divinorum* is a plant with hallucinogenic properties, it meets the definition of a natural health product (NHP) under the *Natural Health Products Regulations* when marketed as such. The sale of unauthorized natural health products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

~~Health Canada is currently reviewing all the available information regarding *Salvia divinorum*,, including the prevalence of its use in Canada, to determine whether regulation of *Salvia divinorum* under the *Controlled Drugs and Substances Act* (CDSA) is warranted.~~

~~A controlled substance is any type of drug that the federal government has categorized as having a higher than average potential for abuse or addiction. Such drugs are divided into categories based on their potential for abuse or addiction. Controlled substances range from illegal street drugs to prescription medications.~~

~~Health Canada considers several factors in determining whether regulation of a substance under the CDSA is warranted.~~

~~These include:-~~

- ~~• Overall risk to public health and safety posed by the substance.~~
- ~~• Chemical and pharmacological similarity to other substances already regulated under the CDSA;~~
- ~~• Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);~~
- ~~• Potential for abuse and risk of addiction associated with the substance;~~
- ~~• Extent of actual abuse of the substance in Canada and internationally; and~~
- ~~• International requirements and trends in international control.~~

**Nicole Prentice**

Junior Communications Officer | Agente junior des Communications  
Regulatory Communications and Media Relations Division | Division des communications réglementaires et des relations avec les médias  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la consultation et des communications  
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----- Forwarded by Nicole Prentice/HC-SC/GC/CA on 2010-12-15 02:58 PM -----

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- Q2) How does HC classify Salvia?
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Deadline: Today ASAP

Thanks

Dave

David Thomas  
Media Relations Officer | Agent des relations avec les médias  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la  
consultation et des communications  
Health Canada | Santé Canada  
613.946.4250  
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Government of Canada | Gouvernement du Canada

Miley Cyrus smokes it, but Health Canada warns against use of 'Magic Mint'

# Miley Cyrus smokes it, but Health Canada warns against use of 'Magic Mint'

## Pop star piques interest in legal hallucinogen

BY RANDY SHORE, POSTMEDIA NEWS DECEMBER 16, 2010 8:11 AM

Health Canada is warning people to avoid using the hallucinogenic Mexican herb *Salvia divinorum* -- made famous in a Internet video showing pop star Miley Cyrus smoking the stuff -- until its effects are better understood.

Native to Oaxaca, Mexico, the plant known as Magic Mint or Seer's Sage has been used for centuries by Mazatec Indian shamans for medicinal purposes and to induce visions, but has also gained a foothold in Canada and the U.S. as a recreational drug.

*Salvia divinorum* is not illegal in Canada, but the herb has been under study by the national health agency since at least 2006 to determine whether it should be regulated under the Controlled Drug and Substance Act.

Health Canada warns that products containing *Salvia divinorum* or its extracts may violate the Food and Drugs Act, said agency spokesman Stephane Shank. Natural health products must be reviewed by Health Canada and approved for sale; so far no *Salvia* products have been approved.

Fortified *Salvia* is sold at head shops and some corner stores in a marijuana-like smokable form as well as in alcohol-based tinctures.

In its more potent forms, a few seconds of smoking *Salvia* induces intense, debilitating hallucinations that may last from 15 to 30 minutes, according to experienced users who responded to the Vancouver Sun.

"It's not even comparable to marijuana. I could not see, move or speak. I thought I had died and gone to hell," wrote a woman identified only as Betty C. "I could not remember my name, what I looked like, what species I was. I felt nothing but fear."

Interest in *Salvia* intensified late last week when a videotape leaked on the Internet showed pop star Miley Cyrus laughing and hallucinating after smoking the herb through a large plastic pipe.

YouTube contains dozens of videos of teens who enter a state of total disorientation and panic after smoking *Salvia divinorum*.

"What the video will do is raise awareness of this drug and that may lead to more people experimenting with it and raise demand and profits for legitimate and illegitimate enterprises," said Robert Gordon,

Miley Cyrus smokes it, but Health Canada warns against use of 'Magic Mint'

director of Simon Fraser University's School of Criminology.

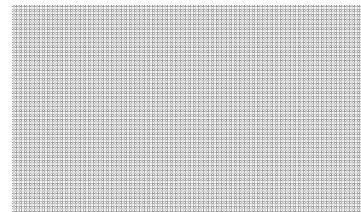
U.S. media reports suggest that sales of the herb have tripled in some states since the Miley Cyrus video was released. But Salvia is banned in 15 states, including Delaware, where the herb was blamed in the 2006 suicide of 16-year-old Brett Chidester.

A 24-year-old man convicted of raping and killing a mother of five on Calgary's C-Train in 2008 claimed to have been drinking and smoking Salvia beforehand. The court ruled that Christopher Watcheston was not so intoxicated that he didn't know what he was doing.

A 2009 drug-and alcohol-use survey conducted by Health Canada found that 0.5 per cent of adults have tried the herb, compared to 7.3 per cent of youth aged 15 to 24.

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Draft V.2

Response to Docket # 10-008895-624

To: [Redacted]

Dear [Redacted]

I am writing in response to your email enquiry dated December 14, 2010 concerning the legal status of *Salvia divinorum*.

The plant *Salvia divinorum* is not regulated under the *Controlled Drugs and Substances Act* (CDSA) and therefore the plant is not considered to be "banned", nor are activities with it considered to be illegal in Canada. However, as *Salvia divinorum* is a plant with hallucinogenic properties, it meets the definition of a natural health product (NHP) under the *Natural Health Products Regulations*, when marketed as a hallucinogen. To date, Health Canada has not licensed for sale any Natural Health Product which contains *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products containing *Salvia divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

authorized

does

It is, however, illegal to sell *Salvia* products if they are specifically marketed for use as hallucinogens.

However, when *Salvia* products are specifically marketed as hallucinogens, they are in

violation

Nonetheless, when specifically marketed for its hallucinogenic properties, *S. Divinorum* meets

s.19(1)



Re: URGENT: Media query - CBC ( [REDACTED] ) - Salvia

Jocelyn Kula to: Christine Roush

2010-12-17 05:22 PM

Cc: Nicole Prentice, Chantal Routhier-Garner, Denis Arsenault, Stephanie Chandler, Suzanne Desjardins

Building on Suzanne's input. Approved for OCS:

**1) Is salvia legal to take in Canada? Is salvia legal to sell in Canada? Has Health Canada Approved the sale of the drug? Is it classified as a banned substance?**

~~A1) Health Canada does not recommend the use of products containing *S. divinorum* and/or salvinorin A because very little is known about these substances and their potential effects on the brain and/or body, and their impact on physical and mental functions.~~

~~To date, Health Canada has not licensed for sale any drug or Natural Health Product which contains salvia as an ingredient.~~

~~It is a contravention of the *Food and Drugs Act* and the *Natural Health Products Regulations* to sell Natural Health Products in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN) on the label. The sale of unauthorized natural health products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.~~

~~Complaints about the sale of unauthorized products containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate by calling 1-800-267-9675.~~

The plant *Salvia divinorum* is not regulated under the *Controlled Drugs and Substances Act* (CDSA) and therefore the plant is not considered to be "banned" nor are activities with it considered to be illegal in Canada. However, as *Salvia divinorum* is a plant with hallucinogenic properties ~~when consumed by humans~~, it meets the definition of a natural health product (NHP) under the *Natural Health Products Regulations* when marketed as a hallucinogen. To date, Health Canada has not licensed for sale any ~~Natural Health Product~~ which contains *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products containing *S. divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

Complaints about the sale of unauthorized products containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate by calling 1-800-267-9675.

**2) Given the negative effects of side effects, why doesn't HC stop the sale of salvia? If it is illegal then why is it readily available? Why isn't there a greater push to enforce (a ban) the substance?**

A2) Health Canada is currently assessing whether the regulation of *Salvia divinorum* and/or salvinorin A under the *Controlled Drugs and Substances Act* is warranted.

**3) Since when has Health Canada been studying salvia?**

A3) Health Canada is taking steps to address the lack of data regarding the use of and/or extent of abuse involving *Salvia divinorum*. Questions regarding the use of *Salvia divinorum* were ~~have been~~ included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. In addition, questions regarding the use of *Salvia divinorum* in the general population were ~~have also been~~ included in the 2009 Canadian Alcohol and Drug Use Monitoring Survey and the data released in July 2010. ~~The data, however, will not likely be available until 2010. In the interim, Health Canada will continue to collect and consider information regarding *Salvia divinorum* as it becomes available. (URL:~~

<http://www.hc-sc.gc.ca/hc-ps/drugs-drogues/stat/index-eng.php>)

**4) What are your reactions to the Saskatchewan radio DJ openly getting high off salvia on his radio show today?**

A4) Health Canada does not recommend the use of products containing *S. divinorum* and/or salvinorin A because very little is known about these substances and their potential effects on the brain and/or body, and their impact on physical and mental functions.

**5) How many complaints has Health Canada received about the substance?**

A5) Health Canada has not received any complaints about this substance. [Could also include the line from past media responses re the four adverse reactions, as long as you also include the caveat about how one can't extrapolate from this because the number is so small....]

**6) Has anyone died from taking the substance?**

A6) We are not aware of a death having occurred in Canada as an immediate consequence of the use of the drug.

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

---

Suzanne Desjardins    Hi Nicole, Please see my input in blue below.    2010-12-17 04:53:37 PM

From: Suzanne Desjardins/HC-SC/GC/CA  
To: Nicole Prentice/HC-SC/GC/CA@HWC  
Cc: Chantal Routhier-Garner/HC-SC/GC/CA@HWC, Christine Roush/HC-SC/GC/CA@HWC, CSTD-DGO, CSTD-OCS-DO, Denis Arsenault/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2010-12-17 04:53 PM  
Subject: Re: URGENT: Media query - CBC ( ) - Salvia

---

Hi Nicole,  
Please see my input in blue below.

Thanks  
Suzanne

---

Nicole Prentice    Hi Jocelyn and Suzanne, Please see the media...    2010-12-17 04:09:27 PM

From: Nicole Prentice/HC-SC/GC/CA  
To: Suzanne Desjardins/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: CSTD-OCS-DO, Stephanie Chandler/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, CSTD-DGO, Christine Roush/HC-SC/GC/CA@HWC, Chantal Routhier-Garner/HC-SC/GC/CA@HWC  
Date: 2010-12-17 04:09 PM  
Subject: URGENT: Media query - CBC ( ) - Salvia

---

Hi Jocelyn and Suzanne,

Please see the media request below for CBC due asap. Can we get your input/approval by 4:45 at the latest. Responses have been pulled from previously approved material.

Suzanne - I think only Q3 is for your group.

Also, can you ensure Christine is cc'd on your response as she will be closing this call.

Thanks in advance.

**1) Is salvia legal to take in Canada? Is salvia legal to sell in Canada? Has Health Canada Approved the sale of the drug? Is it classified as a banned substance?**

A1) Health Canada does not recommend the use of products containing *S. divinorum* and/or salvinorin A because very little is known about these substances and their potential effects on the brain and/or body, and their impact on physical and mental functions.

To date, Health Canada has not licensed for sale any drug or Natural Health Product which contains salvia as an ingredient.

It is a contravention of the *Food and Drugs Act* and the *Natural Health Products Regulations* to sell Natural Health Products in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN) on the label. The sale of unauthorized natural health products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

Complaints about the sale of unauthorized products containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate by calling 1-800-267-9675.

**2) Given the negative effects of side effects, why doesn't HC stop the sale of salvia? If it is illegal then why is it readily available? Why isn't there a greater push to enforce (a ban) the substance?**

A2) Health Canada is currently assessing whether the regulation of *Salvia divinorum* and/or Salvinorin A under the *Controlled Drugs and Substances Act* is warranted.

**3) Since when has Health Canada been studying salvia?**

A3) Health Canada is taking steps to address the lack of data regarding the use of and/or extent of abuse involving *Salvia divinorum*. Questions regarding the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. In addition, questions regarding the use of *Salvia divinorum* in the general population have also been included in the 2009 Canadian Alcohol and Drug Use Monitoring Survey and the data released in July 2010. ~~The data, however, will not likely be available until 2010. In the interim, Health Canada will continue to collect and consider information regarding *Salvia divinorum* as it becomes available.~~ (URL: <http://www.hc-sc.gc.ca/hc-ps/drugs-drogués/stat/index-eng.php>)

**4) What are your reactions to the Saskatchewan radio DJ openly getting high off salvia on his radio show today?**

A4) Health Canada does not recommend the use of products containing *S. divinorum* and/or salvinorin A because very little is known about these substances and their potential effects on the brain and/or body, and their impact on physical and mental functions.

**5) How many complaints has Health Canada received about the substance?**

A5) For OCS input (Or HPFB?)

s.19(1)

**6) Has anyone died from taking the substance?**

A6) For OCS input We are not aware of a death having occurred in Canada as an immediate consequence of the use of the drug.

**Nicole Prentice**

Junior Communications Officer | Agente junior des Communications  
Regulatory Communications and Media Relations Division | Division des communications  
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publiques, de la consultation et des communications  
Health Canada | Santé Canada  
Tel: 613.941.3107  
Fax: 613.948.8085

----- Forwarded by Nicole Prentice/HC-SC/GC/CA on 2010-12-17 04:03 PM -----

From: Christine Roush/HC-SC/GC/CA  
To: Nicole Prentice/HC-SC/GC/CA@HWC  
Date: 2010-12-17 04:02 PM  
Subject: Re: Fw: Media query - CBC [REDACTED] Salvia

---

OK to go. thx.

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
Health Canada/Santé Canada  
Tel/Tél : (613) 954-0712/Cell: (613) 219-7194  
Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca

Nicole Prentice For your review...I know we need to send this to... 2010-12-17 03:25:14 PM

From: Nicole Prentice/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Date: 2010-12-17 03:25 PM  
Subject: Fw: Media query - CBC [REDACTED] - Salvia

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**1) Is salvia legal to take in Canada? Is salvia legal to sell in Canada? Has Health Canada Approved the sale of the drug? Is it classified as a banned substance?**

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**3) Since when has Health Canada been studying salvia?**

A3) Health Canada is taking steps to address the lack of data regarding the use of and/or extent of abuse involving *Salvia divinorum*. Questions regarding the use of *Salvia divinorum* have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. In addition, questions regarding the use of *Salvia divinorum* in the general population have also been included in the 2009 Canadian Alcohol and Drug Use Monitoring Survey. The data, however, will not likely be available until 2010. In the interim, Health Canada will continue to collect and consider information regarding *Salvia divinorum* as it becomes available.

**4) What are your reactions to the Saskatchewan radio DJ openly getting high off salvia on his radio show today?**

A4) Health Canada does not recommend the use of products containing *S. divinorum* and/or salvininorin A because very little is known about these substances and their potential effects on the brain and/or body, and their impact on physical and mental functions.

**5) How many complaints has Health Canada received about the substance?**

A5) For OCS input (Or HPFB?) Should I refer MR to contact HPFB on this - I couldn't find anything in the database.

**6) Has anyone died from taking the substance?**

A6) For OCS input - I couldn't find anything in the database.

**Nicole Prentice**

Junior Communications Officer | Agente junior des Communications  
Regulatory Communications and Media Relations Division | Division des communications réglementaires et des relations avec les médias  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la consultation et des communications  
Health Canada | Santé Canada

s.19(1)

Tel: 613.941.3107  
Fax: 613.948.8085

----- Forwarded by Nicole Prentice/HC-SC/GC/CA on 2010-12-17 03:15 PM -----

From: Gary Holub/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC, Nicole Prentice/HC-SC/GC/CA@HWC  
Cc: Dave Stephens/HC-SC/GC/CA@HWC  
Date: 2010-12-17 03:10 PM  
Subject: Media query - CBC - Salvia

Hi folks,

How quickly can we bring these responses together? I'm working for flexibility with CBC, but they initially requested 4pm. I'll let you know their revised deadline asap.

- 1) Is salvia legal to take in Canada? Is salvia legal to sell in Canada? Has Health Canada Approved the sale of the drug? Is it classified as a banned substance?
- 2) Given the negative effects of side effects, why doesn't HC stop the sale of salvia? If it is illegal then why is it readily available? Why isn't there a greater push to enforce (a ban) the substance?
- 3) Since when has Health Canada been studying salvia?
- 4) What are your reactions to the Saskatchewan radio DJ openly getting high off salvia on his radio show today?
- 5) How many complaints has Health Canada received about the substance?
- 6) Has anyone died from taking the substance?

Deadline ASAP

\*\*\*

thanks,  
Gary

Gary Scott Holub  
Media Relations Officer | Agent des relations avec les médias  
Regulatory Communications and Media Relations Division | Division des communications réglementaires et des relations avec les médias  
Health Canada | Santé Canada  
(t) 613.954.4807  
(e) gary.holub@hc-sc.gc.ca  
Government of Canada | Gouvernement du Canada

----- Forwarded by Gary Holub/HC-SC/GC/CA on 2010-12-17 03:06 PM -----



### Media Enquiry - Demande médiatique

Name/Nom : [REDACTED]	Media/Média : CTV National News
Telephone/Téléphone : [REDACTED]	Language/Langue : English-anglais
Cell Telephone/Téléphone cellulaire : [REDACTED]	Fax/Télécopieur :
Email/Courriel :	
Date and Time Received Date et Heure de réception : 2010-12-17 12:05:30 PM	Date Completed Date d'achèvement :

s.19(1)

Subject/Objet : Controlled Substances/Substances contrôlées

Question:

Add to the Question/ajouter a la question

2010-12-17 12:05:31 PM (Gary Holub)

CTV National News

Re: salvia

2010-12-17 3:05:04 PM (Gary Holub)

Here are the questions I have. HC refers to Health Canada.

- 1) Is salvia legal to take in Canada?
- 2) Is salvia legal to sell in Canada?
- 3) Is it classified as a banned substance?
- 4) Given the negative effects of side effects, why doesn't HC stop the sale of salvia?
- 5) Since when has Health Canada been studying salvia?
- 6) Has Health Canada Approved the sale of the drug?
- 7) If it is illegal then why is it readily available? Why isn't there a greater push to enforce the substance?
- 8) What are your reactions to the Saskatchewan radio DJ openly getting high off salvia on his radio show today?
- 9) How many complaints has Health Canada received about the substance?
- 10) Has anyone died from taking the substance?

If you could get back to me by 4 Eastern that would be terrific!

Response/Réponse :

Add to the Response/ajouter a la réponse

Action Taken/Mesures prises :

Add to the Action Taken/ajouter au mesures prises

2010-12-17 12:07:14 PM (Gary Holub)

Awaitin Qs

2010-12-17 3:06:26 PM (Gary Holub)

Sent to CSTD

Interview with spokesperson granted/Entrevue avec porte-parole accordé:  Yes-Oui  No-Non

Branch/Direction générale : HECS - Controlled Substances & Drug Analysis/DGSESC - Direction de la sécurité des substances chimiques et des produits de consommation

Spokesperson/Porte-parole :

Reporter's Deadline

Heure de tombée du journaliste :

Priority/Priorité : Regular

Telephone/Téléphone :

Story Run Date

Date de parution de l'article :

Status/Rapport de situation : Follow-up

Comment/Commentaire :

Attachments/Pièces jointes :



**Related Clippings/Coupages connexes :**

**Media Relations Officer/Agente de relations avec les médias :** Gary Holub

**Edit History / Historique des révisions**

**Send To / Transmettre à :** Suzanne Desjardins; Stephanie Szick; Christine von Arx; Ken Moore; Christine Roush; Nicole Prentice; Dave Stephens; Jeannine Ritchot; Paul Spendlove; Louise Bertrand; Jesse Arnup-Blondin; Charles Mojsej/HC-SC/GC/CA; Jean Tessier/HC-SC/GC/CA; Tim Vail/HC-SC/GC/CA; Jenny VanAlstyne/HC-SC/GC/CA; Warren Braun/HC-SC/GC/CA;

**Branch Recipient:**

Suzanne Desjardins, Stephanie Szick, Christine von Arx, Ken Moore, Christine Roush, Nicole Prentice, Dave Stephens, Jeannine Ritchot, Paul Spendlove, Louise Bertrand, Jesse Arnup-Blondin

**Mail Recipients:**

CN=Charles Mojsej/OU=HC-SC/O=GC/C=CA, CN=Jean Tessier/OU=HC-SC/O=GC/C=CA, CN=Tim Vail/OU=HC-SC/O=GC/C=CA, CN=Jenny VanAlstyne/OU=HC-SC/O=GC/C=CA, CN=Warren Braun/OU=HC-SC/O=GC/C=CA

DRAFT 14  
December 17, 2010

## Media Lines *Salvia divinorum*

### Issue

Further to ongoing media interest regarding the availability of *Salvia divinorum* in Canada and reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties, Health Canada has concluded that *Salvia divinorum* and its main active ingredient salvinorin A should be regulated under the *Controlled Drugs and Substances Act* (CDSA), in order to protect the health and safety of Canadians, particularly youth.

### Key Messages:

- Health Canada has concluded its assessment of *S. divinorum* and salvinorin A and is proposing to regulate both substances under the CDSA, in order to protect the health and safety of Canadians, particularly youth.
- The inclusion of *S. divinorum* and salvinorin A in one of the Schedules to the CDSA will reduce the potential health and safety risks associated with <sup>the</sup> their ready availability, apparent increased ~~use and~~ abuse and the unknown effects of these substances. Further to the regulation of these substances under the CDSA, the following activities may be prohibited unless authorized by regulation: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation).
- Health Canada will inform stakeholders of its decision by publishing a *Notice to Interested Parties* (NOI) in *Canada Gazette*, Part I. The NOI will provide stakeholders and other interested parties with the opportunity to provide comments on the proposal to regulate these substances as controlled substances.

### Supplementary Messages:

- Canadians should not use products containing *S. divinorum* and/or salvinorin A because very little is known about these substances and their potential effects on the brain and/or body, and their impact on physical and mental functions.
- Because of <sup>may</sup> their hallucinogenic properties, products containing *S. divinorum* and/or salvinorin A <sup>may</sup> meet the definition of a natural health product (NHP) under the Natural Health Products Regulations and the definition of a drug under the Food and Drugs Act.
- As *S. divinorum* is a plant with hallucinogenic properties, it meets the definition of a natural health product under the *Natural Health Products Regulations* (NHPR) when marketed as such. The unauthorized sale of products containing *S. divinorum* and/or

a hallucinogen.

salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*.

### Questions and Answers:

#### **Q1 – Are *Salvia divinorum* and/or salvinorin A controlled internationally? How are these substances regulated in other countries?**

A1 - Neither *S. divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and thus, do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

The move to include *S. divinorum* and salvinorin A in one of the Schedules to the CDSA is consistent with actions taken by several countries (Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. It is also consistent with the fact that some individual U.S. states have implemented laws restricting their use, sale and/or distribution.

#### **Q2 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum* as a controlled substance. What does that involve and what stage is it at?**

A2 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada recently concluded its assessment of *S. divinorum* and salvinorin A against the aforementioned factors and proposes to include both substances in one of the Schedules to the CDSA. The regulation of these products will reduce the potential risks to the health and safety of Canadians associated with their ready availability, apparent increased use and abuse and their unknown effects. <sup>of these substances</sup> The scheduling of *S. divinorum* and salvinorin A will also eliminate the perception that these substances are safe since they are not illegal.

#### **Q3 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why isn't it illegal?**

A3 – Health Canada intends to include *S. divinorum* and salvinorin A under one of the Schedules to the CDSA. Further to the regulation of these substances under the CDSA, the following activities may be prohibited unless authorized by regulation: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of

exportation, and production (or cultivation). Law enforcement agencies will then be able to take action against suspected illegal activities involving these substances.

In the interim, as *S. divinorum* meets the definition of a Natural Health Product (NHP) under the *Natural Health Product Regulations*, it is illegal to manufacture, sell or provide products containing *S. divinorum* and/or salvinorin A without their being authorized by Health Canada prior to sale.

**Q4 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?**

A4 – The *Natural Health Products Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *S. divinorum*. When *S. divinorum* and salvinorin A are included in one of the Schedules to the CDSA, it will be illegal to possess, import, export, produce and distribute these substances in any form unless authorized by regulation. Law enforcement agencies will then be able to take appropriate action in response to such illegal activities.

**Q5 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A5 – Once *S. divinorum* and salvinorin A are included in one of the Schedules to the CDSA, law enforcement will be able to take appropriate action in response to suspected illegal activities with these substances.

In the interim, *S. divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. Complaints about the illegal sale of drugs containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

***If pressed on whether Health Canada has issued any kind of warning to Canadians about *Salvia divinorum****

A - Health Canada is developing an It's Your Health article on *Salvia divinorum* to help inform the general public about the risks associated with the use of this plant.

**Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

Data from the 2008-2009 Youth Smoking Survey indicates that:

- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;
- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year; and.
- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using Salvia in their lifetime (0.2% in the past year); and
- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that:

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;
- 5.4% of students (grades 7-12) ever used *S. divinorum*; and
- the use of *S. divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

**Prepared by:** Stephanie Chandler and Denis Arsenault, OCS, CSTD

**Input by:** Lisa Mackay IYH/PACCB, Suzanne Desjardins HECSB/ODARS, Hanan Abramovici HECSB/ODARS, Bruna Brands HECSB/ODARS, Jocelyn Kula, HECSB/OCS, Robin Marles HPFB/NHPD, Maggie Graham HPFB/NHPD, Stephanie Collins HPFB/NHPD, Mano Murty HPFB/MHPD, Robert Leitch HPFB/MHPD, Shahid Perwaiz HPFB/MHPD, Collin Pinto, HPFB/HPFBI

**Approved by:**

Robin Marles, Director, Bureau of Clinical Trials, NHPD (pending)  
Lindsay Blaney, Director, Policy and Regulatory Affairs, NHPD (pending)  
Duc Vu, Director, Marketed Biologics, Biotechnology and Natural Health Products Bureau, MHPD (pending)  
Kim Dayman-Rutkas, Director, HPFBI (pending)  
Diane Allan, Director, OCS, CSTD, HECS (approved, Sept 29, 2010)  
Suzanne Desjardins, Director, ODARS, CSTD, HECS approved, Sept 30, 2010)  
Cathy Sabiston, DG, CSTD, HECS (pending)  
Chris Turner, DG, MHPD (pending)  
Nancy Richards, DG, NHPD (pending)  
Diana Dowthwaite, DG, HPFBI (pending)  
Ken Polk, Communications Executive, HPFB (pending)  
Jean Tessier, Senior Media Relations, PACCB (pending)  
Warren Braun, Director, Strategic Communications, PACCB (pending)

Peter Yendall, Director, Public Affairs, PACCB (pending)  
HECS Legal (pending)  
HPFB Legal (pending)  
Paul Glover, ADM, HECSB (pending)  
Meena Ballantyne, ADM, HPFB (pending)  
Anne Lamar, ADM, PACCB (pending)  
DMO (pending)  
MO (pending)  
PCO (pending)

DRAFT 14  
December 17, 2010

**Media Lines**  
*Salvia divinorum*

**Issue**

Ongoing media interest regarding the availability of *Salvia divinorum* in Canada and reports from scientific and media sources suggest that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has concluded that *Salvia divinorum* and its main active ingredient salvinorin A should be regulated under the *Controlled Drugs and Substances Act* (CDSA), in order to protect the health and safety of Canadians, particularly youth.

**Key Messages:**

- Health Canada has concluded its assessment of *S. divinorum* and salvinorin A, and is proposing to regulate both substances under the CDSA in order to protect the health and safety of Canadians, particularly youth.
- The inclusion of *S. divinorum* and salvinorin A in one of the Schedules to the CDSA will reduce the potential health and safety risks associated with the ready availability, apparent increased ~~use~~ and unknown effects of these substances. Further to the regulation of these substances under the CDSA, the following activities may be prohibited unless authorized by regulation: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation).
- Health Canada will inform stakeholders of its decision by publishing a *Notice to Interested Parties* (NOI) in *Canada Gazette*, Part I. The NOI will provide stakeholders and other interested parties with the opportunity to provide comments on the proposal to regulate these substances as controlled substances.

use of...

its main active ingredient

proposal

salvia divinorum and salvinorin A

**Supplementary Messages:**

- Canadians should not use products containing *S. divinorum* and/or salvinorin A because very little is known about these substances and their potential effects on the brain and/or body, and their impact on physical and mental functions.
- Because of their hallucinogenic properties, products containing *S. divinorum* and/or salvinorin A may meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*.
- As *S. divinorum* is a plant with hallucinogenic properties, it meets the definition of a natural health product under the *Natural Health Products Regulations* (NHPR) when marketed as a hallucinogen. The unauthorized sale of products containing *S. divinorum*

such

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and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*,

**Questions and Answers:**

**Q1 – Are *Salvia divinorum* and/or salvinorin A controlled internationally? How are these substances regulated in other countries?**

A1 - Neither *S. divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions, and thus, do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

as a result, they

The move to include *S. divinorum* and salvinorin A in one of the Schedules to the CDSA is consistent with actions taken by several countries (Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. It is also consistent with the fact that some individual U.S. states have implemented laws restricting their use, sale and/or distribution.

**Q2 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum* as a controlled substance. What does that involve and what stage is it at?**

A2 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada recently concluded its assessment of *S. divinorum* and salvinorin A against the aforementioned factors and proposes to include both substances in one of the Schedules to the CDSA. The regulation of these products will reduce the potential risks to the health and safety of Canadians associated with the ready availability, apparent increased use and abuse and unknown effects of these substances. The scheduling of *S. divinorum* and salvinorin A will also eliminate the current perception that these substances are safe since they are not presently illegal.

Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, less than 2% of Canadians age 15 and older reported having used *S. divinorum* at least once in their lifetime. Youth, ages 15-24 were much more likely to have used it than adults. The results from the *Canadian 2008-2009 Youth Smoking Survey* show that 5% of 15 year olds have used *S. divinorum* in the past year.

can we formulate this another way?

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It is illegal to sell NHPs in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN). The illegal sale of products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*.

Deleted: ¶ *Salvia divinorum* as a controlled substance:¶

<#>In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA).

<#>Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Contr... [3]

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**Q3 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why isn't it illegal?**

A3 – Health Canada <sup>propose</sup> intends to include *S. divinorum* and salvinorin A under one of the Schedules to the CDSA. Further to the regulation of these substances under the CDSA, the following activities may be prohibited unless authorized by regulation: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation). Law enforcement agencies will then be able to take action against suspected illegal activities involving these substances.

In the interim, as <sup>products containing</sup> *S. divinorum* meets the definition of a Natural Health Product (NHP) under the *Natural Health Product Regulations*, it is illegal to manufacture, sell or provide products containing *S. divinorum* and/or salvinorin A without their being authorized by Health Canada prior to sale.

**Q4 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A4 – Once *S. divinorum* and salvinorin A are included in one of the Schedules to the CDSA, law enforcement will be able to take appropriate action in response to suspected illegal activities with these substances.

In the interim, *S. divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. Complaints about the illegal sale of drugs containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

**If pressed on whether Health Canada has issued any kind of warning to Canadians about *Salvia divinorum***

A - Health Canada is developing an It's Your Health article on *Salvia divinorum* to help inform the general public about the risks associated with the use of this plant.

**Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

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A2 – The *Natural Health Products Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *Salvia divinorum*. ¶

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A4 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:¶  
<#>International requirements and trends in international control;¶  
<#>Chemical and pharmacological similarity to other substances already regulated under the CDSA;¶  
<#>Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);¶  
<#>Potential for abuse and risk of addiction associated with the substance.¶  
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when marketed a) no hallucinogen

need to know this

Data from the 2008-2009 Youth Smoking Survey indicates that:

- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;
- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year; and.
- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

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Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using Salvia in their lifetime (0.2% in the past year); and
- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

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- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;
- 5.4% of students (grades 7-12) ever used *Salvia divinorum*; and
- the use of *Salvia divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

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**Prepared by:** Stephanie Chandler and Denis Arsenault, OCS, CSTD

Deleted: Cheryl Tremblay

**Input by:** Lisa Mackay IYH/PACCB, Suzanne Desjardins HECSB/ODARS, Hanan Abramovici HECSB/ODARS, Bruna Brands HECSB/ODARS, Jocelyn Kula, HECSB/OCS, Robin Marles HPFB/NHPD, Maggie Graham HPFB/NHPD, Stephanie Collins HPFB/NHPD, Mano Murty HPFB/MHPD, Robert Leitch HPFB/MHPD, Shahid Perwaiz HPFB/MHPD, Collin Pinto, HPFB/HPFBI

**Approved by:**

Robin Marles, Director, Bureau of Clinical Trials, NHPD (pending)  
Lindsay Blaney, Director, Policy and Regulatory Affairs, NHPD (pending)  
Duc Vu, Director, Marketed Biologics, Biotechnology and Natural Health Products Bureau, MHPD (pending)  
Kim Dayman-Rutkas, Director, HPFBI (pending)  
Diane Allan, Director, OCS, CSTD, HECS (approved, Sept 29, 2010)  
Suzanne Desjardins, Director, ODARS, CSTD, HECS approved, Sept 30, 2010)  
Cathy Sabiston, DG, CSTD, HECS (pending)  
Chris Turner, DG, MHPD (pending)  
Nancy Richards, DG, NHPD (pending)  
Diana Douthwaite, DG, HPFBI (pending)  
Ken Polk, Communications Executive, HPFB (pending)  
Jean Tessier, Senior Media Relations, PACCB (pending)  
Warren Braun, Director, Strategic Communications, PACCB (pending)  
Peter Yendall, Director, Public Affairs, PACCB (pending)  
HECS Legal (pending)  
HPFB Legal (pending)

Deleted: pending

Deleted: (pending)

Paul Glover, ADM, HECSB (pending)  
Meena Ballantyne, ADM, HPFB (pending)  
Anne Lamar, ADM, PACCB (pending)  
DMO (pending)  
MO (pending)  
PCO (pending)

Deleted: 1

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Page 1: [1] Deleted STCHANDL 2010-12-09 3:21:00 PM  
(Message is unclear – reduce what risks (to health, security, i.e., enforcement).

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Page 1: [2] Deleted STCHANDL 2010-12-17 11:05:00 AM  
It is illegal to sell NHPs in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN).

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Page 2: [3] Deleted STCHANDL 2010-11-26 2:27:00 PM

***Salvia divinorum as a controlled substance:***

In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA).

Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and thus, do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions. Several countries (Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) have placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Although some individual U.S. states have implemented laws restricting its use, sale and/or distribution, *Salvia divinorum* and salvinorin A are not regulated under the federal *Controlled Substances Act* in the United States.

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Page 3: [4] Deleted STCHANDL 2010-12-08 9:51:00 AM

**Q4 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum* as a controlled substance. What does that involve and what stage is it at?**

A4 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada is currently reviewing the available information to determine whether regulation of *Salvia divinorum* under the CDSA is warranted.

**Q5 – Didn't an internal report from Health Canada's Marketed Health Products Directorate recommend that *Salvia divinorum* be scheduled under the CDSA? Why has that recommendation not been acted upon?**

██████ A5 – See A4

**Q6 – What is the significance of the adverse reaction reports that Health Canada has received with respect to the use of *Salvia divinorum*?**

A6 – Health Canada has received four domestic adverse reaction reports related to the use of *Salvia divinorum* as a hallucinogen through the Canada Vigilance database. The number of reports and the nature of reactions reported are, however, not adequate to fully characterize the risk of similar reactions among the general population

**Send To / Transmettre à :** Suzanne Desjardins; Stephanie Szick; Christine von Arx; Ken Moore; Christine Roush; Nicole  
Prentice; Dave Stephens; Jeannine Ritchot; Paul Spendlove; Louise Bertrand; Jesse  
Arnup-Blondin; Charles Mojsej/HC-SC/GC/CA; Jean Tessier/HC-SC/GC/CA; Tim  
Vail/HC-SC/GC/CA; Jenny VanAlstyne/HC-SC/GC/CA; Warren Braun/HC-SC/GC/CA;

**Branch Recipient:**

Suzanne Desjardins, Stephanie Szick, Christine von Arx, Ken Moore, Christine Roush, Nicole Prentice, Dave Stephens, Jeannine  
Ritchot, Paul Spendlove, Louise Bertrand, Jesse Arnup-Blondin

**Mail Recipients:**

CN=Charles Mojsej/OU=HC-SC/O=GC/C=CA, CN=Jean Tessier/OU=HC-SC/O=GC/C=CA, CN=Tim  
Vail/OU=HC-SC/O=GC/C=CA, CN=Jenny VanAlstyne/OU=HC-SC/O=GC/C=CA, CN=Warren  
Braun/OU=HC-SC/O=GC/C=CA



Re: URGENT: Media query - CBC [REDACTED] - Salvia [REDACTED]

Christine Roush to: Stephanie Szick

2010-12-17 05:18 PM

Cc: Jocelyn Kula, Nicole Prentice, CSTD-DGO, CSTD-OCS-DO, Denis Arsenault, Stephanie Chandler, Judith O'Brien, Jesse Arnup-Blondin

Hello Cathy,

We are sending CBC tonight the statement below that was sent to Global and CTV earlier in the week. We have told CBC we will follow up with them on Monday with answers to the rest of the questions.

Jocelyn - I just need a response to Q5, as Suzanne has already provided her input.

### HC Statement on Salvia

Health Canada does not recommend the use of products containing *S. divinorum* and/or salvinorin A because very little is known about these substances and their potential effects on the brain and/or body, and their impact on physical and mental functions.

To date, Health Canada has not licensed for sale any drug or Natural Health Product which contains salvia as an ingredient.

It is a contravention of the *Food and Drugs Act* and the *Natural Health Products Regulations* to sell Natural Health Products in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN) on the label. The sale of unauthorized natural health products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

Complaints about the sale of unauthorized products containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate by calling 1-800-267-9675.

Health Canada is currently assessing whether the regulation of *Salvia divinorum* and/or Salvinorin A under the *Controlled Drugs and Substances Act* is warranted.

\*\*\*

Christine Roush  
Senior Communications Advisor/

E-mail / courriel : christine\_roush@hc-sc.gc.ca

Stephanie Szick

Hi Jocelyn, No need to rejig the responses to Q...

2010-12-17 05:06:29 PM

From: Stephanie Szick/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Christine Roush/HC-SC/GC/CA@HWC, Nicole Prentice/HC-SC/GC/CA@HWC, CSTD-DGO, CSTD-OCS-DO, Denis Arsenault/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2010-12-17 05:06 PM  
Subject: Re: URGENT: Media query - CBC [REDACTED] - Salvia

Hi Jocelyn,

No need to rejig the responses to Q1 and Q2 -- these are recently approved and the "good to go"

s.19(1)

language from Cathy for recent inquiries. This came up earlier this week following the Miley Cyrus coverage -- it was determined this block of language in bold below would be the standard -- already approved. Give me a call if you want more explanation. S

**Health Canada does not recommend the use of products containing *S. divinorum* and/or salvinorin A because very little is known about these substances and their potential effects on the brain and/or body, and their impact on physical and mental functions.**

To date, Health Canada has not licensed for sale any drug or Natural Health Product which contains salvia as an ingredient.

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Complaints about the sale of unauthorized products containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate by calling 1-800-267-9675.

Health Canada is currently assessing whether the regulation of *Salvia divinorum* and/or Salvinorin A under the *Controlled Drugs and Substances Act* is warranted.

Jocelyn Kula                      No one else is here so I am working on it right n...                      2010-12-17 05:01:23 PM

From:                      Jocelyn Kula/HC-SC/GC/CA  
To:                              Christine Roush/HC-SC/GC/CA@HWC  
Cc:                              Suzanne Desjardins/HC-SC/GC/CA@HWC, Nicole Prentice/HC-SC/GC/CA@HWC, Chantal  
Routhier-Garner/HC-SC/GC/CA@HWC, CSTD-DGO, CSTD-OCS-DO, Denis  
Arsenault/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC  
Date:                              2010-12-17 05:01 PM  
Subject:                      Re: URGENT: Media query - CBC ( [REDACTED] ) - Salvia

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No one else is here so I am working on it right now. Q1 and Q2 need work.

JK

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

Christine Roush                      Thx Suzanne Jocelyn - are you able to provide...                      2010-12-17 05:00:08 PM

From:                      Christine Roush/HC-SC/GC/CA  
To:                              Suzanne Desjardins/HC-SC/GC/CA@HWC  
Cc:                              Nicole Prentice/HC-SC/GC/CA@HWC, Chantal Routhier-Garner/HC-SC/GC/CA@HWC,





**Fw: CTV National News - Many think salvia should be banned - Dec 17 2010,  
11:25PM**

Denis Arsenault to: Stephanie Chandler

2010-12-20 09:12 AM

FYI - For the file.

Denis

---

Denis Arsenault, A/Manager / Gestionnaire p.i.  
Regulatory Policy Division /  
Division des politiques réglementaires,  
Office of Controlled Substances /  
Bureau des substances contrôlées,  
Health Canada / Santé Canada  
Tel/Tél: (613) 957-6828  
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E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca

----- Forwarded by Denis Arsenault/HC-SC/GC/CA on 2010-12-20 09:11 AM -----

From: HC\_Media\_SC/HC-SC/GC/CA  
To:  
Date: 2010-12-20 08:57 AM  
Subject: CTV National News - Many think salvia should be banned - Dec 17 2010, 11:25PM  
Sent by: Nicolas Frate

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Distribution group/Groupe de distribution: Controlled Substances - Substances contrôlées -  
HECSB/DGSESC, Natural Health Products - Produits de santé naturels - HPFB/DGPSA,

CTV National News  
Fri Dec 17 2010  
11:25 PM ET

**Many think salvia should be banned**

DAN MATHESON: Before Miley Cyrus ended up on the internet smoking a bong, many people had never heard of salvia. But the pop star celebrated her 18th birthday by smoking the stuff, which is technically legal, but it can cause powerful hallucinations, and there are many who think it should be banned. CTV's Omar Sachedina on what the buzz is all about.

OMAR SACHEDINA (Reporter): The performance isn't among her finest, former Disney star Miley Cyrus caught on tape using a bong to smoke salvia, a hallucinogenic drug derived from a plant native to southern Mexico.

UNIDENTIFIED WOMAN: He has inhaled it, he's holding it in.

SACHEDINA: Saskatoon disc jockey Ryder experienced a salvia high live on his radio show.

DJ RYDER (Radio Disc Jockey): This is really hard core.

SACHEDINA: An instant high he describes as downright frightening.

RYDER: So hot right now. God.

SACHEDINA: Which is exactly the side of the drug Rider said his listeners needed to know about, and why he decided to smoke the substance on air.

RYDER: Miley glorifying it, especially to that young audience, really scared us, and it was an immediate problem that we felt needed an immediate answer, and we knew this would be a big one.

SACHEDINA: What surprises many people is how easy it is to get salvia. Just walk into a store and pay, a gram costing about \$20 to \$80 depending on the potency. Salvia is not approved for sale by Health Canada, but it isn't classified as a banned substance under the criminal code either, which leaves the drug in legal limbo.

CASSIE WALDI: I'm lucky to be alive.

SACHEDINA: Cassie Waldi's experience with the drug almost killed her. Jumping from the window of this building after smoking salvia, Waldi knocked out several teeth. Doctors even forced to stitch up her fractured jaw.

WALDI: I woke up outside on pavement three storey's down screaming. SACHEDINA: A horrific trip, but the exception, say those who sell salvia.

REBECCA AMBROSE (Vancouver Seed Bank): She is an adult legally. So, I mean, she is allowed to make her own choices.

SACHEDINA: Like Miley Cyrus did when she became legal, celebrating with salvia on her 18th birthday, tripling sales of the drug and also lighting up the controversy surrounding it. Omar Sachedina, CTV News, Toronto.

MATHESON: And that's our program for this Friday, December the 17th. I'm Dan Matheson. For Lloyd Robertson and everyone that works here at CTV News, have a great night. For many of you, your local CTV news is next.

-End-

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You are receiving this e-mail because you are subscribed to the distribution group identified at the top of this e-mail message. If you wish to unsubscribe from this group, please reply to this message or send a request to [HC\\_Media\\_SC@hc-sc.gc.ca](mailto:HC_Media_SC@hc-sc.gc.ca)

Thank you.

Media Monitoring Team  
Health Canada

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Merci.

L'Équipe de surveillance des médias  
Santé Canada

DRAFT 14  
December 20, 2010

**Media Lines**  
***Salvia divinorum***

**Issue**

Ongoing media interest regarding the availability of *Salvia divinorum* in Canada and reports from scientific and media sources suggest that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has concluded that *Salvia divinorum* and its main active ingredient salvinorin A should be regulated under the *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth.

**Key Messages:**

- Health Canada has concluded its assessment of *Salvia divinorum* and its main active ingredient salvinorin A and is proposing to regulate both substances under the CDSA in order to protect the health and safety of Canadians, particularly youth.
- The inclusion of *Salvia divinorum* and salvinorin A in one of the Schedules to the CDSA will reduce the potential health and safety risks associated with the ready availability, apparent increased use and unknown effects of these substances. Further to the regulation of these substances under the CDSA, the following activities may be prohibited unless authorized by regulation: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation).
- Health Canada will inform stakeholders of its proposal by publishing a *Notice to Interested Parties* (NOI) in *Canada Gazette*, Part I. The NOI will provide stakeholders and other interested parties with the opportunity to provide comments on the proposal to regulate *Salvia divinorum* and salvinorin A as controlled substances.

**Supplementary Messages:**

- Canadians should not use products containing *Salvia divinorum* and/or salvinorin A because very little is known about these substances and their potential effects on the brain and/or body, and their impact on physical and mental functions.
- Because of their hallucinogenic properties, products containing *Salvia divinorum* and/or salvinorin A may meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*.
- As *Salvia divinorum* is a plant with hallucinogenic properties, it meets the definition of a natural health product under the *Natural Health Products Regulations* (NHPR) when marketed as a hallucinogen. The unauthorized sale of such products containing *Salvia*

*divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*.

#### Questions and Answers:

#### **Q1 – Are *Salvia divinorum* and/or salvinorin A controlled internationally? How are these substances regulated in other countries?**

A1 - Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions; as a result, they do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

The move to include *Salvia divinorum* and salvinorin A in one of the Schedules to the CDSA is consistent with actions taken by several countries (Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. It is also consistent with the fact that some individual U.S. states have implemented laws restricting their use, sale and/or distribution.

#### **Q2 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum* as a controlled substance. What does that involve and what stage is it at?**

A2 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada recently concluded its assessment of *Salvia divinorum* and salvinorin A against the aforementioned factors and proposes to include both substances in one of the Schedules to the CDSA. The regulation of these products will reduce the potential risks to the health and safety of Canadians associated with the ready availability, apparent increased use and abuse and unknown effects of these substances. The scheduling of *Salvia divinorum* and salvinorin A will also eliminate the current perception that these substances are safe since they are not presently illegal.

Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, 1.6% of Canadians age 15 and older reported having used *Salvia divinorum* at least once in their lifetime. Youth, ages 15-24, were much more likely to have used it than adults. The results from the *Canadian 2008-2009 Youth Smoking Survey* show that 5% of 15 year olds have used *Salvia divinorum* in the past year.

**Q3 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why isn't it illegal?**

A3 – Health Canada proposes to include *Salvia divinorum* and salvinorin A under one of the Schedules to the CDSA. Further to the regulation of these substances under the CDSA, the following activities may be prohibited unless authorized by regulation: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation). Law enforcement agencies will then be able to take action against suspected illegal activities involving these substances.

In the interim, as *Salvia divinorum* is a plant with hallucinogenic properties, it meets the definition of a natural health product under the *Natural Health Products Regulations* (NHPR) when marketed as a hallucinogen. The unauthorized sale of such products containing *Salvia divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*.

**Q4 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A4 – Once *Salvia divinorum* and salvinorin A are included in one of the Schedules to the CDSA, law enforcement will be able to take appropriate action in response to suspected illegal activities with these substances.

In the interim, *S. divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. Complaints about the illegal sale of drugs containing *Salvia divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

***If pressed on whether Health Canada has issued any kind of warning to Canadians about *Salvia divinorum****

A - Health Canada is developing an It's Your Health article on *Salvia divinorum* to help inform the general public about the risks associated with the use of this plant.

**Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

Data from the 2008-2009 Youth Smoking Survey indicates that:

- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;
- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year; and.
- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using Salvia in their lifetime (0.2% in the past year); and
- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that:

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;
- 5.4% of students (grades 7-12) ever used *Salvia divinorum*; and
- the use of *Salvia divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

**Prepared by:** Stephanie Chandler and Denis Arsenault, OCS, CSTD

**Input by:** Lisa Mackay IYH/PACCB, Suzanne Desjardins HECSB/ODARS, Hanan Abramovici HECSB/ODARS, Bruna Brands HECSB/ODARS, Jocelyn Kula, HECSB/OCS, Robin Marles HPFB/NHPD, Maggie Graham HPFB/NHPD, Stephanie Collins HPFB/NHPD, Mano Murty HPFB/MHPD, Robert Leitch HPFB/MHPD, Shahid Perwaiz HPFB/MHPD, Collin Pinto, HPFB/HPFBI

**Approved by:**

Robin Marles, Director, Bureau of Clinical Trials, NHPD (pending)  
Lindsay Blaney, Director, Policy and Regulatory Affairs, NHPD (pending)  
Duc Vu, Director, Marketed Biologics, Biotechnology and Natural Health Products Bureau, MHPD (pending)  
Kim Dayman-Rutkas, Director, HPFBI (pending)  
Diane Allan, Director, OCS, CSTD, HECS (approved, Sept 29, 2010)  
Suzanne Desjardins, Director, ODARS, CSTD, HECS approved, Sept 30, 2010)  
Cathy Sabiston, DG, CSTD, HECS (pending)  
Chris Turner, DG, MHPD (pending)  
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Diana Dowthwaite, DG, HPFBI (pending)  
Ken Polk, Communications Executive, HPFB (pending)  
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Peter Yendall, Director, Public Affairs, PACCB (pending)

HECS Legal (pending)

HPFB Legal (pending)

Paul Glover, ADM, HECSB (pending)

Meena Ballantyne, ADM, HPFB (pending)

Anne Lamar, ADM, PACCB (pending)

DMO (pending)

MO (pending)

PCO (pending)

**Salvia IAS**

Jocelyn Kula to: Stephanie Chandler

2010-12-20 09:52 PM

Cc: "Denis Arsenault", "Carmen Berube"

---

History: This message has been replied to.

---

Possible briefing in MO tomorrow afternoon (and if not tomorrow, early in the new year) so need copy of completed IAS. If not completely ready for approval, pls send anyways and note what is needed to complete.

Carmen- pls print 2 copies of doc when received.

JK

Sent by blackberry

Jocelyn Kula

A/ Director/ Directrice par interim

Office of Controlled Substances/ Bureau des substances contrôllées



DRAFT 14  
December 20, 2010

### Media Lines *Salvia divinorum*

#### Issue

Ongoing media interest regarding the availability of *Salvia divinorum* in Canada and reports from scientific and media sources suggest that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has concluded that *Salvia divinorum* and its main active ingredient salvinorin A should be regulated under the *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth.

#### Key Messages:

- Health Canada has concluded its assessment of *Salvia divinorum* and its main active ingredient salvinorin A and is proposing to regulate both substances under the CDSA in order to protect the health and safety of Canadians, particularly youth.
- The inclusion of *Salvia divinorum* and salvinorin A in one of the Schedules to the CDSA will reduce the potential health and safety risks associated with the ready availability, ~~apparent~~ increased use and unknown effects of these substances. Further to the regulation of these substances under the CDSA, the following activities may be prohibited unless authorized by regulation: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation).
- Health Canada will inform stakeholders of its proposal by publishing a *Notice to Interested Parties* (NOI) in *Canada Gazette*, Part I. The NOI will provide stakeholders and other interested parties with the opportunity to provide comments on the proposal to regulate *Salvia divinorum* and salvinorin A as controlled substances.

#### Supplementary Messages:

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- Deleted: September 16
- Deleted: Since 2006, Health Canada has noted
- Deleted: o
- Deleted: .
- Deleted: Health Canada has also received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum*, particularly given
- Deleted: ing
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- Deleted: ¶
- Deleted: has concluded its assessment of *S. divinorum* and salvinorin A and is proposing to include both substances in one of the Schedules to the CDSA. ¶
- Formatted: Bullets and Numbering
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- Deleted: proposing that *S. divinorum* and salvinorin A be regulated as controlled substances under the *Controlled Drugs and Substances Act* (CDSA).
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*divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*,

**Questions and Answers:**

**Q1 – Are *Salvia divinorum* and/or salvinorin A controlled internationally? How are these substances regulated in other countries?**

A1 – Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions; as a result, they do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

The move to include *Salvia divinorum* and salvinorin A in one of the Schedules to the CDSA is consistent with actions taken by several countries (Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. ~~It is also consistent with the fact that~~ Some individual U.S. states have implemented laws restricting their use, sale and/or distribution.

**Q2 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum* as a controlled substance. What does that involve and what stage is it at?**

A2 – Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada recently concluded its assessment of *Salvia divinorum* and salvinorin A against the aforementioned factors and proposes to include both substances in ~~one of the Schedules~~ to the CDSA. The regulation of these products will reduce the potential risks to the health and safety of Canadians associated with ~~the ready availability, apparent increased use and abuse and unknown effects of these substances.~~ <sup>their</sup> The scheduling of *Salvia divinorum* and salvinorin A will also eliminate the current perception that these substances are safe ~~since they are not presently~~ <sup>have</sup> illegal ~~drugs.~~ <sup>a</sup> ~~alternative to other~~ <sup>Schedule III</sup>

Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, 1.6% of Canadians aged 15 years and older reported ~~having used~~ <sup>using</sup> *Salvia divinorum* at least once in their lifetime. Youth, ages 15-24, were much more likely to have used it than adults. The results from the *Canadian 2008-2009 Youth Smoking Survey* show that 5% of 15 year olds have used *Salvia divinorum* in the past year.

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Deleted: <#>Because of their hallucinogenic properties, products containing *S. divinorum* and/or salvinorin A meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*. ¶

It is illegal to sell NHPs in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN). The illegal sale of products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*. ¶

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*Salvia divinorum* as a controlled substance.¶

<#>In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA). ¶

<#>Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and thus, do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.¶

Several countries (Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) have placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Although some individual U.S. states have implemented laws restricting its use, sale and/or distribution, *Salvia divinorum* and salvinorin A are not regulated under the federal *Controlled Substances Act* in the United States.¶

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**Q3 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why isn't it illegal?**

A3 – Health Canada proposes to include *Salvia divinorum* and salvinorin A under one of the Schedules to the CDSA. Further to the regulation of these substances under the CDSA, the following activities may be prohibited unless authorized by regulation: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation). Law enforcement agencies will then be able to take action against suspected illegal activities involving these substances.

In the interim, as *Salvia divinorum* is a plant with hallucinogenic properties, it meets the definition of a natural health product under the *Natural Health Products Regulations* (NHPR) when marketed as a hallucinogen. The unauthorized sale of such products containing *Salvia divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*.

**Q4 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A4 – Once *Salvia divinorum* and salvinorin A are included in one of the Schedules to the CDSA, law enforcement will be able to take appropriate action in response to suspected illegal activities with these substances.

In the interim, *S. divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. Complaints about the illegal sale of drugs containing *Salvia divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

**If pressed on whether Health Canada has issued any kind of warning to Canadians about *Salvia divinorum***

A - Health Canada is developing an It's Your Health article on *Salvia divinorum* to help inform the general public about the risks associated with the use of this plant.

**Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

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Deleted: Q2 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?

A2 – The *Natural Health Products Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *Salvia divinorum*.

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A4 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include: International requirements and trends in international contr...

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The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

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Data from the 2008-2009 Youth Smoking Survey indicates that:

- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;
- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year; and
- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

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Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using Salvia in their lifetime (0.2% in the past year); and
- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that:

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;
- 5.4% of students (grades 7-12) ever used *Salvia divinorum*; and
- the use of *Salvia divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

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**Prepared by:** Stephanie Chandler and Denis Arsenault, OCS, CSTD

Deleted: Cheryl Tremblay

**Input by:** Lisa Mackay IYH/PACCB, Suzanne Desjardins HECSB/ODARS, Hanan Abramovici HECSB/ODARS, Bruna Brands HECSB/ODARS, Jocelyn Kula, HECSB/OCS, Robin Marles HPFB/NHPD, Maggie Graham HPFB/NHPD, Stephanie Collins HPFB/NHPD, Mano Murty HPFB/MHPD, Robert Leitch HPFB/MHPD, Shahid Perwaiz HPFB/MHPD, Collin Pinto, HPFB/HPFBI

**Approved by:**

Robin Marles, Director, Bureau of Clinical Trials, NHPD (pending)  
Lindsay Blaney, Director, Policy and Regulatory Affairs, NHPD (pending)  
Duc Vu, Director, Marketed Biologics, Biotechnology and Natural Health Products Bureau, MHPD (pending)

Kim Dayman-Rutkas, Director, HPFBI (pending)

Diane Allan, Director, OCS, CSTD, HECS (approved, Sept 29, 2010)

Suzanne Desjardins, Director, ODARS, CSTD, HECS approved, Sept 30, 2010)

Cathy Sabiston, DG, CSTD, HECS (pending)

Chris Turner, DG, MHPD (pending)

Nancy Richards, DG, NHPD (pending)

Diana Douthwaite, DG, HPFBI (pending)

Ken Polk, Communications Executive, HPFB (pending)

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Meena Ballantyne, ADM, HPFB (pending)  
Anne Lamar, ADM, PACCB (pending)  
DMO (pending)  
MO (pending)  
PCO (pending)

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It is illegal to sell NHPs in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN).

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Page 3: [2] Deleted STCHANDL 2010-12-08 9:51:00 AM

**Q4 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum* as a controlled substance. What does that involve and what stage is it at?**

A4 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada is currently reviewing the available information to determine whether regulation of *Salvia divinorum* under the CDSA is warranted.


**Q5 – Didn't an internal report from Health Canada's Marketed Health Products Directorate recommend that *Salvia divinorum* be scheduled under the CDSA? Why has that recommendation not been acted upon?**

██████████ A5 – See A4

**Q6 – What is the significance of the adverse reaction reports that Health Canada has received with respect to the use of *Salvia divinorum*?**

A6 – Health Canada has received four domestic adverse reaction reports related to the use of *Salvia divinorum* as a hallucinogen through the Canada Vigilance database. The number of reports and the nature of reactions reported are, however, not adequate to fully characterize the risk of similar reactions among the general population



Re: Salvia IAS   
Stephanie Chandler to: Jocelyn Kula  
Cc: "Carmen Berube", "Denis Arsenault"

2010-12-21 09:37 AM

Hi Jocelyn,

This is the latest version of the IAS which incorporates your comments as well as some additional information from CSS-WG (re: Salvia at the border). It has been reviewed by Denis and is ready for your review. However, as the IAS will be updated according to comments from the NOI, I'm unsure as to at what stage approval should take place. The CSS-WG would also like to see a copy after NOI comments have been incorporated.



Draft Salvia Divinorum IAS\_Dec 6 2010.doc

Regards,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

Jocelyn Kula Possible briefing in MO tomorrow afternoon (an... 2010-12-20 09:52:25 PM

From: Jocelyn Kula/HC-SC/GC/CA  
To: "Stephanie Chandler" <stephanie.chandler@hc-sc.gc.ca>  
Cc: "Denis Arsenault" <denis.arsenault@hc-sc.gc.ca>, "Carmen Berube" <carmen.berube@hc-sc.gc.ca>  
Date: 2010-12-20 09:52 PM  
Subject: Salvia IAS

Possible briefing in MO tomorrow afternoon (and if not tomorrow, early in the new year) so need copy of completed IAS. If not completely ready for approval, pls send anyways and note what is needed to complete.

Carmen- pls print 2 copies of doc when received.

JK  
Sent by blackberry

Jocelyn Kula  
A/ Director/ Directrice par interim  
Office of Controlled Substances/ Bureau des substances contrôlées

# Issue Analysis Summary

DRAFT

## Scheduling *Salvia Divinorum* under the CDSA

Regulatory Policy Division  
Office of Controlled Substances  
Controlled Substances and Tobacco and Directorate

December 6, 2010

### CONTENTS

1. APPROVALS
2. ISSUE
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8. RECOMMENDATION(S)
9. CONSULTATIONS
10. IMPLEMENTATION AND EVALUATION

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### 1. APPROVALS

This Issue Analysis Summary is approved.

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Jocelyn Kula, A/Director  
Office of Controlled Substances  
Controlled Substances and Tobacco Directorate

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[DD/MM/2010]

### 2. ISSUE

Health Canada has received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum* (*S. divinorum*) under the *Controlled Drugs and Substances Act* (CDSA). These requests are further to reports from scientific and media sources suggesting that *S. divinorum* is being used by youth specifically for its hallucinogenic properties. Health Canada has also noted an ongoing media interest regarding the availability of *S. divinorum* in Canada.



### 3. PURPOSE

To assess *S. divinorum* against the criteria for the addition of a substance to one of the Schedules to the CDSA, and determine whether this substance should be regulated as a controlled substance in Canada.

### 4. CONTEXT

*S. divinorum* is a species of sage which belongs to the mint family, and which is found in the form of dried leaves, extracts and plant cuttings. Also called "diviner's sage", the plant is known to induce illusions and hallucinations when chewed or smoked. Salvinorin A, the psychoactive ingredient in *S. divinorum* is a neoclerodane diterpene which is found primarily in the leaves, and to a lesser extent in the stem of the plant.<sup>1</sup>

*S. divinorum* is widely touted as a "legal" hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs among adolescents and young adults.<sup>2</sup> While very little is known about how and where *S. divinorum* is sold in Canada, it is suspected that it is mainly purchased over the Internet and/or bought at head shops or alternative life style stores, etc. *S. divinorum* cuttings are also available from a number of garden supply companies.

*S. divinorum* is a substance not currently scheduled under the CDSA. It can be imported and sold legally in Canada to anyone of any age, anywhere in Canada provided it is not sold as a health product or marketed as a hallucinogen. In addition, the *S. divinorum* sold in Canada is currently not subject to any specific quality or safety standards.

The use of *S. divinorum* as a psychotropic agent first came to Health Canada's attention in 2002. In 2004, Health Canada received four adverse drug reaction (ADR) reports associated with the use of *S. divinorum* as a hallucinogen, with three being considered non-serious (requiring no medical attention) and the fourth being considered serious (medical intervention was required). The serious ADR report involved the concomitant use of alcohol in a person diagnosed with Attention Deficit Disorder.

Further to the receipt of the aforementioned ADRs, the Marketed Health Products Directorate (MHPD) and the Natural Health Products Directorate (NHPD) of the Health Products and Food Branch (HPFB) prepared an issue analysis summary (IAS) in November 2005, which recommended that *S. divinorum* and its active ingredient salvinorin A be regulated as controlled substances. This recommendation was maintained when the IAS was updated in November

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<sup>1</sup> U.S. Department of Justice Drug Enforcement Administration. 2002. Drugs and Chemicals of Concern: Salvia Divinorum (salvinorin A, divinorin A) URL:

[http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm) Nov 2008

<sup>2</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.

2006.

Later, in December 2005, MHPD and NHPD prepared a Signal Assessment (SA) (updated in June 2007) that eventually led to the preparation of a Health Risk Assessment (HRA), which concluded that *S. divinorum* or salvinorin A-containing health products would constitute a Type II Health Risk according to the Health Hazard Classification of the Recall Policy of the Health Products and Food Branch Inspectorate (HBFBI). Such a risk is defined as “a situation in which the use of, or exposure to, a product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote”.

Further to a discussion with the Assistant Deputy Minister (ADM) of the Healthy Environments and Consumer Safety Branch (HECSB) in April 2007, the (then) Drug Strategy and Controlled Substances Directorate (DSCSD) (now the Controlled Substances and Tobacco Directorate, CSTD) organized a meeting with MHPD, NHPD and HPFBI to discuss *S. divinorum*. HPFBI was to determine appropriate compliance activities regarding *S. divinorum* and consult with the Canada Border Services Agency (CBSA) regarding the movement of products containing *S. divinorum* into and out of Canada.

On September 13, 2007, a further meeting between DSCSD, MHPD, NHPD and HPFBI led to the conclusion that DSCSD would conduct a scheduling assessment of *S. divinorum* in order to explore the possibility of scheduling this substance under the CDSA.

In September 2008, the Director Generals of DSCSD, MHPD, TPD and the HPFBI agreed that media lines and an “It’s Your Health” article on *S. divinorum* would be prepared.

#### **4.1 Relevant Legislative Frameworks in Canada**

##### **4.1.1 Food and Drug Regulations (under the Food and Drugs Act)**

The *Food and Drug Regulations* (F&DR) serve to ensure the safety, efficacy, and quality of health products offered for sale in Canada, including drugs and medical devices. Prior to being given market authorization, a manufacturer must present substantive scientific evidence that their product is safe, efficacious and of high quality. For drugs, Health Canada reviews this information carefully and, if the review is satisfactory, a Notice of Compliance (NOC) is issued and appropriate Drug Identification Numbers (DINs) are assigned.

A “drug” is defined under the F&DR as any substance or mixture of substances manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
- (b) restoration, correction or modification of organic functions in human beings or animals, or

- (c) disinfection in premises in which food is manufactured, prepared or kept;

As no products containing *S. divinorum* or its extracts have been reviewed and approved by Health Canada as of October 2010, it is illegal to market *S. divinorum* when it is represented as a drug.

#### 4.1.2 Natural Health Products Regulations (under the Food and Drugs Act)

The *Natural Health Products Regulations* (NHPR) aim to provide Canadians with ready access to natural health products (NHPs) that are safe, effective, and of high quality, while respecting freedom of choice and philosophical and cultural diversity. The NHPR require that all licensed products display a Natural Product Number (NPN), or, in the case of a homeopathic medicine, a Drug Identification Number - Homeopathic Medicine (DIN-HM), on their labels. These numbers are issued once a product is authorized for sale in Canada. A product licence may be obtained pursuant to an application in which the applicant attests to all of the conditions set out in a natural health product monograph prepared and published by the Natural Health Products Directorate. Alternatively, an applicant may submit a product license application that provides evidence of quality, safety and efficacy that is assessed as being sufficient and approved by NHPD by the full submission route. The NHPR also require that all manufacturers, packagers, labelers, and importers have a site license issued on the basis of sufficient evidence of procedures respecting distribution records, product recalls, product handling, storage and delivery, and all other aspects of Good Manufacturing Practices as set out in the NHPR.

The definition of an NHP under the NHPR has both a function and substance component. The function component refers to those substances that are manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
- (b) restoring or correcting organic functions in humans; or
- (c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

The substance component refers to the requirement that all of the medicinal ingredients of an NHP must be substances set out in Schedule 1 (a list of included substances) to the NHPR, a traditional medicine or a homeopathic medicine, and none of the ingredients can be substances set out in Schedule 2, a list of excluded substances which includes any substance listed on Schedules I to V of the CDSA. Section 2(2) of the NHPR excludes those substances (except homeopathic medicines) whose sale is required to be pursuant to a prescription as per Section C.01.043 of the F&DR.

As per section 93(1)(b)(vi) of the NHPR, every natural health product must be labeled with its

authorized recommended use or purpose. In the case of *S. divinorum*, it is generally marketed for its hallucinogenic properties which are considered a modification of an organic function. Therefore products that contain *S. divinorum* and are manufactured, sold or represented for use as a hallucinogen meet the definition of an NHP.

As of October 2010, no products containing *S. divinorum* have been authorized by Health Canada. Therefore no NPNs or DIN-HMs have been issued for such products. Therefore sales of *S. divinorum* are illegal under the NHPR if the product is represented for use as a hallucinogen or if other health claims are made.

#### **4.1.3 Controlled Drugs and Substances Act and its Regulations**

The CDSA provides a legislative framework for the control of substances that can alter mental processes and that may produce harm to the health of an individual or to society when diverted or misused. Except as authorized under its regulations, activities such as possession, possession for the purposes of trafficking, trafficking, importation, exportation, possession for the purposes of exportation and production of controlled substances are prohibited under the CDSA.

The substances regulated under the CDSA are grouped into eight Schedules, and each Schedule is associated with particular offences and penalties as described in Part I of the CDSA.

In determining whether a substance should be regulated as a controlled substance, and into which Schedule of the CDSA it should be placed, Health Canada considers the following factors:

- International requirements and trends in control and/or scheduling;
- Chemical and/or pharmacological similarity to substances listed in the Schedules to the CDSA;
- Legitimate use of the substance, including therapeutic, scientific, or industrial uses;
- Potential for abuse and/or addiction liability;
- Evidence of extent of actual abuse of the substance in Canada and internationally; and
- Risk to personal and public health and safety.

#### **4.2 Assessment of *S. Divinorum* for Scheduling Purposes**

##### **4.2.1 International Requirements and Trends in Control and/or Scheduling**

At the present time, neither *S. divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and therefore do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

##### ***Australia***

In June 2002, Australia became the first country to prohibit the sale, supply, possession and use of *S. divinorum* and salvinorin A. Both *S. divinorum* and salvinorin A are listed in Schedule 9 of

Australia's *Standard for the Uniform Scheduling of Drugs and Poisons* on the basis of "high potential for abuse and risk to public health and safety."<sup>3</sup> Schedule 9 is Australia's most restrictive drug schedule, and includes "substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities."<sup>4</sup>

### **Belgium**

A decree was passed in Belgium on October 22, 2006 which added *S. divinorum* to the list of controlled substances. This list includes substances such as psilocybin mushrooms, khat and peyote cactus.<sup>5</sup>

### **Denmark**

In 2003, Denmark added *S. divinorum* and salvinorin A to their list of "category B" controlled substances, a category which also includes psilocybin mushrooms, cocaine, amphetamine, and several others substances that are only legal for medicinal and scientific purposes. Illegal possession carries a penalty of up to two years in prison.

### **Germany**

*S. divinorum* (plant and plant parts) was added to Appendix I of the *Narcotics Act* in Germany on March 1, 2008, making it illegal to produce, traffic, or possess. The law does not specifically mention salvinorin A.

### **Italy**

On June 25, 2004, the Italian Ministry of Health issued an ordinance prohibiting the sale of *S. divinorum* and its active constituent salvinorin A. On January 11, 2005, the Ministry of Health made possession of *S. divinorum* and salvinorin A illegal by placing them in "*Tabella 1*" of the *Tabella Sostanze Stupefacenti o Psicotrope*.

### **Japan**

On November 9, 2006, the Japanese government added a group of thirty-three drugs to its list of controlled substances, including salvinorin A. The drugs are banned under a revised pharmaceutical law, under which persons involved in their illegal import, production, and sale, i.e. beyond medical treatment or research purposes, will be subject to up to five years

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<sup>3</sup> <http://www.tga.gov.au/ndpsc/record/rr200111.pdf>

<sup>4</sup> [http://www.cognitiveliberty.org/news/salvia\\_australia.htm](http://www.cognitiveliberty.org/news/salvia_australia.htm)

<sup>5</sup>

<http://eldd.emcdda.europa.eu/html.cfm/index5176EN.html?pluginMethod=eldd.shownewsdetails&id=20/12/2006BELGIUM:%20New%20substances%20controlled%20include%20mCPP%20and%20khat>

imprisonment or a fine of up to five million yen.

### ***Spain***

On January 28, 2004, the Spanish Ministry of Health and Consumption issued an order prohibiting the sale of *S. divinorum*. The regulation went into effect on May 6, 2004 and only prohibits activities related to commerce. Possession and/or use are not considered to be criminal offences.

### ***Other Countries***

It is illegal to possess or sell *S. divinorum* in Croatia, Latvia, Lithuania, Poland, Romania, South Korea and Sweden. In Russia it is illegal to grow or sell *S. divinorum*, but it is legal to possess it. In Estonia, Finland, Iceland and Norway, *S. divinorum* is treated as a medicinal herb and it is illegal to import it without a relevant prescription from a doctor.

### ***United States of America***

*S. divinorum* and salvinorin A are not included in the Schedules to the United States *Controlled Substances Act*. Although both *S. divinorum* and salvinorin A have been added to a list of chemicals "of concern", this has no legal implications. According to the National Institute for Drug Abuse, the Drug Enforcement Administration is considering classifying *S. divinorum* and/or salvinorin A as Schedule I drugs. This Schedule includes substances such as LSD and marihuana.

At the state level, some state legislatures have implemented laws restricting the use, sale and/or distribution of *S. divinorum* and/or salvinorin A. As of July 2010, a number of states have placed regulatory controls on *S. divinorum* and/or salvinorin A including Delaware, Georgia, Florida, Hawaii, Illinois, Kansas, Kentucky, Maryland, Mississippi, Missouri, Nebraska, North Dakota, Ohio, Oklahoma, South Dakota, Wisconsin, Virginia, California, Louisiana, Maine, North Carolina, and Tennessee. By way of example, additional details regarding the regulation of *S. divinorum* in these last five states are provided below.

#### ***California***

As of January 1, 2009, the sale or distribution of *S. divinorum* or salvinorin A, or any substance or material containing *S. divinorum* or salvinorin A, to any person under 18 years of age is a misdemeanor punishable by imprisonment in a county jail for not more than six months, a fine of no more than \$1,000, or both.

#### ***Louisiana***

In 2005, Louisiana passed a bill which prohibits the possession, production, manufacture and distribution of a material, compound, mixture, or preparation intended for human

consumption and that contains a hallucinogenic plant. A "hallucinogenic plant" is defined as "any part or portion" of a plant on a list of forty plants, which includes *S. divinorum*.

### ***Maine***

In Maine, *S. divinorum* and salvinorin A are regulated in the same way as tobacco products; adults eighteen years of age or over can legally purchase and use the material, but selling or providing *S. divinorum* or salvinorin A to anyone under the age of eighteen is a criminal offence. Possession by a minor is a civil violation, punishable by a fine, community service, or both.

### ***North Carolina***

On December 1, 2009, the North Carolina State Legislature brought a new law into force which made *S. divinorum* and salvinorin A illegal. The only legal *S. divinorum* activities are the growing for aesthetic, landscaping, or decorative purposes or university-affiliated medical or pharmacological research.

### ***Tennessee***

On July 1, 2006, Tennessee classified the deliberate production, manufacture, distribution, or possession of the active chemical ingredient in the hallucinogenic plant *S. divinorum* as a Class A misdemeanor. It is not, however, a criminal offence to possess, plant, cultivate, grow, or harvest *S. divinorum* for aesthetic, landscaping, or decorative purposes. The law also does not apply to any dosage that is legally obtainable from a retail establishment without a prescription when (and if) it is recognized by the Food and Drug Administration as a homeopathic drug.

#### **4.2.2 Chemical and/or Pharmacological Similarity to Substances Listed in the Schedules to the CDSA**

The psychoactive ingredient in *S. divinorum* is the neoclerodane diterpene salvinorin A.<sup>6</sup> As a diterpene, salvinorin A is part of a family of substances that contain terpenoids. Another plant which contains psychotropic terpenoids is *Artemisia absinthium* (wormwood).<sup>7</sup> Salvinorin A is a hallucinogen with a distinct structure and it does not interact with the serotonin type-2A receptor or any other molecular target of classical hallucinogens.<sup>8</sup> Instead, the available research suggests that the psychotropic effects of salvinorin A are mediated by its agonistic actions at the  $\kappa$ -opioid

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<sup>6</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage *Salvia divinorum*. *Life Sci.* 2005 Dec 22;78(5):527-31.

<sup>7</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.

(KOR) receptor.<sup>9</sup> Its mechanism of action is therefore unique.<sup>10</sup>

The psychoactive effects of *S. divinorum* vary in onset and duration and include perceptual distortions such as the sensation of becoming an object, having visions of various two-dimensional surfaces, films and membranes, revisiting places of the past (particularly childhood), perceived loss of the body and/or identity, various sensations of motion (being pulled or twisted by a force of some kind), uncontrollable hysterical laughter, and overlapping realities (perceptions of being in more than one place).<sup>11</sup> Laughter, happiness, a sense of well-being and dissociative effects were deemed the most positive aspects of *S. divinorum* by users, second only to the "trip" that the drug elicits.<sup>12</sup> Depersonalization, speaking gibberish, widening of consciousness and subjective illusions of rapid movement, flying or hovering have also been reported.<sup>13</sup>

The psychotomimetic effects of *S. divinorum* closely resemble the schizoid symptoms induced by lysergic acid diethylamide (LSD) or phencyclidine (PCP).<sup>14</sup> Yet, it is said to have only a weak influence on the prevailing mood of the user which differentiates it from other hallucinogens such as LSD and psilocybin.<sup>15</sup> Its strong dissociative effects are often compared to those of ketamine.<sup>16</sup> Users have reported that the psychedelic effects of *S. divinorum* were most similar to those caused by psilocybin mushrooms.<sup>17</sup> However, users familiar with the effects of other hallucinogens agree that despite certain similarities to classical hallucinogens, the visions and overall experience are quite unique.<sup>18</sup>

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<sup>9</sup> Roth BL, Baner K, Westkaemper R, Siebert D, Rice KC, Steinberg S, Ernsberger P, Rothman RB. Salvinorin A: a potent naturally occurring nonnitrogenous kappa opioid selective agonist. *Proc Natl Acad Sci U S A*. 2002 Sep 3;99(18):11934-9.

<sup>10</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>11</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>12</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>13</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5 and Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>14</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>15</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6.

<sup>16</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five Salvia divinorum herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.

<sup>17</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>18</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. *J Ethnopharmacol*. 1994 Jun;43(1):53-6 and González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.



*S. divinorum* causes an unusually high degree of sedation, weakness and fatigue, and the increased de-realization is not commonly reported for classical psychedelics.<sup>19</sup> The combination of these effects seems to correlate with that of other KOR agonists such as pentazocine.<sup>20</sup>

The onset and intensity of the effects of *S. divinorum* appear to be related to the route of administration. Traditional uses generally produce mild effects because the leaves are rolled and chewed or crushed and prepared as a foamy infusion whereby the salvinorin A is degraded in the gastrointestinal system before being absorbed into the bloodstream. Hence, the level of effect relates quite closely to the length of time the material spends in the mouth, with the onset of effect generally taking 5-10 minutes. The effects build over the next hour and last for another hour before they begin to subside.<sup>21</sup>

Routes of administration that avoid the hepatic first-pass effect (i.e. inhalation, intravenous, intramuscular and sublingual use) provide the quickest and most intense effect.<sup>22</sup> Salvinorin A can be isolated from the plant to make a powder which can be vaporized and inhaled. The effects felt from vaporizing salvinorin A are experienced in about 30 seconds, last for about 5-10 minutes, and then subside over the next 30 minutes.<sup>23</sup>

Smoking the dried leaves or a concentrated extract using a pipe or bong is by far the most popular method of administration.<sup>24</sup> Dried leaves may also be fortified with a concentrated extract of salvinorin A. A concentrated extract can also be used sublingually. Neither *S. divinorum* nor salvinorin A can be injected because the powder is insoluble in water.<sup>25</sup>

#### 4.2.3 Legitimate Use of the Substance (Therapeutic, Scientific, Industrial)

*S. divinorum* has traditionally been used for spiritual and medicinal purposes by the Mazatec Indians in Oaxaca, Mexico.<sup>26</sup> For medicinal purposes (gastrointestinal problems, headaches,

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<sup>19</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>20</sup> Arasteh K, Poudevida S, Farre M, Roset PN, Cami J. Response patterns of the Spanish version of the 49-item short form of the Addiction Research Center Inventory after the use of sedatives, stimulants, and opioids. *Drug Alcohol Depend.* 1999 Jun 1;55(1-2):117-25.

<sup>21</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>22</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.

<sup>23</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>24</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62 and Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>25</sup> Valdés LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs.* 1994 Jul-Sep;26(3):277-83.

<sup>26</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

rheumatism, anemia and swelling of the stomach) an infusion of the leaves or the leaves themselves are ingested.<sup>27</sup> However, its main use in Mexico today is believed to be for its psychedelic properties in the aid of producing “mystical” or hallucinogenic experiences as part of spiritual rituals.<sup>28</sup>

Although selective KOR agonists have been shown to produce analgesic effects, adverse effects such as psychotomimesis, dysphoria and diuresis have been observed in studies investigating their therapeutic use.<sup>29</sup> In addition, while it has been speculated that KOR agonists may be useful in the treatment of certain psychiatric disorders including Alzheimer’s disease, schizophrenia, dementia and bipolar disorder, there has been no clinical research to support these hypotheses.<sup>30</sup> There are presently no recognized medical uses for *S. divinorum* in Canada.

Similarly, there are no known industrial or commercial uses for *S. divinorum* in Canada. Most websites offering *S. divinorum* cuttings and seeds for sale appear to do so in the context of growing the plant for “recreational” purposes, rather than out of horticultural interest or for its esthetic appeal. However, it should be acknowledged that this does not preclude the possibility of a person growing this plant for purely decorative purposes. *S. divinorum* is also marketed as incense. However, there is no evidence that *S. divinorum* has any fragrant properties that would legitimize such a use. Therefore it is believed that the marketing of this plant as an incense is a means to avoid compliance and enforcement actions by Health Canada.

#### 4.2.4 Potential for Abuse and/or Addiction Liability

Salvinorin A is a potent, KOR-selective agonist and in contrast to the euphoria produced by MOR agonists such as morphine, KOR agonists are negatively reinforcing and aversive.<sup>31</sup> In addition, KOR agonists have analgesic properties, but are not associated with respiratory depression like MOR agonists.<sup>32</sup> Finally, while MOR agonists increase the release of dopamine, the activation of KOR decreases dopamine release in the nucleus accumbens.<sup>33</sup> In the case of

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<sup>27</sup> Munro, T. The Chemistry of Salvia divinorum. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

<sup>28</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage Salvia divinorum. Life Sci. 2005 Dec 22;78(5):527-31.

<sup>29</sup> Barker RL, Fawcett J, Barkin SJ. 2002. Chronic pain management with a focus on the role of newer antidepressants and centrally acting agents. In: Pain Management: A Practical Guide for Clinicians, 6th edition, Weiner RS ed. CRC Press, Boca Raton, FL. pp. 415-34 and Tidgewell et al., 2004. A facile method for the preparation of deuterium labelled salvinorin A: Biorganic & Medicinal Chemistry Letters, 14: 5099-5102.

<sup>30</sup> Sheffler DJ & Roth BL. Salvinorin A: the ‘magic mint’ hallucinogen finds a molecular target in the kappa opioid receptor. Trends Pharmacol Sci. 2003 Mar;24(3):107-109.

<sup>31</sup> Killinger BA, Peet MM, Baker LE. Salvinorin A fails to substitute for the discriminative stimulus effects of LSD or ketamine in Sprague–Dawley rats. Pharmacology, Biochemistry & Behaviour. 2010 May 96; 260-265.

<sup>32</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman’s The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.

<sup>33</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman’s The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.

MOR agonists, the increase of dopamine acts as a positive reinforcer. This action motivates the user to use the drug again, which could lead to drug abuse and/or addiction. For KOR agonists, this is not the case.

The aversive effects of KOR agonists suggest that the risk of addiction to *S. divinorum* is negligible. Users have reported the negative effects of *S. divinorum* as: the short duration of action, lack of control over the experience, persisting negative effects (most often anxiety),<sup>34</sup> sweating, chills, increased diuresis, impaired vigilance,<sup>35</sup> and negative after-effects including tiredness, feeling head heavy, dizziness, physical exhaustion, and some degree of malaise or 'hangover' as they 'comedown' from the drug.<sup>36</sup> Despite these reports, very few controlled scientific studies of the physical and psychotropic effects of *S. divinorum* on humans have been carried out and the results have been conflicting. For example, one author states: "Many who have used salvinorin A find the experience extremely unnerving, frightening and overly intense and most have no desire to repeat the experience."<sup>37</sup> However, another study suggested that this is not the experience of all recreational users of *S. divinorum*.<sup>38</sup> Over eighty percent of users surveyed on a web-based questionnaire about their *S. divinorum* use said that they would probably or definitely use *S. divinorum* again.<sup>39</sup>

In addition, some users have noted that they require increasing doses of salvinorin A in order to achieve the desired effect and the stimulated cerebral KOR may act as a mechanism of tolerance.<sup>40</sup> Therefore, it is difficult to predict with certainty its potential for addiction and abuse.

In studies that have been conducted, there is conflicting information around the addiction liability of *S. divinorum* in both animals and humans. Further studies in this area and on the KOR mediated decrease of dopamine are also required in order to fully understand the addiction potential of this substance.

While concerns for the potential of abuse were initially considered minimal given that 1 kg of

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<sup>34</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>35</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>36</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>37</sup> Turner DM. *Salvinorin - The Psychedelic Essence of Salvia Divinorum*. Panther Press, San Francisco, CA 1996.

<sup>38</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62, Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5, and Valdès LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs*. 1994 Jul-Sep;26(3):277-83.

<sup>39</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>40</sup> Bucheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

dried leaves only yield 3 to 6 human doses of salvinorin A for oral consumption, it was then discovered that vaporizing and inhaling 200-500 micrograms has profound hallucinogenic effects.<sup>41</sup> Given that only small doses of this substance are now necessary to achieve the desired effects through inhalation, the potential for abuse is much higher. Also, the extraction of salvinorin A from the plant is simple, and with care, approximately 1.5 grams of pure salvinorin A per kilogram of dried leaves (8kg of fresh leaves) can be isolated. This is enough for 2000 oral doses.<sup>42</sup>

#### 4.2.5 Evidence of Extent of Actual Abuse of the Substance in Canada and Internationally

In Canada, the prevalence of use of *S. divinorum* has recently been documented. Questions about the use of salvia were included in the 2009 Ontario Student Drug Use and Health Survey, the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey.\*

The results from the 2009 Ontario Student Drug Use and Health Survey were published on November 18, 2009 and indicate that:

- Among all responding students in Ontario, 4.4% reported using *S. divinorum* at least once in the past year. In comparison, 58.2% indicated they had used alcohol, 25.6% indicated they had used cannabis and 5.0% indicated they had used hallucinogens other than LSD and PCP in the past year;
- Males (6.2%) were significantly more likely than females (2.3%) to report using *S. divinorum*;
- There is significant grade variation, with *S. divinorum* use most likely among 11<sup>th</sup> graders (8.6%) and 12<sup>th</sup> graders (8.4%); and

The results of the 2008-2009 Youth Smoking Survey were published on May 31, 2010 and indicate that:

- 4.9% of students stated that they had used salvia in the last twelve months. In comparison, 53.0% indicated they had used alcohol, 27.3% indicated they had used cannabis and 6.9% indicated they had used other hallucinogens in the last twelve months;
- 2.6% of students in Grades 7-9 and 7.0% of students in Grades 10-12 had used salvia in the last twelve months; and

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<sup>41</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>42</sup> Valdès LJ 3rd. Salvia divinorum and the unique diterpene hallucinogen, Salvinorin (divinorin) A. J Psychoactive Drugs. 1994 Jul-Sep;26(3):277-83.

\* It should be noted that in some cases it is not clear if responses indicate the use of *S. divinorum* or salvinorin A given the use of the term "salvia" within the survey question.

- Males (6.6%) were more likely to have used salvia in the past twelve months compared to females (3.2%).

The Canadian Alcohol and Drug Use Monitoring Survey specifically examined salvia for the first time in 2009. An estimated 1.6% of Canadians, aged 15 years and older, reported that they had used salvia in their lifetime, and 0.2% reported using it in the past-year. In comparison, the prevalence of past-year cannabis use among Canadians 15 years of age and older was 10.6%, while 1.2% of respondents reported using cocaine or crack in the past 12 months, 0.9% ecstasy and 0.7% illicit hallucinogens. In conclusion, 'salvia' appears to be a substance that is tried largely by youth with a 7.3% prevalence of lifetime use.

According to the 2009 Monitoring the Future survey, the annual prevalence of use of *S. divinorum* among 12th graders in the United States is 5.7%. The American Substance Abuse and Mental Health Services Administration's 2006 National Survey on Drug Use and Health found that, of respondents aged 12 or older, 1.8 million had used *S. divinorum* at least once in their lifetime and 756,000 had used the substance in the past year. Among youth aged 12 to 17, males were more likely than females to have used *S. divinorum* in the past year (0.9% vs. 0.3%).

Health Canada's Drug Analysis Services (DAS) has identified salvinorin A in a number of samples seized by law enforcement, ranging from 9 samples in 2006 to 20 samples in 2009. It is, however, difficult to determine how this data reflects the extent of actual abuse of salvinorin A in Canada, given that it is not an illegal substance and would likely only be seized accidentally or during the seizure of other controlled substances.

Between 2003 and 2009, the Border Integrity Unit of the Health Products and Food Branch Inspectorate (HPFBI) reported that a total of 26 (23 refused, 3 released) records of imports and attempted imports of *Salvia divinorum* products in their databases. These records represent British Columbia and Ontario only. Data for other provinces is not available. However, the practice of recording imports has since been replaced by a national database in which only refused shipments are tracked. As of November 2010, there is no record of a refused shipment of *Salvia divinorum* in the national database. This may reflect decreased volume of incoming shipments, decreased referral of such shipments by Canada Border Services Agency (CBSA), or adaptation by importers/sellers to import requirements (e.g. labelling as incense).

The National Forensic Laboratory Information System (NFLIS) and the System to Retrieve Information from Drug Evidence (STRIDE) in the United States are Drug Enforcement Administration (DEA) databases that collect scientifically verified data on analyzed samples in state and local forensic labs as well as samples from DEA labs. While in 2000 no seized samples were found to contain *S. divinorum* or salvinorin A, 70 samples tested positive in 2008. Once again, it is difficult to determine how this data can be used to reflect the actual extent of abuse of *S. divinorum* and salvinorin A in the United States as neither substance is listed in the *Controlled Substances Act*.

The increase in both the number of enquiries to Health Canada from various municipalities and members of the public and the amount of media interest regarding the availability of *S. divinorum* in Canada may be an indication that the recreational use of *S. divinorum* as a

hallucinogen is on the rise. However, it may also reflect an increased awareness of the phenomenon, rather than an increased incidence of use.

#### 4.2.6 Risk to Personal and Public Health and Safety

The potential for harm to the user and/or other individuals is primarily related to the hallucinogenic properties of the substance. As this substance is typically smoked, there is no risk of infectious disease transmission as is the case when a drug is injected. Users may get up and walk around without apparent awareness of their movements, behaviour or surroundings, and distinction between self and surroundings is often lost. At doses greater than 1mg of salvinorin A, out of body experiences are frequent and loss of consciousness has been reported.<sup>43</sup> There is little information regarding the social behaviours of persons under the influence of *S. divinorum* products, and what risks their activities such as operating a motorized vehicle may pose to the general public. There is also very little data regarding the toxicity, teratogenicity or other long-term effects of *S. divinorum* use.<sup>44</sup>

As far as law enforcement is concerned, the Department has only received a limited number of communications indicating concern with respect to *S. divinorum*. The Royal Canadian Mounted Police (RCMP) has stated that while *S. divinorum* is readily available, it has not become a popular drug in Canada, probably due to its aversive effects such as anxiety and introversion.

A handful of case reports regarding physiological and psychotropic effects of *S. divinorum* use have been published in the scientific/medical literature. For example, an international case report described the perceptions of a 19 year-old man after inhaling *S. divinorum* smoke. The peak psychotropic effects, including prickling of the skin, fever-like hot flashes, muscular tremor, and depersonalization, were reached in less than five minutes after inhalation of an unknown amount of smoke from burning dried leaves.<sup>45</sup> Another report involved a 15-year-old male who presented to psychiatric emergency services with acute onset of paranoia, déjà vu, blunted affect, difficulties in thought processing and slowed speech after smoking *S. divinorum* over an unknown period of time. During his hospitalization all symptoms improved significantly except the feeling of déjà vu. Based on this case presentation, the author suggested that the feelings of déjà vu may be a long-term effect of *S. divinorum* use.<sup>46</sup> However, given that this is the only case report in which déjà vu was associated with the use of *S. divinorum*, more reports are needed to substantiate this finding.

In addition to the above-mentioned reports, in 2006, a case was reported in the U.S. in which a 17-year-old boy committed suicide after smoking *S. divinorum* for an unknown period of time.<sup>47</sup> It should be noted that alcohol and general depression were the main confounders in this case. After this case was reported, the state of Delaware passed a law which classified *S. divinorum* as a Schedule I controlled substance along with other hallucinogenic substances.

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<sup>43</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>44</sup> Grundmann O, Phipps SM, Zadezensky I, Butterweck V. *Salvia divinorum* and Salvinorin A: An Update on Pharmacology and Analytical Methodology. Planta Med 2007 Jun;73:1039-1046.

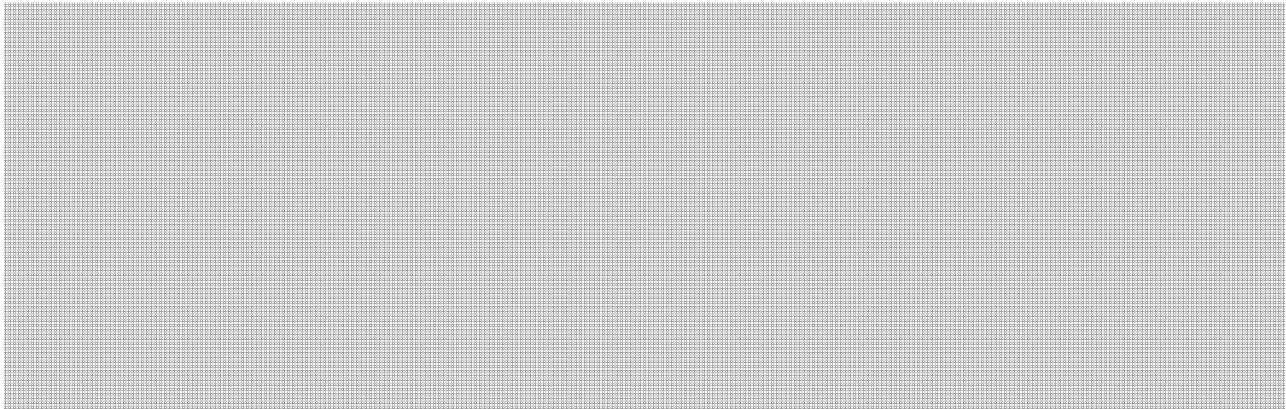
<sup>46</sup> Singh S. (2007) Adolescent salvia substance abuse. Addiction. 102, 823-824.

<sup>47</sup> <http://www.kvbc.com/Global/story.asp?S=4893692>

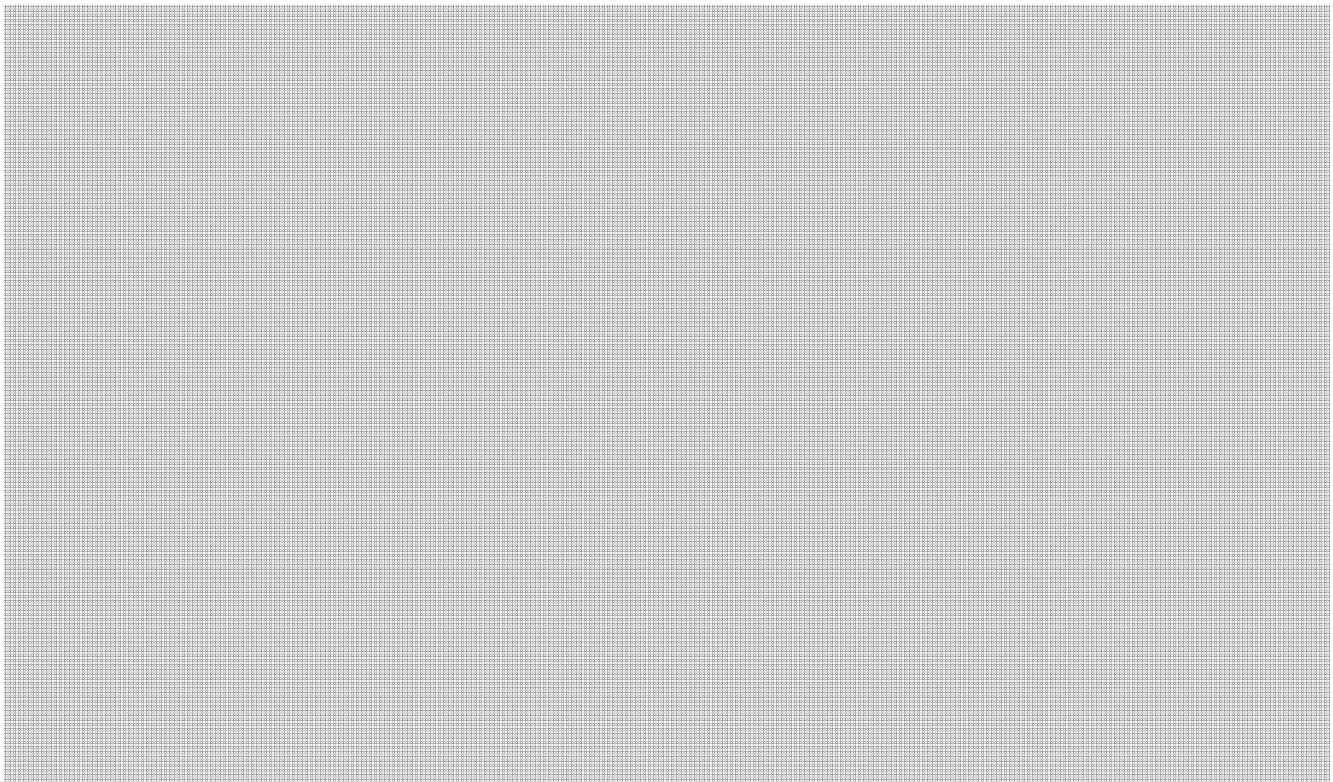
Like many drugs of abuse, users are often unaware of the potency and adulterants in the product they purchase. A study by Wolowich *et al.* (2006), showed that the salvinorin A content in five out of five *S. divinorum* products was falsely indicated on the label and 4 out of 5 products contained unidentified adulterants (i.e. vitamin E, caffeine).<sup>48</sup>

There are also several reports of domestic adverse reactions related to the use of *S. divinorum* that have been received through the Canada Vigilance database. However, this does not reflect true incidence due to under-reporting.

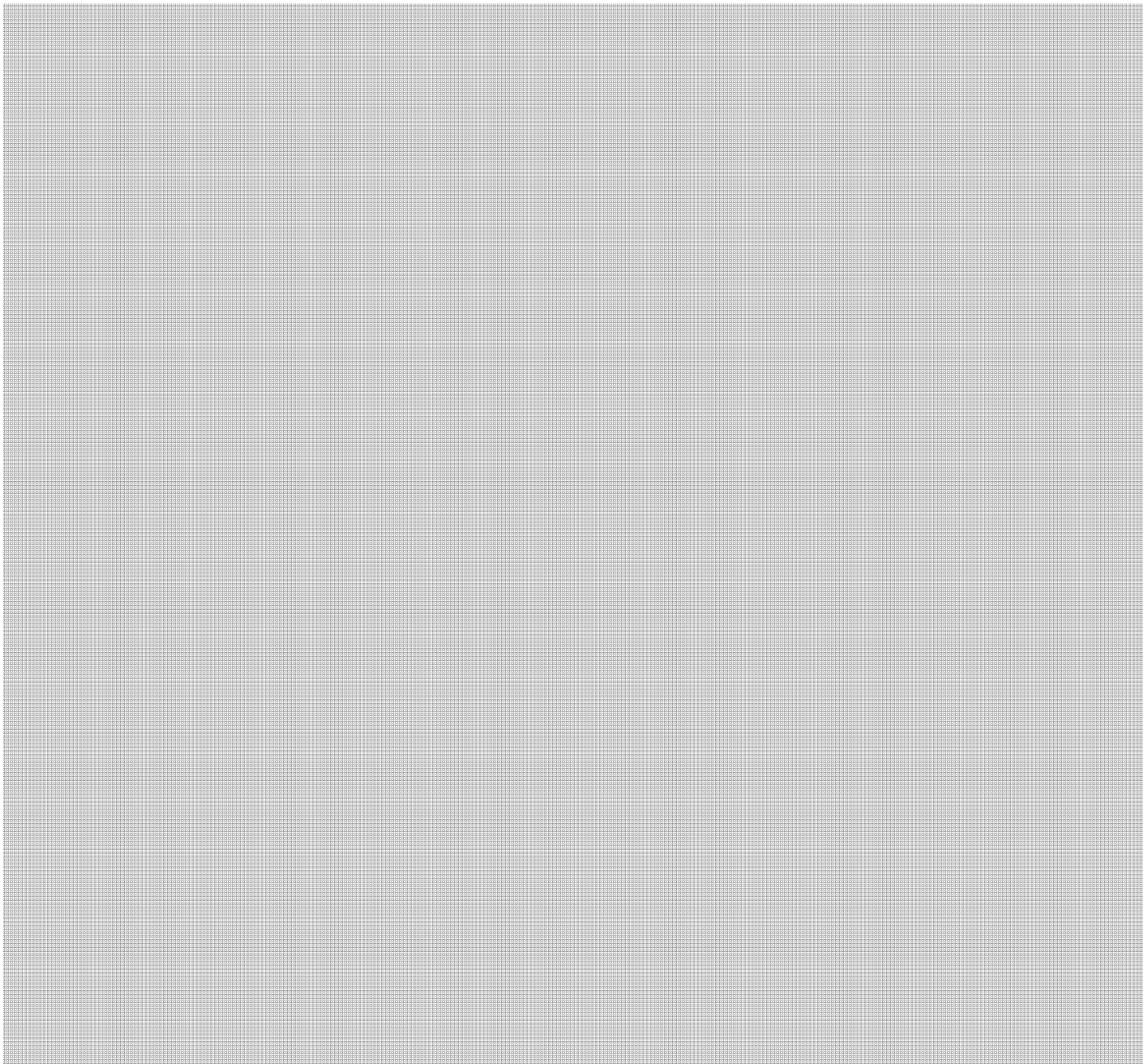
## 5. ASSESSMENT OF RISKS AND BENEFITS



## 6. IDENTIFICATION AND ANALYSIS OF OPTIONS



<sup>48</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.



## 7. CONSIDERATIONS

The NHPR are limited in their capacity to control the availability of *S. divinorum* in that *S. divinorum* products are often declared as incense and therefore cannot be considered unapproved natural health products. In addition, compliance and enforcement actions such as voluntary stop-sales, forfeiture, destruction, and administrative seizure, cannot be implemented unless the marketing of the product indicates that it is to be sold for human consumption in order to modify an organic function. Unlicensed natural health products are also permitted to be imported provided they are for personal use only.

Non-regulatory options for the control of *S. divinorum*, such as the development of an educational campaign to highlight the risks associated with using this plant, were also



s.21(1)(a)

s.21(1)(b)

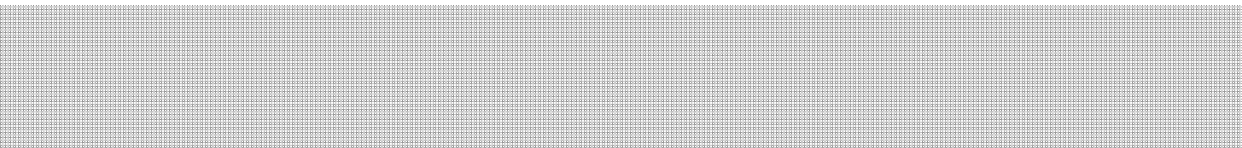
considered. However, the risks associated with this substance, as well as the confusion concerning its enforcement as a natural health product only when it is sold for use with a health claim, do not make this option viable.

*S. divinorum* meets the criteria for scheduling a substance under the CDSA. While neither the plant nor its main active component salvinorin A are scheduled under any of the UN Drug Control Conventions, a number of countries and American states have taken steps to control the distribution and use of these substances. *S. divinorum* and salvinorin A are pharmacologically similar to other substances included in Schedule III to the CDSA, such as LSD and psilocybin. There are also currently no legitimate therapeutic, commercial or industrial uses for *S. divinorum*.

While the addiction potential of *S. divinorum* appears to be low, there is a significant potential for its abuse as a 'legal' hallucinogen. There is very little information with regards to the long-term effects of *S. divinorum* use. There is also evidence of use, particularly by Canadian youth and potential for individual health risks as well as risks to public health and safety.

In light of a recommendation to include *S. divinorum* under Schedule III to the CDSA, it is also recommended that the main psychoactive ingredient of this plant, salvinorin A, be scheduled. Salvinorin A can easily be extracted from *S. divinorum* and this substance gives the plant its hallucinogenic properties. Therefore the use of salvinorin A poses the same risks as *S. divinorum* and should also be controlled under the CDSA in the same manner as *S. divinorum*.

## 8. RECOMMENDATIONS



## 9. CONSULTATIONS

The Drug Analysis Services (DAS) was contacted in order to provide any data available regarding the identification of salvinorin A in samples submitted by law enforcement.

The Royal Canadian Mounted Police (RCMP) was contacted in order to establish their views with respect to *S. divinorum* use in Canada. The RCMP advised that *S. divinorum* is readily available and law enforcement agencies have no legal means to prevent its sale.

OCS has received a number of correspondences from Canada Border Services Agency (CBSA) officers concerning a lack of information regarding the status of *S. divinorum* and how the plant should be treated at the border. CBSA officers have also expressed concern regarding the plant's hallucinogenic properties. At present, only shipments of *S. divinorum* that are represented for sale as health products that modify organic functions can be refused for import under the NHPR.

OCS brought *S. divinorum* to the Controlled Substances Scheduling Working Group (CSS-WG) in August 2010 to discuss the possibility of regulatory control of this substance. After assessing the available information against the six criteria listed in the Context section of this Issue Analysis Summary, the CSS-WG recommended that *S. divinorum* be included under Schedule III to the CDSA.

**Page(s) 002103 to\à 002103**

**Is(Are) exempted pursuant to section(s)  
est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**

**Page(s) 002104 to\à 002106**

**Is(Are) exempted pursuant to section(s)  
est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**



**Fw: CSS-WG Stakeholders for Salvia NOI**  
Sara O'Connor to: Stephanie Chandler

2010-12-21 04:48 PM

History: This message has been replied to.

---

Stephanie, is this notice of intent sent via email?

Sara

----- Forwarded by Sara O'Connor/HC-SC/GC/CA on 2010-12-21 04:45 PM -----

From: Robin Marles/HC-SC/GC/CA  
To: Sara O'Connor/HC-SC/GC/CA@HWC  
Cc: don\_boyer@hc-sc.gc.ca, Carol Toone/HC-SC/GC/CA@HWC  
Date: 2010-12-21 04:37 PM  
Subject: Fw: CSS-WG Stakeholders for Salvia NOI

---

Could you please forward to the Office of Controlled Substances a list of stakeholders (BEEP?) to whom OCS should copy their upcoming Notice of Intent to add Salvia divinorum to Schedule III of the Controlled Drugs and Substances Act?

Robin

----- Forwarded by Robin Marles/HC-SC/GC/CA on 2010-12-21 04:35 PM -----

From: Stephanie Chandler/HC-SC/GC/CA  
To: Robin Marles/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2010-12-21 04:34 PM  
Subject: CSS-WG Stakeholders for Salvia NOI

---

Hi Robin,

I am just wondering if you have any updates with regards to when we will be receiving the HPFB / NHPD list of stakeholders with regard to the Salvia NOI. We are hoping to publish the NOI in January, so we'd like to be able to compile the list of stakeholders ASAP.

Thanks,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca



**Re: Fw: FYI Deadlines for Canada Gazette Part I Publication**

Jocelyn Kula to: Denis Arsenault

Cc: Stephanie Chandler

2010-12-21 05:46 PM

merci- hang on to this, we may need.....

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

Denis Arsenault Hi Jocelyn, As requested in connection with the... 2010-12-21 04:14:18 PM

From: Denis Arsenault/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2010-12-21 04:14 PM  
Subject: Fw: FYI Deadlines for Canada Gazette Part I Publication

Hi Jocelyn,

As requested in connection with the salvia NOI.

Denis

Denis Arsenault, A/Manager / Gestionnaire p.i.  
Regulatory Policy Division /  
Division des politiques réglementaires,  
Office of Controlled Substances /  
Bureau des substances contrôlées,  
Health Canada / Santé Canada  
Tel/Tél: (613) 957-6828  
Fax / Télécopieur : (613) 946-4224  
E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca  
----- Forwarded by Denis Arsenault/HC-SC/GC/CA on 2010-12-21 04:13 PM -----

From: Stephanie Chandler/HC-SC/GC/CA  
To: Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2010-12-21 04:03 PM  
Subject: FYI Deadlines for Canada Gazette Part I Publication


FYI The deadlines for submission and publication dates for Canada Gazette Part I for December and January

Publication Date	Deadline
December 4, 2010	November 26, 2010
December 11, 2010	December 3, 2010
December 18, 2010	December 10, 2010

December 25, 2010	December 17, 2010
January 1, 2011	December 21, 2010
January 8, 2011	December 29, 2010
January 15, 2011	January 7, 2011
January 22, 2011	January 14, 2011
January 29, 2011	January 21, 2011

<http://www.gazette.gc.ca/schedule-echeancier-eng.html>



**Re: Salvia NOI and Stakeholders**   
Tiffany Thornton to: Stephanie Chandler

2010-12-22 11:15 AM

---

History: This message has been replied to.

---

okay sorry... no problem I will send a reminder to all.  
Tiffany

---

Stephanie Chandler No I haven't sent you the NOI because it hasn't... 2010-12-22 09:15:01 AM

From: Stephanie Chandler/HC-SC/GC/CA  
To: Tiffany Thornton/HC-SC/GC/CA@HWC  
Date: 2010-12-22 09:15 AM  
Subject: Re: Salvia NOI and Stakeholders

---

No I haven't sent you the NOI because it hasn't been approved yet. We are just looking for a list of stakeholders who HPFB and HPFBI felt would be interested to know about our proposal to schedule Salvia. First week of January would be fine.

Stephanie

---

Tiffany Thornton Okay, did you send that to me? Can you please... 2010-12-22 08:03:58 AM

From: Tiffany Thornton/HC-SC/GC/CA  
To: Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2010-12-22 08:03 AM  
Subject: Re: Salvia NOI and Stakeholders

---

Okay, did you send that to me? Can you please re-send and I will re-circulate to the WG with a reminder. Can we give them to the first week of January?

Let me know,  
Thanks,  
Tiffany

---

Stephanie Chandler Hi Tiffany, Neither Denis nor myself has receiv... 2010-12-21 10:29:20 AM

From: Stephanie Chandler/HC-SC/GC/CA  
To: Tiffany Thornton/HC-SC/GC/CA@HWC  
Cc: Denis Arseneault/HC-SC/GC/CA@HWC  
Date: 2010-12-21 10:29 AM  
Subject: Salvia NOI and Stakeholders

---

Hi Tiffany,

Neither Denis nor myself has received any stakeholder information from members of the CSS-WG re: the Salvia NOI. Just wondering if you have received anything? We are hoping to publish the NOI in January, so we would appreciate this info ASAP.

Thanks,

Stephanie

**Stephanie Chandler**  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: [stephanie.chandler@hc-sc.gc.ca](mailto:stephanie.chandler@hc-sc.gc.ca)





**Reminder: Stakeholder List for NOI on Salvia.**  
Tiffany Thornton to: Robin Marles, Courtney Smith  
Cc: Stephanie Chandler

2010-12-22 11:29 AM

Hi Robin and Courtney,

Just a reminder to send your stakeholder list to Stephanie Chandler regarding those who should be notified of the NOI. They would like to send out the NOI some time in January so if you could provide the list in the next couple of weeks that would be helpful.

Thanks,  
Tiffany

----- Forwarded by Tiffany Thornton/HC-SC/GC/CA on 2010-12-22 11:27 AM -----

From: Tiffany Thornton/HC-SC/GC/CA  
To: Colette Strnad/HC-SC/GC/CA@HWC, Collin Pinto/HC-SC/GC/CA@HWC, Courtney Smith/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, Evelyn Soo/HC-SC/GC/CA@HWC, Hanan Abramovici/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Robin Marles/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC, Tanja Kalajdzic/HC-SC/GC/CA@HWC, Tiana Branch/HC-SC/GC/CA@HWC, Bruna Brands/HC-SC/GC/CA@HWC  
Cc: Stephanie Chandler/HC-SC/GC/CA@HWC, Laura Cooney/HC-SC/GC/CA@HWC, Isabel Shanahan/HC-SC/GC/CA@HWC  
Date: 2010-12-06 12:57 PM  
Subject: CSS-WG Meeting: ROD November 16

Please find attached the ROD from November 16. Should you have any revisions/feedback please do not hesitate to send them to me for incorporation. The meeting for Wednesday December 15 is still tentative at this time - most likely it will be cancelled if there are no emerging issues for discussion.



CSS-WG November 16 2010 Meeting ROD\_TB.doc

Thank you,  
Tiffany

----- Forwarded by Tiffany Thornton/HC-SC/GC/CA on 2010-12-06 12:51 PM -----

**CSS-WG Meeting**



**2010-11-16 Tue 10:30 AM - 12:00 PM**

Location: 123 Slater Street, Rm 629B

Required:

Colette Strnad/HC-SC/GC/CA@HWC, Collin Pinto/HC-SC/GC/CA@HWC, Courtney Smith/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, Evelyn Soo/HC-SC/GC/CA@HWC, Hanan Abramovici/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Robin Marles/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC, Tanja Kalajdzic/HC-SC/GC/CA@HWC, Tiana Branch/HC-SC/GC/CA@HWC

Optional:

Isabel Shanahan/HC-SC/GC/CA@HWC, Laura Cooney/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC, Valence Nebie/HC-SC/GC/CA@HWC

**Description**

Hi everyone,

Please mark your calendars. The Agenda for the next meeting and the Record of Discussion from October 27 to follow shortly. Please find attached (from Robin)

- the most recent versions of the Salvia divinorum HRA and IAS documents prepared by MHPD and NHPD and
- background information on "morning glory"

Thanks,  
Tiffany

\*\*\*\*\*



Health Risk Assessment of Salvia divinorum as a Health Product 2010-08-25.doc



Salvia divinorum IAS 2006-11-03.doc

At the last CSS-WG meeting we reviewed the deck "Scheduling Substances under the *Controlled Drugs and Substances Act*". On slide 7, I pointed out that "morning glory" was identified as a plant with psychoactive properties but that may be a bit misleading because the psychoactive species are not the common morning glory that people have in their gardens. I promised I would provide details by e-mail.

The psychoactive "morning glory" plant, species name *Turbina corymbosa* (L.) Raf., Convolvulaceae, widely published synonym *Rivea corymbosa* (L.) Hallier f., is better known in the scientific literature by its Mexican Nahuatl name of "Ololiuqui". Horticulturally it has the English common names "Christmaspops" or "Christmasvine." The seeds were consumed in water traditionally by the Mexican Chinotec, Mazatec, Mixtec and Zapotec peoples as a narcotic hallucinogen for purposes of divination by traditional healers. Hallucinations occur during the somnambulistic stage of intoxication.

The psychoactive properties are due to biosynthesis of ergoline alkaloids by fungi of the order Clavicipitales (related to ergot) that colonize the adaxial (upper) leaf surface and seeds of certain members of the morning glory family, especially *Turbina corymbosa* and *Ipomoea asarifolia*. A closely related fungus is found on *Ipomoea violacea*. The fungus-derived ergoline alkaloids: chanoclavine, lysergic acid-alpha-hydroxyethylamide, lysergic acid amide, and ergonovine, accumulate in the leaves and seeds of the host plant. The fungi are seed-transmitted to the next generation of plants.

The common garden morning glory is *Ipomoea purpurea* (L.) Roth. Additional horticultural species include *I. pes-caprae*, *I. pandurata*, *I. carnea*, *I. cairica*, *I. quamoclit*, *I. tricolor*, *I. hederifolia*, *I. nil*, *I. aquatica*, *Convolvulus tricolor*, *Argyrea nervosa*, and *Merremia tuberosa*. The wild morning glory or bindweed plants that infest our gardens as noxious weeds are *Convolvulus arvensis* L. (small-flowered) and *Calystegia sepium* (L.) R.Br. (greater bindweed).



Markert et al ergoline alkaloids fungi and Convolvulaceae.pdf



**Fw: CSS-WG Stakeholders for Salvia NOI**  
Lisa M Young to: Stephanie Chandler

2010-12-22 03:41 PM

History: This message has been replied to.

---

Hi Stephanie,

Below is an example of a message we recently issued regarding some changes to the scheduling of certain NHP ingredients. This was sent to NHPD's Stakeholder list, which primarily includes applicants, however also includes industry members, pharmacists who are interested in receiving this type of information.

Please let me know if you need anything else.

Thanks  
Lisa Young  
613-954-2940

\*\*\*\*\*

October 21, 2010

**Re: Update on the Assessment of Naturally-Sourced Medicinal Ingredients found on Schedule F**

Dear Stakeholders,

In March 2009 Health Canada announced that it would be undertaking the scientific assessment of a number of naturally-sourced substances currently listed in Schedule F to the *Food and Drug Regulations*. The purpose of this initiative was to determine which of these substances should remain unchanged, be modified, or removed entirely from the Schedule. Health Canada followed up this announcement with an update in December 2009

(  
[http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/notice-avis\\_schedulef\\_annexef-dec2009-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/notice-avis_schedulef_annexef-dec2009-eng.php)).

This message is to provide *an update on* this initiative:

**1) Four (4) medicinal ingredients proposed for removal from Schedule F: apiol oil, centella asiatica extract and active principles thereof, deanol and its salts and derivatives, and theobromine and its salts.**

Targeting consideration by Treasury Board Ministers for final publication in the *Canada Gazette*, Part II in January/February 2011.

**2) Six (6) medicinal ingredients proposed to remain on Schedule F with qualifiers: dopamine and its salts, gold and its salts, uracil and its salts, dimethyl sulfoxide, levocarnitine, and l-tryptophan.**

Prescription status for specific strengths, uses, routes of administration or dosages.

Targeting consideration by Treasury Board Ministers for final publication in the *Canada Gazette*, Part II in February/March 2011.

**3) Lovastatin**

Moving forward as its own regulatory package.

Health Canada is reviewing comments received further to the Notice of Intent and undertaking further internal analysis.

Further updates will be provided when appropriate.

Respectfully,

The Natural Health Products Directorate  
Health Canada

\*\*\*\*\*

----- Forwarded by Sara O'Connor/HC-SC/GC/CA on 2010-12-21 06:04 PM -----

From: Stephanie Chandler/HC-SC/GC/CA  
To: Sara O'Connor/HC-SC/GC/CA@HWC  
Date: 2010-12-21 04:57 PM  
Subject: Re: Fw: CSS-WG Stakeholders for Salvia NOI

---

Hi Sara,

The Notice of Intent is published in the Canada Gazette, but we will send a letter to stakeholders indicating that the NOI has been published and include a link to the document. In this Office the majority of our stakeholders will be contacted by email unless we don't have an email on file for them. While email is the preferred method of contact, if this option isn't available we could mail or fax.

Let me know if you have any other questions.

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

Sara O'Connor      Stephanie, is this notice of intent sent via email?...      2010-12-21 04:48:05 PM

From: Sara O'Connor/HC-SC/GC/CA  
To: Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2010-12-21 04:48 PM  
Subject: Fw: CSS-WG Stakeholders for Salvia NOI

---

Stephanie, is this notice of intent sent via email?

Sara

----- Forwarded by Sara O'Connor/HC-SC/GC/CA on 2010-12-21 04:45 PM -----

From: Robin Marles/HC-SC/GC/CA  
To: Sara O'Connor/HC-SC/GC/CA@HWC  
Cc: don\_boyer@hc-sc.gc.ca, Carol Toone/HC-SC/GC/CA@HWC  
Date: 2010-12-21 04:37 PM  
Subject: Fw: CSS-WG Stakeholders for Salvia NOI

---

Could you please forward to the Office of Controlled Substances a list of stakeholders (BEEP?) to whom OCS should copy their upcoming Notice of Intent to add Salvia divinorum to Schedule III of the Controlled Drugs and Substances Act?

Robin

----- Forwarded by Robin Marles/HC-SC/GC/CA on 2010-12-21 04:35 PM -----

From: Stephanie Chandler/HC-SC/GC/CA  
To: Robin Marles/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2010-12-21 04:34 PM  
Subject: CSS-WG Stakeholders for Salvia NOI

---

Hi Robin,

I am just wondering if you have any updates with regards to when we will be receiving the HPFB / NHPD list of stakeholders with regard to the Salvia NOI. We are hoping to publish the NOI in January, so we'd like to be able to compile the list of stakeholders ASAP.

Thanks,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

DRAFT 14  
December 22, 2010

**Media Lines**  
**Salvia divinorum**

**Issue**

Ongoing media interest regarding the availability of *Salvia divinorum* in Canada and reports from scientific and media sources suggest that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has concluded that *Salvia divinorum* and its main active ingredient salvinorin A should be regulated under the *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth.

**Key Messages:**

- Health Canada has concluded its assessment of *Salvia divinorum* and its main active ingredient salvinorin A and is proposing to regulate both substances under the CDSA in order to protect the health and safety of Canadians, particularly youth.
- The inclusion of *Salvia divinorum* and salvinorin A in Schedule III to the CDSA will reduce the potential health and safety risks associated with the ready availability, increased use and unknown effects of these substances. Further to the regulation of these substances under the CDSA, the following activities would be prohibited unless authorized by regulation: possession, trafficking, possession for the purposes of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation).
- Health Canada will inform stakeholders of its proposal by publishing a *Notice to Interested Parties* (NOI) in *Canada Gazette*, Part I. The NOI will provide stakeholders and other interested parties with the opportunity to provide comments on the proposal to regulate *Salvia divinorum* and salvinorin A as controlled substances.

**Supplementary Messages:**

- Canadians should not use products containing *Salvia divinorum* and/or salvinorin A because very little is known about these substances and their potential effects on the brain and/or body, and their impact on physical and mental functions.
- As *Salvia divinorum* is a plant with hallucinogenic properties, it meets the definition of a natural health product under the *Natural Health Products Regulations* (NHPR) when marketed as a hallucinogen. The unauthorized sale of such products containing *Salvia divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*.

**Questions and Answers:**

- Deleted: 3
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- Deleted: Since 2006, Health Canada has noted
- Deleted: o
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- Deleted: Health Canada has also received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum*, particularly given
- Deleted: ing
- Deleted: .
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- Deleted: has concluded its assessment of *S. divinorum* and salvinorin A and is proposi... [1]
- Formatted: Bullets and Numbering ... [2]
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- Deleted: proposing that S... [3]
- Formatted: Bullets and Numbering ... [4]
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- Deleted: It is illegal to se... [7]
- Deleted: illegal
- Deleted: *S. divinorum*
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- Deleted: <#>Because of f... [8]
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chg per locker

**Q1 – Are *Salvia divinorum* and/or salvinorin A controlled internationally? How are these substances regulated in other countries?**

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A1 - Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions; as a result, they do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

The move to include *Salvia divinorum* and salvinorin A in Schedule III to the CDSA is consistent with actions taken by several countries (Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Some individual U.S. states have implemented laws restricting their use, sale and/or distribution.

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**Q2 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum* as a controlled substance. What does that involve and what stage is it at?**

A2 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

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Health Canada recently concluded its assessment of *Salvia divinorum* and salvinorin A against the aforementioned factors and proposes to include both substances in Schedule III to the CDSA. The regulation of these products will reduce the potential risks to the health and safety of Canadians associated with their ready availability, increased use and unknown effects. The scheduling of *Salvia divinorum* and salvinorin A will also eliminate the current perception that these substances are a safe alternative to other illegal drugs.

Results from the *Canadian Alcohol and Drug Use Monitoring Survey* (CADUMS) reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *Salvia divinorum* at least once in their lifetime, and that youth aged 15-24 were much more likely to have used it than adults aged 25 years and older. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *Salvia divinorum* in the past year. The 2009 *Ontario Student Drug Use and Health Survey* (OSDUHS) indicated that 5.4% of Ontario students in grades 7-12 reported ever using *Salvia divinorum* and 4.4% of these students reported using this substance in the past year.

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**Q3 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why isn't it illegal?**

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A3 – Health Canada proposes to include *Salvia divinorum* and salvinorin A under Schedule III to the CDSA. Further to the regulation of these substances under the CDSA, the following activities may be prohibited unless authorized by regulation: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation). Law enforcement agencies will then be able to take action against suspected illegal activities involving these substances.

In the interim, as *Salvia divinorum* is a plant with hallucinogenic properties, it meets the definition of a natural health product under the *Natural Health Products Regulations* (NHPR) when marketed as a hallucinogen. The unauthorized sale of such products containing *Salvia divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*.

**Q4 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A4 – Once *Salvia divinorum* and salvinorin A are included in Schedule III to the CDSA, law enforcement will be able to take appropriate action in response to suspected illegal activities with these substances.

In the interim, *S. divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. Complaints about the illegal sale of drugs containing *Salvia divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

**If pressed on whether Health Canada has issued any kind of warning to Canadians about *Salvia divinorum***

A - Health Canada is developing an It's Your Health article on *Salvia divinorum* to help inform the general public about the risks associated with the use of this plant.

**Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

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Deleted: Natural Health Product (NHP) under the *Natural Health Products Regulations*, it is illegal to manufacture, sell or provide products containing *S. divinorum* and/or salvinorin A without their being authorized by Health Canada prior to sale. Health Canada is currently reviewing all the available information regarding *Salvia divinorum*, including the prevalence of its use in Canada, to determine whether it should be regulated under the *Controlled Drugs and Substances Act*.

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Deleted: Q2 – How can Health Canada regulate a product containing *Salvia divinorum*, but not the sale of *Salvia divinorum* itself?

A2 – The *Natural Health Products Regulations* apply to finished natural health products that are packaged, labelled and ready to be marketed to consumers. They do not apply to raw materials, such as the plant, *Salvia divinorum*.

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A4 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

<#>International requirement ... [10]

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Data from the 2008-2009 Youth Smoking Survey indicates that:

- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;
- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year;
- and.
- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

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Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using Salvia in their lifetime (0.2% in the past year); and
- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that:

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;
- 5.4% of students (grades 7-12) ever used *Salvia divinorum*; and
- the use of *Salvia divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

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**Prepared by:** Stephanie Chandler and Denis Arsenault, OCS, CSTD

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**Input by:** Lisa Mackay IYH/PACCB, Suzanne Desjardins HECSB/ODARS, Hanan Abramovici HECSB/ODARS, Bruna Brands HECSB/ODARS, Jocelyn Kula, HECSB/OCS, Robin Marles HPFB/NHPD, Maggie Graham HPFB/NHPD, Stephanie Collins HPFB/NHPD, Mano Murty HPFB/MHPD, Robert Leitch HPFB/MHPD, Shahid Perwaiz HPFB/MHPD, Collin Pinto, HPFB/HPFBI

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Anne Lamar, ADM, PACCB (pending)  
DMO (pending)  
MO (pending)  
PCO (pending)

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**Page 1: [1] Deleted** **STCHANDL** **2010-12-09 3:20:00 PM**  
has concluded its assessment of *S. divinorum* and salvinorin A and is proposing to include both substances in one of the Schedules to the CDSA.

**Page 1: [2] Change** **STCHANDL** **2010-12-08 12:46:00 PM**  
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**Page 1: [3] Deleted** **CROUSH** **2010-12-09 2:20:00 PM**  
proposing that *S. divinorum* and salvinorin A be regulated as controlled substances under the *Controlled Drugs and Substances Act* (CDSA).

**Page 1: [4] Change** **CROUSH** **2010-12-09 2:18:00 PM**  
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(Message is unclear – reduce what risks (to health, security, i.e., enforcement).

**Page 1: [6] Deleted** **STCHANDL** **2010-12-22 10:28:00 AM**  
Because of their hallucinogenic properties, products containing *S. divinorum* and/or salvinorin A meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*.

**Page 1: [7] Deleted** **STCHANDL** **2010-12-17 11:05:00 AM**  
It is illegal to sell NHPs in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN).

**Page 1: [8] Deleted** **STCHANDL** **2010-11-26 2:35:00 PM**  
Because of their hallucinogenic properties, products containing *S. divinorum* and/or salvinorin A meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*.

It is illegal to sell NHPs in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN). The illegal sale of products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*.

**Page 1: [9] Deleted** **STCHANDL** **2010-11-26 2:27:00 PM**

***Salvia divinorum as a controlled substance:***

In Canada, neither the herb *Salvia divinorum* nor its main active ingredient, salvinorin A, are regulated under the *Controlled Drugs and Substances Act* (CDSA).

Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and thus, do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions. Several countries (Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) have placed controls on the import and/or sale of *Salvia*

*divinorum* and/or salvinorin A. Although some individual U.S. states have implemented laws restricting its use, sale and/or distribution, *Salvia divinorum* and salvinorin A are not regulated under the federal *Controlled Substances Act* in the United States.

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STCHANDL

2010-12-08 9:51:00 AM

**Q4 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum* as a controlled substance. What does that involve and what stage is it at?**

A4 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada is currently reviewing the available information to determine whether regulation of *Salvia divinorum* under the CDSA is warranted.

**Q5 – Didn't an internal report from Health Canada's Marketed Health Products Directorate recommend that *Salvia divinorum* be scheduled under the CDSA? Why has that recommendation not been acted upon?**

██████████ A5 – See A4

**Q6 – What is the significance of the adverse reaction reports that Health Canada has received with respect to the use of *Salvia divinorum*?**

A6 – Health Canada has received four domestic adverse reaction reports related to the use of *Salvia divinorum* as a hallucinogen through the Canada Vigilance database. The number of reports and the nature of reactions reported are, however, not adequate to fully characterize the risk of similar reactions among the general population

*Not very well done*

# QUESTION PERIOD NOTE NOTE POUR LA PÉRIODE DE QUESTIONS

Date:	December 23, 2010
Classification :	HECS PROTECTED - SESC PROTÉGÉ

## SUBJECT - SUJET

English:

**DRUGS - SALVIA DIVINORUM**

Français:

**DROGUES - SALVIA DIVINORUM**

*Has HPFB  
seen?  
legal?*

## SYNOPSIS - SOMMAIRE

English:

Media interest in Salvia divinorum is recurrent. Questions around this substance generally focus on its legality. Recently, a number of media reports have commented on a YouTube video which reportedly shows the young Hollywood celebrity Miley Cyrus smoking Salvia divinorum. There have also been several reports from scientific and media sources, indicating that Salvia divinorum has the potential for abuse, and is used by adolescents and young adults for its hallucinogenic properties.

## ANTICIPATED QUESTION - QUESTION PRÉVUE

English:

What is Health Canada doing to protect Canadians from the potential adverse effects associated with the use of Salvia divinorum?

Français:

Quelles mesures Santé Canada prend-il pour protéger les Canadiens contre les effets indésirables possibles liés à l'utilisation de la Salvia divinorum?

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long

English:

- Health Canada has concluded its assessment of Salvia and its main active ingredient ~~Salvia divinorum~~ salvinorin A and is proposing to add ~~schedule~~ both substances to Schedule III to ~~under in one of the Schedules to the~~ *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth.
- ~~The inclusion of Salvia divinorum and salvinorin A in one of the Schedules to the CDSA~~ The regulation of these substances as controlled substances will reduce the potential health and safety risks associated with their use ~~them. availability and potential abuse of this substance.~~
- Health Canada will ~~inform stakeholders of its proposal by~~ publish a *Notice to Interested Parties* in *Canada Gazette*, Part I ~~early next year~~. This notice will <sup>give</sup> ~~provide~~ <sup>people</sup> ~~stakeholders and other interested parties with our~~ the opportunity to provide comments on our ~~the~~ proposal to regulate ~~Salvia divinorum and salvinorin A as controlled substances.~~

HC intends to reg.

Therefore see NOI

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no possession drugs etc.

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2011  
This  
January / in late January 2011

these two

Francais:

## BACKGROUND - CONTEXTE

English:

### BACKGROUND / CONTEXTE

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, diviner's sage, magic mint, and puff. Certain websites are

also promoting the use of *S. divinorum* as a "legal" alternative to street drugs.

Both the plant *S. divinorum* and its main active ingredient salvinorin A are known to have both physical and mental effects which are often described as unpleasant, including:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

not in the medicinal lines?

Pls see medicinal lines p. 10. Canada?

Neither

International Control of *S. divinorum*

At the present time, *S. divinorum* and its main active ingredient salvinorin A are not listed under the United Nations Drug Control Conventions which means that they are not required to be regulated as a controlled substances in any of the countries that are signatories to these Conventions. However, some countries have decided to control *S. divinorum* and/or salvinorin A on their own. In Australia, Belgium, Denmark, Sweden, and SouthNorth Korea, the possession and sale of *S. divinorum* is illegal. In Spain, the sale of *S. divinorum* is prohibited, but possession or use is not. In Norway, *S. divinorum* cannot be imported without a prescription, and in Japan has recently passed a law that will take effect in April 2007 which totally bans all activities with salvinorin A have been banned. In the United States, neither *S. divinorum* nor salvinorin A are regulated as controlled substances by the US Drug Enforcement Administration; however, although some states such as Missouri, Louisiana, Tennessee and Delaware have implemented laws restricting the use, sale and/or distribution of one or both substances.

? Finland? Germany?

Current Situation in Canada

Health Canada considers several factors in determining whether regulation of a substance under is currently completing a review of *Salvia divinorum* against the criteria considered in adding substances to one of the Schedules to the *Controlled Drugs and Substances Act* (CDSA) is warranted, namely:

- International requirements and trends in control and/or scheduling;
- Chemical and pharmacological similarity to other substances already regulated under drugs listed in the CDSA;
- Dependence potential; Legitimate uses of the substance (i.e. therapeutic, scientific, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.
- Likelihood of abuse/misuse;
- Extent of abuse/misuse in Canada;
- Danger to public health and safety; and,
- Legitimate use in Canada

Health Canada recently concluded its assessment of *S. divinorum* and its main active ingredient salvinorin A against the aforementioned factors and now proposes to include both substances in Schedule III to the CDSA.

Once this work has been completed, Health Canada will inform stakeholders of its decision. A regulatory proposal will be developed in the coming months.

The plant *S. divinorum* is not currently regulated under the CDSA and therefore the plant is not considered to be "banned", nor are activities with it considered to be illegal in Canada. Nevertheless, when specifically marketed for its hallucinogenic properties, *S. divinorum* meets the definition of a natural health product in accordance with under the *Natural Health Products Regulations*. To date, however, Health Canada has not authorized for sale any natural health products which contain *S. divinorum* as an ingredient. The sale of unauthorized natural health products containing *S. divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

PKS  
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from wire  
\* refer to 305 new comment  
Step

**ATTACHMENTS / PIÈCE(S) JOINTE(S)**

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	Mobile/ Cellulaire: 613-296-4239	Title/ Titre:	Mobile/ Cellulaire:
Alternate/ Secondaire: Jocelyn Kula	Telephone/ Téléphone: 613-952-2177		
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**Date Prepared/Préparé le :** 2010-09-07

**Prepared by/Préparé par :** Stephanie Chandler **Phone/ No de tél. :** 613-946-0124

**Office/Bureau :** CSTD - Office of Controlled Substances

**Date Contact Signed/  
Signature de la personne  
ressource :**  Contact Signed - Signé

**D.G. Verification/  
Vérification par le D.E. :** Cathy Sabiston  D.G. Approved / Approuvé D.E.

**Date D.G. Verified/  
Date vérifié par le D.E. :**

**Programme :** Controlled Substances and Tobacco Directorate

**ADM Approved/ Approbation  
par le SMA :** Paul Glover  
(946-6701)

**Branch/ Direction générale :** HECS/SESC

**Department/ Ministère :** Health Canada / Santé Canada



## QUESTION PERIOD NOTE

## NOTE POUR LA PÉRIODE DE QUESTIONS

Date:	December 23, 2010
Classification :	HECS PROTECTED - SESC PROTÉGÉ

---

### SUBJECT - SUJET

English:

**DRUGS - SALVIA DIVINORUM**

Français:

**DROGUES - SALVIA DIVINORUM**

---

### SYNOPSIS - SOMMAIRE

English:

Media interest in Salvia divinorum is recurrent. Questions around this substance generally focus on its legality. Recently, a number of media reports have commented on a YouTube video which reportedly shows the young Hollywood celebrity Miley Cyrus smoking Salvia divinorum. There have also been several reports from scientific and media sources, indicating that Salvia divinorum has the potential for abuse, and is used by adolescents and young adults for its hallucinogenic properties.

---

### ANTICIPATED QUESTION - QUESTION PRÉVUE

English:

What is Health Canada doing to protect Canadians from the potential adverse effects associated with the use of Salvia divinorum?

Français:

Quelles mesures Santé Canada prend-il pour protéger les Canadiens contre les effets indésirables possibles liés à l'utilisation de la Salvia divinorum?

---

English:

- Health Canada is proposing to add Salvia and its main active ingredient salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA).
- Health Canada will publish a *Notice to Interested Parties* in *Canada Gazette*, Part I in February 2011. The NOI will give people the opportunity to provide comments on the proposal to regulate these two substances.
- The inclusion of Salvia in Schedule III to the CDSA would prohibit, unless authorized by regulation: possession, trafficking, possession for the purposes of trafficking, importation, exportation, possession for the purpose of exportation, and production (cultivation).

Français:

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## **BACKGROUND - CONTEXTE**

English:

### **BACKGROUND / CONTEXTE**

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, diviner's sage, magic mint, and puff. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs.

Both the plant *S. divinorum* and its main active ingredient salvinorin A are known to have physical and mental effects which are often described as unpleasant, including:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter

- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

International Control of *S. divinorum*

Neither *Salvia divinorum* nor its main active ingredient salvinorin A are listed under the United Nations Drug Control Conventions; as a result, they do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions. The move to include *Salvia divinorum* and salvinorin A in Schedule III to the CDSA is consistent with actions taken by several countries (Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Some individual U.S. states have implemented laws restricting their use, sale and/or distribution.

Current Situation in Canada

Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted, namely:

- International requirements and trends in control and/or scheduling;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e. therapeutic, scientific, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada recently concluded its assessment of *S. divinorum* and its main active ingredient salvinorin A against the aforementioned factors and now proposes to include both substances in Schedule III to the CDSA.

The plant *Salvia divinorum* is not regulated under the *Controlled Drugs and Substances Act* (CDSA) and therefore the plant is not considered to be "banned" nor are activities with it considered to be illegal in Canada. However, as *Salvia divinorum* is a plant with hallucinogenic properties when consumed by humans, it meets the definition of a natural health product (NHP) under the *Natural Health Products Regulations* when marketed as a hallucinogen. To date, Health Canada has not licensed for sale any Natural Health Product which contains *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products containing *Salvia divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act* .

**ATTACHMENTS / PIÈCE(S)-JOINTE(S)**

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Alternate/ Secondaire: Jocelyn Kula	Telephone/ Téléphone: 613-952-2177		
	Mobile/ Cellulaire: 613-797-2103		

**Date Prepared/Préparé le :** 2010-09-07

**Prepared by/Préparé par :** Stephanie Chandler **Phone/ No de tél. :** 613-946-0124

**Office/Bureau :** CSTD - Office of Controlled Substances

**Date Contact Signed/  
Signature de la personne  
ressource :**

Contact Signed - Signé

**D.G. Verification/  
Vérification par le D.E. :**

Cathy Sabiston

D.G. Approved / Approuvé D.E.

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par le SMA :** Paul Glover  
(946-6701)

**Branch/ Direction générale :** HECS/SESC

**Department/ Ministère :** Health Canada / Santé Canada

See comments  
HT  
DRAFT V.7

DEPARTMENT OF HEALTH

CONTROLLED DRUGS AND SUBSTANCES ACT

Notice to interested parties - Proposal regarding the addition of *Salvia divinorum* and salvinorin A to Schedule III to the Controlled Drugs and Substances Act

This notice provides interested stakeholders with the opportunity to provide ~~preliminary~~ comments on Health Canada's proposal to add the plant *Salvia divinorum* (*S. divinorum*) and its active ingredient salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA). Stakeholders may also identify themselves for inclusion in any future consultation.

*S. divinorum* is a species of sage belonging to the mint family. Its leaves are generally chewed or smoked to obtain psychotropic effects. While uncertainty remains surrounding the health risks of *S. divinorum*, known effects are reported to be short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant. Neither *S. divinorum* nor salvinorin A are currently included in any of the Schedules to the CDSA.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. *S. divinorum* is widely touted as a "legal hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs.<sup>1</sup> Results from the *Canadian Alcohol and Drug Use Monitoring Survey* (CADUMS) reveal that, in 2009, 1.6% of Canadians aged 15 years and older reported having used *S. divinorum* at least once in their lifetime, and that youth aged 15-24 were much more likely to have used it than adults aged 25 years and older. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *S. divinorum* in the past year. Moreover, the 2009 *Ontario Student Drug Use and Health Survey* (OSDUHS) indicated that 5.4% of Ontario students in grades 7-12 reported ever using *S. divinorum* and 4.4% of these students reported using this substance in the past year. Given its unknown effects and pharmacological similarity to other substances included in Schedule III to the CDSA such as LSD and psilocybin, Health Canada is concerned that the ready availability and use of *S. divinorum* poses a risk to the health and safety of Canadians, particularly youth.

shld this be spelled out 1st?

While *S. divinorum* and salvinorin A are not currently included in any of the United Nations Drug Control Conventions, a number of countries have chosen to regulate one or both as controlled substances. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden have all placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. Some American states have also implemented laws restricting their use, sale and/or distribution.

<sup>1</sup>Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.

Including these substances within Schedule III to the CDSA would prohibit: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation). The control of *S. divinorum* and salvinorin A under the CDSA will enable law enforcement agencies to take action against suspected illegal activities involving these substances.

As this action is not intended to interfere with the use and availability of *S. divinorum* and/or salvinorin A for legitimate medical, scientific or industrial purposes, Health Canada is seeking information from stakeholders on whether there are any such uses in Canada. Information received in response to this notice will be instrumental in determining appropriate regulation under the CDSA.

The publication of this notice begins a 30-day comment period. ~~There will be additional opportunities to provide comments following prepublication of the scheduling proposal in Canada Gazette, Part I.~~

*as the regulatory process progresses.*

*can it be more generic*

If you are ~~interested in this process or~~ have comments on this proposal, please contact Stephanie Chandler, Regulatory Policy Division, Office of Controlled Substances, Address Locator: 3503D, 123 Slater St., Ottawa, Ontario, Canada, K1A 1B9, by fax at (613) 946-4224 or by email at [OCS\\_Policy\\_and\\_Regulatory\\_Affairs@hc-sc.gc.ca](mailto:OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca).

*E say*

*GC*

*is*

*considering whether*

*it would*

*do*

*CAI*

*a*

*go*

*straight*

*KG-2?*

Standard NOI line.

Cathy A. Sabiston  
Director General  
Controlled Substances and Tobacco Directorate

Date \_\_\_\_\_

*- Option -  
- Remove this*



**Fw: AR 10-127205 - 634 Verbal Briefing re: Update of scheduling status of  
Salvia under the CDSA December 21 at 1:00 PM**

Jocelyn Kula to: Stephanie Chandler

2010-12-24 12:02 PM

Cc: Denis Arseneault, Robin Marles, Victoria Anderson-Selst

Final of what was sent to ADMO (for everyone's records)

---

Jocelyn Kula

Acting Director/ Directrice par intérim

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs

Health Canada/ Santé Canada

Tel: (613) 952-2177 Fax: (613) 946-4224

----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2010-12-24 12:01 PM -----

From: Paula Robert/HC-SC/GC/CA

To: Claudia Lafleur/HC-SC/GC/CA@HWC

Cc: Jesse Arnup-Blondin/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Cyndi  
Vaughan/HC-SC/GC/CA@HWC, SoniaH Lindblad1/HC-SC/GC/CA@HWC, Stephanie  
Szick/HC-SC/GC/CA@HWC, Cathy A Sabiston/HC-SC/GC/CA@HWC

Date: 2010-12-24 07:39 AM

Subject: Re: AR 10-127205 - 634 Verbal Briefing re: Update of scheduling status of Salvia under the CDSA  
December 21 at 1:00 PM

---

Bonjour ma belle Claudia,

Please see CSTD's DG approved meeting summary with 2 supporting documents. Je te souhaite de très  
belle fêtes. À bientôt.



10\_127205\_634 including HPFB input\_Dec 22\_10.wpd



Summary of MO Brfng on Salvia Surveillance Attachment.doc



Summary of MO Brfng on Salvia CDSA Attachment.doc

P.

Paula Robert

Correspondence Officer / Adjointe à la correspondance

Director General's Office (DGO) / Bureau de la Directrice générale

Controlled Substances and Tobacco Directorate (CSTD) / Direction des substances contrôlées et de la  
lutte au tabagisme (DSCLT)

HECS / SESC

Health Canada / Santé Canada

123 rue Slater Street / AL: 3509A

Tel: (613) 948-2165

e-mail: paula.robert@hc-sc.gc.ca

---

Claudia Lafleur

Please see the attached template to use for the...

2010-12-21 09:34:41 AM

002134

From: Claudia Lafleur/HC-SC/GC/CA  
To: Jesse Arnup-Blondin/HC-SC/GC/CA@HWC  
Cc: Jocelyn Kula/HC-SC/GC/CA@HWC, Cyndi Vaughan/HC-SC/GC/CA@HWC, Paula Robert/HC-SC/GC/CA@HWC, SoniaH Lindblad1/HC-SC/GC/CA@HWC, Stephanie Szick/HC-SC/GC/CA@HWC, Cathy A Sabiston/HC-SC/GC/CA@HWC  
Date: 2010-12-21 09:34 AM  
Subject: Re: AR 10-127205 - 634 Verbal Briefing re: Update of scheduling status of Salvia under the CDSA December 21 at 1:00 PM

---

Please see the attached template to use for the summary report due to me by 10:00 on December 24.



Internal Meeting\_Debrief\_Template\_rev Oct 27 2010.wpd

Merci,  
Claudia Lafleur  
Executive Assistant to the ADM/Adjointe Exécutive au SMA  
Assistant Deputy Minister's Office/Bureau du sous-ministre adjoint  
HECSB/DGSESC  
Health Canada/Santé Canada  
(613) 946-6700

Jesse Arnup-Blondin Hi everyone - This briefing is still going ahea... 2010-12-21 09:28:54 AM

From: Jesse Arnup-Blondin/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC, Cyndi Vaughan/HC-SC/GC/CA@HWC, Paula Robert/HC-SC/GC/CA@HWC, SoniaH Lindblad1/HC-SC/GC/CA@HWC, Stephanie Szick/HC-SC/GC/CA@HWC  
Cc: Cathy A Sabiston/HC-SC/GC/CA@HWC, Claudia Lafleur/HC-SC/GC/CA@HWC  
Date: 2010-12-21 09:28 AM  
Subject: Re: AR 10-127205 - 634 Verbal Briefing re: Update of scheduling status of Salvia under the CDSA December 21 at 1:00 PM

---

Hi everyone -

This briefing is still going ahead this afternoon. Cathy has agreed to attend with Jocelyn. I have already provided Claudia with the names, so she has everything she needs. We have also asked to have HPFB invited in case there are NHP related questions.

Jesse

Jocelyn Kula Only to say that the best doc to refer to at this p... 2010-12-20 08:41:20 PM

From: Jocelyn Kula/HC-SC/GC/CA  
To: Jesse Arnup-Blondin/HC-SC/GC/CA@HWC, Cathy A Sabiston/HC-SC/GC/CA@HWC, Stephanie Szick/HC-SC/GC/CA@HWC, SoniaH Lindblad1/HC-SC/GC/CA@HWC, Paula Robert/HC-SC/GC/CA@HWC, Cyndi Vaughan/HC-SC/GC/CA@HWC  
Cc: Claudia Lafleur/HC-SC/GC/CA@HWC  
Date: 2010-12-20 08:41 PM  
Subject: Re: AR 10-127205 - 634 Verbal Briefing re: Update of scheduling status of Salvia under the CDSA December 21 at 1:00 PM

---

s.21(1)(a)

s.21(1)(b)



s.21(1)(a)  
s.21(1)(b)

[REDACTED]

Jocelyn  
Sent by blackberry

Jocelyn Kula  
A/ Director/ Directrice par interim  
Office of Controlled Substances/ Bureau des substances contrôllées

**From:** Jesse Arnup-Blondin  
**Sent:** 2010-12-20 08:08 PM EST  
**To:** Cathy A Sabiston; Stephanie Szick; SoniaH Lindblad1; Paula Robert; Cyndi Vaughan  
**Cc:** Claudia Lafleur; Jocelyn Kula  
**Subject:** Re: AR 10-127205 - 634 Verbal Briefing re: Update of scheduling status of Salvia under the CDSA  
December 21 at 1:00 PM

[REDACTED]

Jesse

**From:** Jesse Arnup-Blondin  
**Sent:** 2010-12-20 06:18 PM EST  
**To:** Cathy A Sabiston; Stephanie Szick; SoniaH Lindblad1; Paula Robert; Cyndi Vaughan  
**Cc:** Claudia Lafleur; Jocelyn Kula  
**Subject:** Re: AR 10-127205 - 634 Verbal Briefing re: Update of scheduling status of Salvia under the CDSA  
December 21 at 1:00 PM

No docs needed - paper only. I will ask Paul abt you stepping out to attend.

[REDACTED]

Will keep you posted.

Thanks!

**From:** Cathy A Sabiston  
**Sent:** 2010-12-20 05:39 PM EST  
**To:** Jesse Arnup-Blondin; Stephanie Szick; SoniaH Lindblad1; Paula Robert; Cyndi Vaughan  
**Cc:** Claudia Lafleur; Jocelyn Kula  
**Subject:** Re: AR 10-127205 - 634 Verbal Briefing re: Update of scheduling status of Salvia under the CDSA  
December 21 at 1:00 PM

It would be jocelyn kula who I have copied on this note. That said, if paul says okay I could 'step out' of retreat

s.21(1)(a)

s.21(1)(b)

tomorrow to attend with jocelyn

Will this be verbal?

Thx cas

**From:** Jesse Arnup-Blondin  
**Sent:** 2010-12-20 05:19 PM EST  
**To:** Cathy A Sabiston; Stephanie Szick; SoniaH Lindblad1; Paula Robert; Cyndi Vaughan  
**Cc:** Claudia Lafleur  
**Subject:** Fw: AR 10-127205 - 634 Verbal Briefing re: Update of scheduling status of Salvia under the CDSA  
December 21 at 1:00 PM

Can you please have someone on stand-by in case we are unable to reschedule?

Will keep you posted.

Thanks,

Jesse

----- Forwarded by Jesse Arnup-Blondin/HC-SC/GC/CA on 2010-12-20 05:17 PM -----

**From:** Lisa Whittleton/HC-SC/GC/CA  
**To:** HECSB\_Briefing  
**Cc:** Bryan Takeda/HC-SC/GC/CA@HWC, Jennifer Kuyek/HC-SC/GC/CA@HWC, Sandra Rose Roy/HC-SC/GC/CA@HWC, Meghan Lax/HC-SC/GC/CA@HWC, Steven Schwendt/HC-SC/GC/CA@HWC, Ian Hobler/HC-SC/GC/CA@HWC, Sarah-Emily Carle/HC-SC/GC/CA@HWC, Christine Gillis/HC-SC/GC/CA@HWC  
**Date:** 2010-12-20 03:58 PM  
**Subject:** Fw: AR 10-127205 - 634 Verbal Briefing re: Update of scheduling status of Salvia under the CDSA December 21 at 1:00 PM

Apologies, this meeting is scheduled for **Tuesday, December 21, 2010 at 1:00 PM and NOT 4:00 PM.**

Please see revisions below, in red.

---

Lisa Whittleton  
Briefing Analyst | Analyste de l'information  
Ministerial Briefing Unit (MBU) | Unité d'information Ministérielle (UIM)  
Departmental Secretariat | Secrétariat du ministère  
Deputy Minister's Office | Cabinet du sous-ministre

002137

Health Canada | Santé Canada  
Phone | Téléphone: (613) 954-1637

----- Forwarded by Lisa Whittleton/HC-SC/GC/CA on 2010-12-20 03:52 PM -----

From: Lisa Whittleton/HC-SC/GC/CA  
To: HECSB\_Briefing  
Cc: Bryan Takeda/HC-SC/GC/CA@HWC, Jennifer Kuyek/HC-SC/GC/CA@HWC, Sandra Rose Roy/HC-SC/GC/CA@HWC, Meghan Lax/HC-SC/GC/CA@HWC, Steven Schwendt/HC-SC/GC/CA@HWC, Ian Hobler/HC-SC/GC/CA@HWC, Sarah-Emily Carle/HC-SC/GC/CA@HWC, Christine Gillis/HC-SC/GC/CA@HWC  
Date: 2010-12-20 03:36 PM  
Subject: AR 10-127205 - 634 Verbal Briefing re: Update of scheduling status of Salvia under the CDSA Dec. 21

Good afternoon,

Please see the action request below.

Thank you

---

Lisa Whittleton  
Briefing Analyst | Analyste de l'information  
Ministerial Briefing Unit (MBU) | Unité d'information Ministérielle (UIM)  
Departmental Secretariat | Secrétariat du ministère  
Deputy Minister's Office | Cabinet du sous-ministre  
Health Canada | Santé Canada  
Phone | Téléphone: (613) 954-1637

----- Forwarded by Lisa Whittleton/HC-SC/GC/CA on 2010-12-20 03:33 PM -----

Status: Open/Ouvert

**ACTION REQUEST - DEMANDE D'ACTION**

REQUESTOR'S NAME - NOM DU DEMANDEUR	DATE	NUMBER - NUMÉRO
Lisa Whittleton	2010-12-20	10-127205-634
REQUEST ORIGIN - ORIGINE DE LA DEMANDE		
SUBJECT - OBJET		
Martina Vorel		

Update of scheduling status of Salvia under the CDSA

REQUEST - DEMANDE (YYYY-MM-DD)

(1)Date: 2010-12-20

HECSB LEAD:

MO has requested a verbal briefing on the scheduling status of Salvia under the CDSA (Controlled Drugs and Substances Act). The verbal briefing has been scheduled to take place on Tuesday, December 21, 2010 at 4:00 PM 1:00 PM in the MO Boardroom. MO staff in attendance include: Leah Canning, Clarke Olsen and Carly Wolff.

Please provide the names, phone numbers (for the participant and his/her EA, if applicable), and titles of departmental official(s) (at DG level or higher) who will be attending this meeting via email by 10:00 AM on Tuesday, December 21, 2010. Lead branch to send up to three participants maximum (must include rationale on why three participants are required).

Please forward any material that will be presented at this meeting via email to MBU by 2:00 PM on Tuesday, December 21, 2010 to allow sufficient time for MO review prior to the meeting

Following the meeting, HECSB, please ensure that a debrief is prepared for the MO participants, outlining the salient points that were raised and any action to be taken by your sector. Please use the appropriate template that is attached in the MECS Tips & Samples section. Please ensure that the debrief is approved by, and sent from, your ADMO via email by noon on December 24, 2010 to Sandra Rose Roy, copying Lisa Whittleton and Jennifer Kuyek and adding the document to the attachments in MECS.

Please copy MBU Services UIM on any email regarding this request to ensure that your message reaches all concerned.

(2)Date:

(3)Date:

REQUIRED ON - REQUIS LE Date: 2010-12-27	AT - A Time: 12:00 PM
DEPARTMENTAL CONTACT - AGENT DE LIAISON DU MINISTERE Lisa Whittleton	TELEPHONE NUMBER - NUMÉRO DE TÉLÉPHONE

MECS #10-127205-634

**Debrief of Internal Meeting with the Minister's Office**  
*Salvia Divinorum*

**Purpose of the meeting:**

Verbal Briefing regarding scheduling status of Salvia under the CDSA

**Date and time of the meeting:**

December 21, 2010

1:00 PM

**Minister's staff present at the meeting:**

Carly Wolff

Clarke Olsen

Carlo Oliviero

**Names of Portfolio participants and their titles:**

Cathy Sabiston, DG, Controlled Substances and Tobacco Directorate, HECSB

Jocelyn Kula, A/Director, Office of Controlled Substances, CSTD, HECSB

Robin Marles, Director, Bureau of Clinical Trials and Health Sciences, Natural Health Products Directorate, HPFB

Victoria Anderson-Selst, Senior Advisor, HPFB ADMO

**DMO representative:**

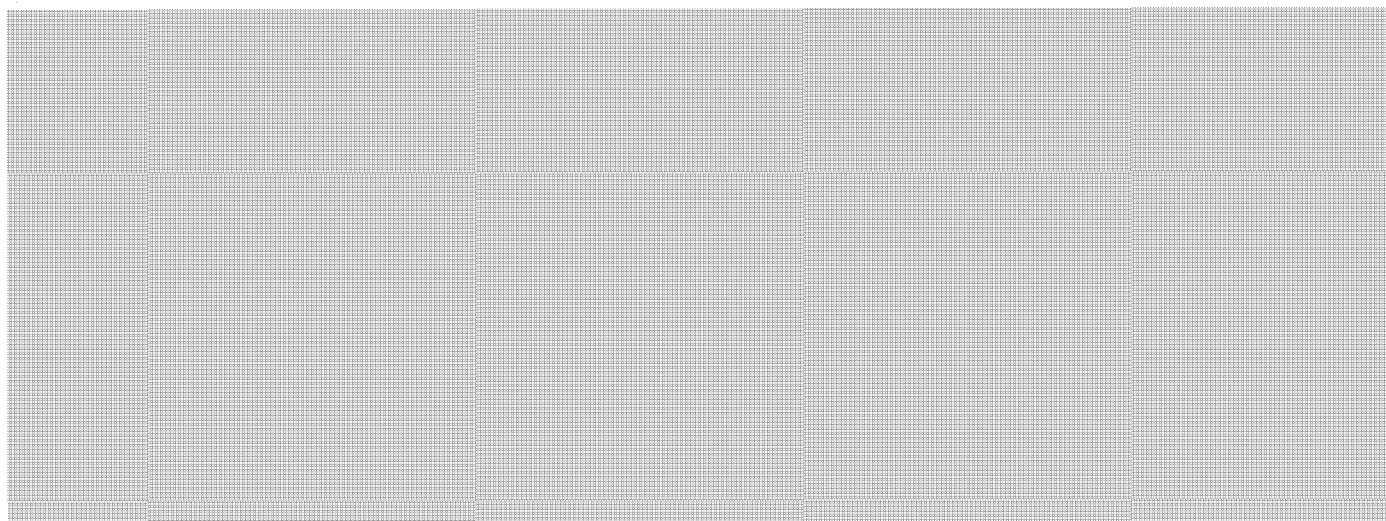
Ian Hobler, Policy Advisor

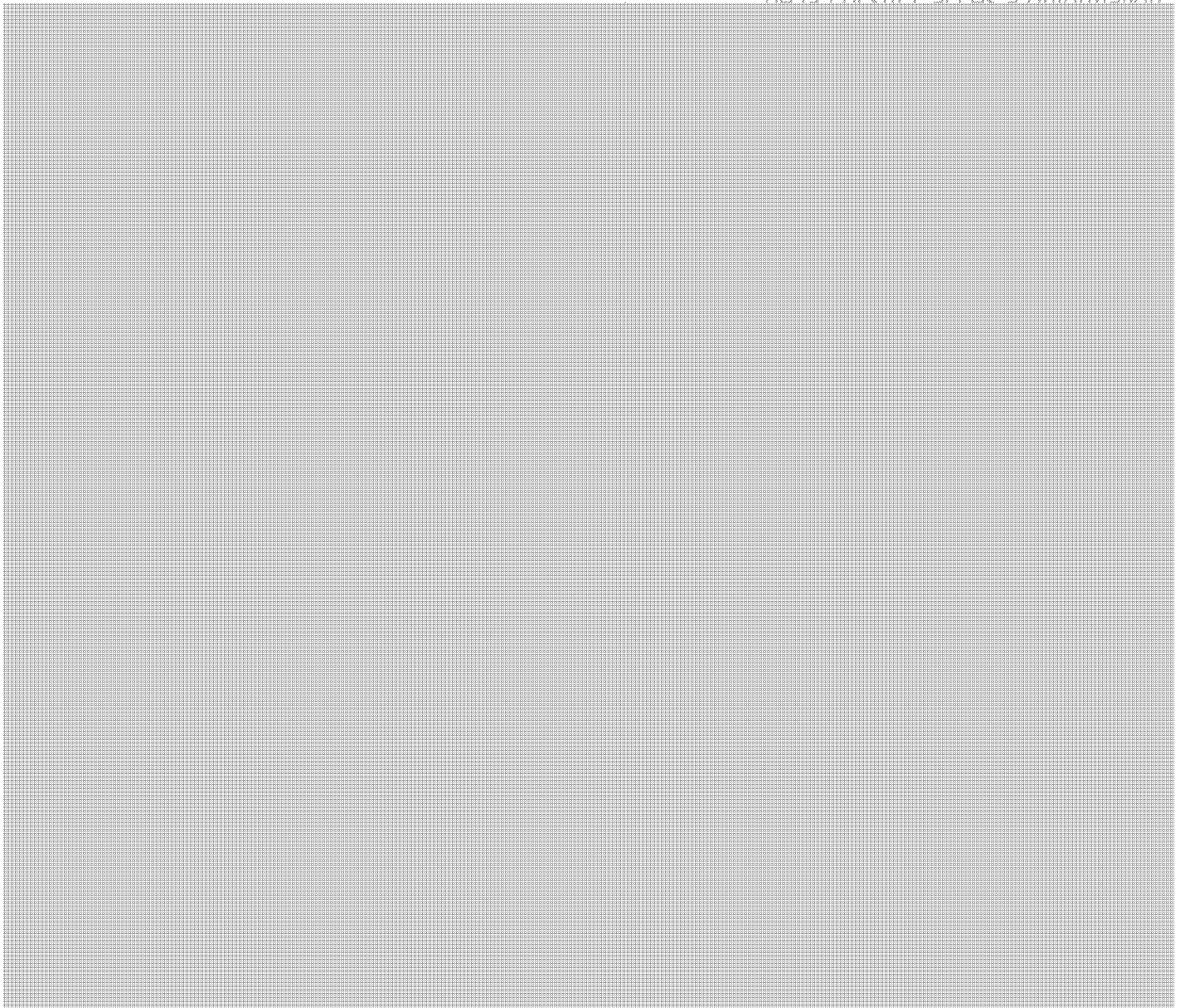
s.21(1)(a)

s.21(1)(b)

**High-level issues raised:**

Departmental officials provided a general overview of *Salvia divinorum*, in the context of the *Controlled Drugs and Substances Act* and the *Natural Health Products Regulations*.





**Branch Head:** Paul Glover  
**Telephone:** 613-946-6701  
**Date:** December 23, 2010

**s.21(1)(a)**  
**s.21(1)(b)**

### **Summary of Surveillance Data Supporting the Scheduling of Salvia under the CDSA**

Data from the 2008-2009 Youth Smoking Survey indicates that:

- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;
- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year; and.
- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using Salvia in their lifetime (0.2% in the past year); and
- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that:

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;
- 5.4% of students (grades 7-12) ever used *Salvia divinorum*; and
- the use of *Salvia divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

## Overview of Schedules to the *Controlled Drugs and Substances Act* and Applicable Penalties

The substances regulated under the CDSA are grouped into six of the eight Schedules (Schedules I to VI) to the Act. Schedules I to V list controlled substances while Schedule VI lists precursor chemicals. Schedule VII provides the threshold quantities for trafficking offences involving cannabis and cannabis resin. Schedule VIII provides the threshold quantities for possession offences involving cannabis and cannabis resin.

The following table provides examples of the substances included in the different Schedules to the CDSA:

Schedule	Examples of Substances Included
I	Opium, coca, morphine, fentanyls, other substances like methamphetamine (meth is not a narcotic)
II	Cannabis, its preparations, derivatives and synthetic preparations
III	Amphetamines, methylphenidate, mescaline, 4-hydroxybutanoic acid (GHB)
IV	Barbiturates, benzodiazepines, anabolic steroids
V	Propylhexedrine
VI	Pseudoephedrine, acetone, hydriodic acid

Each Schedule to the CDSA is associated with particular offences and punishments described in Part I of the Act. Offences associated with substances in Schedule I, II or III include illegal (or unauthorized) possession, trafficking, possession for the purposes of trafficking, importation and exportation, possession for the purposes of exportation, and production. The offences associated with substances in Schedule IV are similar to those associated with substances in Schedule I, II or III except that there is no criminal offence for simple possession. The offences associated with substances in Schedules V and VI are limited to illegal importation, exportation and possession for the purposes of exportation.

The CDSA also prohibits double doctoring, i.e., seeking or obtaining, or seeking or obtaining authorization to obtain, any substance included in Schedule I, II, III or IV from a practitioner without disclosing the particulars relating to the acquisition or authorization to obtain such a substance from any other practitioner within the past 30 days.

For the most part, the offences in the CDSA are *hybrid* which means they can be prosecuted either by *summary conviction (summary conviction offences)* or *indictment (indictable offences)*, as chosen by the Crown. *Summary conviction offences* encompass the most minor offences in the CDSA. Unless a different penalty is specified in the CDSA, *summary conviction offences* are all punishable by a fine of up to \$2,000 and/or six months imprisonment. Appendix I outlines the current maximum penalties applicable when a person is found guilty of a *summary conviction offence* as described in Part I of the Act.



*Indictable offences* are more serious than summary conviction offences. Conviction of an *indictable offence* exposes the accused to greater penalties. Appendix II outlines the current maximum penalties applicable when a person is found guilty of an *indictable offence* as described in Part I of the Act.

**Appendix I:**

Maximum penalties for a person found guilty of an offence prosecuted by *summary conviction* associated with each Schedule to the CDSA, as described in Part I of the Act

Schedule	Type of Offence	OFFENCE						
		Simple Possession 4(1)	Double Doctoring 4(2)	Trafficking 5(1)	Possession for the purpose of trafficking 5(2)	Importing and exporting 6(1)	Possession for the purpose of exporting 6(2)	Production 7(1)
I	First Offence	Fine up to \$1,000, or up to 6 months imprisonment, or both	Fine up to \$1,000, or up to 6 months imprisonment, or both					
	Subsequent Offence	Fine up to \$2,000, or up to 1 year imprisonment, or both	Fine up to \$2,000, or up to 1 year imprisonment, or both					
II	First Offence	Fine up to \$1,000, or up to 6 months imprisonment, or both	Fine up to \$1,000, or up to 6 months imprisonment, or both					
	Subsequent Offence	Fine up to \$2,000, or up to 1 year imprisonment, or both (Not applicable for Schedule VIII (marihuana, 30G, cannabis resin, 1G))	Fine up to \$2,000, or up to 1 year imprisonment, or both					
III	First Offence	Fine up to \$1,000, or up to 6 months imprisonment, or both	Fine up to \$1,000, or up to 6 months imprisonment, or both	up to 18 months	up to 18 months	up to 18 months	up to 18 months	up to 18 months
	Subsequent Offence	Fine up to \$2,000, or up to 1 year imprisonment, or both	Fine up to \$2,000, or up to 1 year imprisonment, or both					
IV	First Offence		Fine up to \$1,000, or up to 6 months imprisonment, or both	up to 1 year	up to 1 year	up to 1 year	up to 1 year	up to 1 year
	Subsequent Offence		Fine up to \$2,000, or up to 1 year imprisonment, or both					
V	First Offence					up to 1 year	up to 1 year	
	Subsequent Offence							
VI	First Offence					up to 18 months	up to 18 months	
	Subsequent Offence							

**Appendix II:**

Maximum penalties for a person found guilty of an offence prosecuted by *indictment* associated with each Schedule to the CDSA, as described in Part I of the Act

Schedule	OFFENCE						
	Simple Possession 4(1)	Double Doctoring 4(2)	Trafficking 5(1)	Possession for the purpose of trafficking 5(2)	Importing and exporting 6(1)	Possession for the purpose of exporting 6(2)	Production 7(1)
I	Imprisonment up to 7 years	Imprisonment up to 7 years	Life imprisonment	Life imprisonment	Life imprisonment	Life imprisonment	Life imprisonment
II	Imprisonment up to 5 years less a day  (Not applicable for Schedule VIII (marihuana, 30G, cannabis resin, 1G))	Imprisonment up to 5 years less a day	Life imprisonment  Schedule VII (marihuana/cannabis resin <3KG: imprisonment up to 5 years less a day)	Life imprisonment  Schedule VII (marihuana/cannabis resin <3KG: imprisonment up to 5 years less a day.	Life imprisonment	Life imprisonment	Life imprisonment  However, if cannabis (marihuana) imprisonment up to 7 years
III	up to 3 years	up to 3 years	up to 10 years	up to 10 years	up to 10 years	up to 10 years	up to 10 years
IV		up to 18 months	up to 3 years	up to 3 years	up to 3 years	up to 3 years	up to 3 years
V					up to 3 years	up to 3 years	
VI					up to 10 years	up to 10 years	

s.19(1)



**Salvia divinorum**

Jocelyn Kula to: [REDACTED]

2010-12-24 12:54 PM

Cc: Denis Arsenault, Stephanie Chandler

Hi [REDACTED]

It is a long while since we have spoken I know, so trust that this message finds you well.

I am writing about *Salvia divinorum* and its active ingredient Salvinorin A, which are not yet regulated as controlled substances in Canada.


We are currently finalizing a comprehensive scheduling assessment of the substances, and would appreciate clarification of some information we came across on the National Institute of Drug Abuse (NIDA) website. Essentially, the page we found (I regrettably don't have the link at hand but can provide if you need it), seems to suggest that the DEA is considering classifying *S. divinorum* as a Schedule I drug. We would appreciate confirmation of this information as it was always my understanding that while the import and/or distribution of Salvia is illegal in some individual states, the DEA only considers it to be a substance of concern at this point in time. In this regard, any additional information regarding the federal control of these substances (actual or planned if you can share) which you can provide would be greatly appreciated. As you can imagine, there is an intense amount of interest in products containing salvia further to the appearance of the Miley Cyrus video on Youtube.

Best wishes of the season, and I look forward to hearing from you.

Jocelyn

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

**Re: BF: 10:00am Friday December 31, 2010, 10-127340 - 194 - Action Request -  
Follow-up to the December 21, 2010, internal meeting to discuss scheduling salvia  
divinorum under the Controlled Drugs and Substances Act and relativity with NHP  
regulations** 

Jocelyn Kula to: Cyndi Vaughan

2010-12-29 09:31 AM

Cc: CSTD-OCS-DO, SoniaH Lindblad1, Paula Robert, Stephanie Szick, "Stephanie  
Chandler", "Denis Arsenault"

From: Jocelyn Kula/HC-SC/GC/CA

To: Cyndi Vaughan/HC-SC/GC/CA@HWC

Cc: CSTD-OCS-DO, SoniaH Lindblad1/HC-SC/GC/CA@HWC, Paula  
Robert/HC-SC/GC/CA@HWC, Stephanie Szick/HC-SC/GC/CA@HWC, "Stephanie Chandler"  
<stephanie.chandler@hc-sc.gc.ca>, "Denis Arsenault" <denis.arsenault@hc-sc.gc.ca>

Just to be clear- this is the note for PCO that we are talking about here right?

Just that this AR talks about a briefing note when Cathy told me the product for PCO could be in an  
email...

Pls confirm and reply to all as I am not in the office today but Stephanie Chandler in RPD/ OCS will be  
starting on this today.

JK

Sent by blackberry

Jocelyn Kula

A/ Director/ Directrice par interim

Office of Controlled Substances/ Bureau des substances contrôllées

Cyndi Vaughan

----- Original Message -----

**From:** Cyndi Vaughan

**Sent:** 2010-12-29 09:28 AM EST

**To:** Jocelyn Kula

**Cc:** CSTD-OCS-DO; SoniaH Lindblad1; Paula Robert; Stephanie Szick

**Subject:** BF: 10:00am Friday December 31, 2010, 10-127340 - 194 - Action  
Request - Follow-up to the December 21, 2010, internal meeting to discuss  
scheduling salvia divinorum under the Controlled Drugs and Substances Act and  
relativity with NHP regulations

Please provide one Briefing Note as per exchange below between Jesse and Stephanie. Due in DGO by  
Friday December 31, 10:00am.

Thank you

Cyndi Vaughan

Director General's Office (DGO) / Bureau de la Directrice générale

Controlled Substances and Tobacco Directorate (CSTD) / Direction des substances contrôllées et de la  
lutte au tabagisme (DSCLT)

HECS / SESC

Health Canada / Santé Canada

123 rue Slater Street / AL: 3509A

Tel: (613) 946-3596

cyndi.vaughan@hc-sc.gc.ca

----- Forwarded by Cyndi Vaughan/HC-SC/GC/CA on 2010-12-29 09:20 AM -----

From: Stephanie Szick/HC-SC/GC/CA  
To: Jesse Arnup-Blondin/HC-SC/GC/CA@HWC  
Cc: CSTD-DGO, Linda Corrigan/HC-SC/GC/CA@HWC, Michel Prud'Homme/HC-SC/GC/CA@HWC, Karen Schwerdtfeger/HC-SC/GC/CA@HWC, Linsey Hollett/HC-SC/GC/CA@HWC  
Date: 2010-12-29 08:06 AM  
Subject: Re: Fw: 10-127340 - 194 - Action Request - Follow-up to the December 21, 2010, internal meeting to discuss scheduling salvia divinorum under the Controlled Drugs and Substances Act and relativity with NHP regulations

---

Thanks Jesse,

Karen and Linsey -- please let us know on process for this BN.

Cyndi - - this will need to be tasked to OCS for a quick turn around to DGO as the BN is due in MBU next Tuesday, Jan. 4/11.

Stephanie Szick  
Director General's Office / Bureau du directeur général  
Controlled Substances & Tobacco Directorate (CSTD) /  
Direction des substances contrôlées et de la lutte au tabagisme (DSCLT)  
Health Canada / Santé Canada  
Tel / Tél: (613) 948-8651

Jesse Arnup-Blondin      Hi Stephanie - I will advise MBU that #1 and...      2010-12-24 12:58:03 PM

From: Jesse Arnup-Blondin/HC-SC/GC/CA  
To: Stephanie Szick/HC-SC/GC/CA@HWC  
Cc: CSTD-DGO, Linda Corrigan/HC-SC/GC/CA@HWC, Michel Prud'Homme/HC-SC/GC/CA@HWC, Karen Schwerdtfeger/HC-SC/GC/CA@HWC, Linsey Hollett/HC-SC/GC/CA@HWC  
Date: 2010-12-24 12:58 PM  
Subject: Re: Fw: 10-127340 - 194 - Action Request - Follow-up to the December 21, 2010, internal meeting to discuss scheduling salvia divinorum under the Controlled Drugs and Substances Act and relativity with NHP regulations

---

Hi Stephanie -

I will advise MBU that #1 and 3 have already been provided as follow-up to the verbal briefing.

However, for the BN request, we cannot close this request. Rather, CSTD will still prepare one briefing note, on the same schedule as originally requested. We will request that MO approve this note for it to be sent to PCO. If we need to have it to PCO by the 7th, a deadline of the 4th to MBU will still be necessary.

Karen and Linsey will advise next week on the best process for getting the green light to send this BN to PCO.

Thanks,

Jesse

Stephanie Szick      Hi Jesse, Further to our conversation --- in resp...      2010-12-24 12:46:17 PM

From: Stephanie Szick/HC-SC/GC/CA  
To: Jesse Arnup-Blondin/HC-SC/GC/CA@HWC  
Cc: CSTD-DGO, Linda Corrigan/HC-SC/GC/CA@HWC, Michel Prud'Homme/HC-SC/GC/CA@HWC, Karen Schwerdtfeger/HC-SC/GC/CA@HWC, Linsey Hollett/HC-SC/GC/CA@HWC

Date: 2010-12-24 12:46 PM  
Subject: Re: Fw: 10-127340 - 194 - Action Request - Follow-up to the December 21, 2010, internal meeting to discuss scheduling salvia divinorum under the Controlled Drugs and Substances Act and relativity with NHP regulations

---

Hi Jesse,

Further to our conversation --- in response to this action request below:

1) Appended to our meeting summary sent this morning to Claudia re: the Salvia MO briefing on Tuesday, we provided the info. requested below (re. CDSA info. and CADUMS/Youth Smoking Survey data).

2) Cathy received a call today from PCO asking for a BN for the PMO on Salvia (due in PCO Jan. 7). Ruth is to call her next Wed. to discuss further re; what they are looking for precisely.

RECOMMENDATION - rather than provide a separate BN on this same issue per the request below, we suggest that the Note for PCO/PMO over-ride this request as MO will need to approve the note before it goes to PCO/PMO.

i.e. It would be duplicative to write two separate notes on the same issue in the same time frame, esp. given one is for PCO/PMO and MO will be involved.

Please let us know if the PCO/PMO note will suffice, and that this request below can be closed.

Thanks very much,  
S

Paula Robert                      Paula Robert Correspondence Officer / Adjointe...                      2010-12-24 12:08:51 PM

----- Forwarded by Paula Robert/HC-SC/GC/CA on 2010-12-24 12:08 PM -----

From: Michel Prud'Homme/HC-SC/GC/CA  
To: Paula Robert/HC-SC/GC/CA@HWC  
Cc: Cyndi Vaughan/HC-SC/GC/CA@HWC, SoniaH Lindblad1/HC-SC/GC/CA@HWC, Linda Corrigan/HC-SC/GC/CA@HWC  
Date: 2010-12-22 11:06 AM  
Subject: Fw: 10-127340 - 194 - Action Request - Follow-up to the December 21, 2010, internal meeting to discuss scheduling salvia divinorum under the Controlled Drugs and Substances Act and relativity with NHP regulations

---

Further to the previous e-mail, please provide a **Briefing Note** and not a Memo.

Thank you,  
Michel Prud'homme

----- Forwarded by Michel Prud'Homme/HC-SC/GC/CA on 2010-12-22 11:05 AM -----

From: Michel Prud'Homme/HC-SC/GC/CA  
To: Paula Robert/HC-SC/GC/CA@HWC  
Cc: Cyndi Vaughan/HC-SC/GC/CA@HWC, SoniaH Lindblad1/HC-SC/GC/CA@HWC, Linsey Hollett/HC-SC/GC/CA@HWC, Diane Staynor/HC-SC/GC/CA@HWC, Linda Corrigan/HC-SC/GC/CA@HWC  
Date: 2010-12-22 10:48 AM  
Subject: 10-127340 - 194 - Action Request - Follow-up to the December 21, 2010, internal meeting to discuss scheduling salvia divinorum under the Controlled Drugs and Substances Act and relativity with NHP regulations

---

Please see the action request below and provide the input by 4:00 p.m. Thursday, December 30, 2010 and return to Linda's attention once approved.

Thank you,  
Michel Prud'homme

----- Forwarded by Michel Prud'Homme/HC-SC/GC/CA on 2010-12-22 10:45 AM -----

From: Frederick Coyle/HC-SC/GC/CA  
To: HECSB\_Action Request\_48h  
Cc: Bryan Takeda/HC-SC/GC/CA@HWC, Konrad Iwasiew/HC-SC/GC/CA@HWC, Gisele Jean/HC-SC/GC/CA@HWC, Ian Hobler/HC-SC/GC/CA@HWC, Christine Gillis/HC-SC/GC/CA@HWC  
Date: 2010-12-22 10:20 AM  
Subject: Follow-up to the December 21, 2010, internal meeting to discuss scheduling salvia divinorum under the Controlled Drugs and Substances Act and relativity with NHP regulations

Status: Open/Ouvert  
[Close Request](#)

Docket No.: 10-127340 - 194

Branch: HECSB-ADM

cc :

**ACTION REQUEST - DEMANDE D'ACTION**

REQUESTOR'S NAME - NOM DU DEMANDEUR Frederick Coyle	DATE 2010-12-22	NUMBER - NUMÉRO MECS#10-127340-194
--	--------------------	---------------------------------------

REQUEST ORIGIN - ORIGINE DE LA DEMANDE <input type="radio"/> DEC/CHG <input type="radio"/> Associate Deputy Minister's Office/ Bureau du Sous-Ministre délégué <input type="radio"/> Deputy Minister's Office/Cabinet du Sous-Ministre <input checked="" type="radio"/> Minister's Office/Cabinet du Ministre <input type="radio"/> Ministerial Meeting/Réunion Ministérielle
SUBJECT - OBJET  Follow-up to the December 21, 2010, internal meeting to discuss scheduling salvia divinorum under the Controlled Drugs and Substances Act and relativity with NHP regulations
REQUEST - DEMANDE (YYYY-MM-DD) (1)Date: 2010-12-22  HECSB:  Further to the December 21, 2010, internal meeting to discuss scheduling salvia divinorum under the Controlled Drugs and Substances Act and relativity with NHP regulations, the Minister's office has requested the following information:  - Chart explaining CDSA schedules, substances and penalties - Criteria for listing under the CDSA - Summary of CADUMS and Ontario Youth Smoking Survey with focus on salvia use data in comparison with other CDSA substances  Please provide a briefing note for information on this issue, to MBU by 12:00PM by 12:00PM on Tuesday, January 4, 2011.  PLEASE ADVISE MBU IMMEDIATELY IF THIS REQUEST NEEDS TO BE REDIRECTED TO A DIFFERENT BRANCH OR IF OTHER BRANCHES NEED TO BE INVOLVED, OR IF FURTHER CLARIFICATION IS REQUIRED.



(2)Date:

(3)Date:

- Bilingual/Bilingue
- French/Français
- English/Anglais

REQUIRED ON - REQUIS LE Date: 2011-01-04	AT - À Time: 12:00 PM
DEPARTMENTAL CONTACT - AGENT DE LIAISON DU MINISTÈRE Frederick Coyle	TELEPHONE NUMBER - NUMÉRO DE TÉLÉPHONE 941-6093



**BF: 10:00am Friday December 31, 2010, 10-127340 - 194 - Action Request - Follow-up to the December 21, 2010, internal meeting to discuss scheduling salvia divinorum under the Controlled Drugs and Substances Act and relativity with NHP regulations**

Carmen Berube to: Denis Arsenault

2010-12-29 11:00 AM

Cc: Jocelyn Kula, CSTD-OCS-DO, Stephanie Chandler, Isabel Shanahan, Arafo Talane

Just spoke to Stephanie Szick about being unclear on the format. She told me to tell Stephanie Chandler to proceed with Briefing note to the Minister (following template):



BRIEFING NOTE - TO THE MINISTRE'S OFFICE.wpd

She said if she finds out differently, she will let us know.

We'll need something by tomorrow to meet Friday's 10:00 AM deadline.

Thanks!

Carmen Bérubé

Assistant to the Director | Adjointe à la Directrice

Office of Controlled Substances | Bureau des substances contrôlées

Controlled Substances and Tobacco Directorate (CSTD) | Direction des substances contrôlées et de la lutte au tabagisme (DSCLT)

Health Canada | Santé Canada

Tel./Tél.: 613-952-2131 | Fax/Télec.: 613-946-4224

Cyndi Vaughan

Hi Jocelyn, This is the note for PCO, and it will n...

2010-12-29 10:41:14 AM

From: Cyndi Vaughan/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: CSTD-OCS-DO, "Denis Arsenault" <denis.arsenault@hc-sc.gc.ca>, Paula Robert/HC-SC/GC/CA@HWC, SoniaH Lindblad1/HC-SC/GC/CA@HWC, Stephanie Szick/HC-SC/GC/CA@HWC, "Stephanie Chandler" <stephanie.chandler@hc-sc.gc.ca>  
Date: 2010-12-29 10:41 AM  
Subject: Re: BF: 10:00am Friday December 31, 2010, 10-127340 - 194 - Action Request - Follow-up to the December 21, 2010, internal meeting to discuss scheduling salvia divinorum under the Controlled Drugs and Substances Act and relativity with NHP regulations

Hi Jocelyn,

This is the note for PCO, and it will need to be a briefing note.

Thanks

Cyndi Vaughan

Director General's Office (DGO) / Bureau de la Directrice générale

Controlled Substances and Tobacco Directorate (CSTD) / Direction des substances contrôlées et de la

lutte au tabagisme (DSCLT)  
HECS / SESC  
Health Canada / Santé Canada  
123 rue Slater Street / AL: 3509A  
Tel: (613) 946-3596  
cyndi.vaughan@hc-sc.gc.ca

Jocelyn Kula                      Just to be clear- this is the note for PCO that we...                      2010-12-29 09:31:54 AM  
Cyndi Vaughan

----- Original Message -----

**From:** Cyndi Vaughan  
**Sent:** 2010-12-29 09:28 AM EST  
**To:** Jocelyn Kula  
**Cc:** CSTD-OCS-DO; SoniaH Lindblad1; Paula Robert; Stephanie Szick  
**Subject:** BF: 10:00am Friday December 31, 2010, 10-127340 - 194 - Action Request - Follow-up to the December 21, 2010, internal meeting to discuss scheduling salvia divinorum under the Controlled Drugs and Substances Act and relativity with NHP regulations  
Please provide one Briefing Note as per exchange below between Jesse and Stephanie. Due in DGO by Friday December 31, 10:00am.

Thank you

Cyndi Vaughan

Director General's Office (DGO) / Bureau de la Directrice générale  
Controlled Substances and Tobacco Directorate (CSTD) / Direction des substances contrôlées et de la lutte au tabagisme (DSCLT)  
HECS / SESC  
Health Canada / Santé Canada  
123 rue Slater Street / AL: 3509A  
Tel: (613) 946-3596  
cyndi.vaughan@hc-sc.gc.ca

----- Forwarded by Cyndi Vaughan/HC-SC/GC/CA on 2010-12-29 09:20 AM -----

**From:** Stephanie Szick/HC-SC/GC/CA  
**To:** Jesse Arnup-Blondin/HC-SC/GC/CA@HWC  
**Cc:** CSTD-DGO, Linda Corrigan/HC-SC/GC/CA@HWC, Michel Prud'Homme/HC-SC/GC/CA@HWC, Karen Schwerdtfeger/HC-SC/GC/CA@HWC, Linsey Hollett/HC-SC/GC/CA@HWC  
**Date:** 2010-12-29 08:06 AM  
**Subject:** Re: Fw: 10-127340 - 194 - Action Request - Follow-up to the December 21, 2010, internal meeting to discuss scheduling salvia divinorum under the Controlled Drugs and Substances Act and relativity with NHP regulations

Thanks Jesse,

Karen and Linsey -- please let us know on process for this BN.

Cyndi - - this will need to be tasked to OCS for a quick turn around to DGO as the BN is due in MBU next Tuesday, Jan. 4/11.

Stephanie Szick  
Director General's Office / Bureau du directeur général  
Controlled Substances & Tobacco Directorate (CSTD) /  
Direction des substances contrôlées et de la lutte au tabagisme (DSCLT)

Health Canada / Santé Canada  
Tel / Tél: (613) 948-8651

Jesse Arnup-Blondin	Hi Stephanie - I will advise MBU that #1 and...	2010-12-24 12:58:03 PM
Stephanie Szick	Hi Jesse, Further to our conversation --- in resp...	2010-12-24 12:46:17 PM
Paula Robert	Paula Robert Correspondence Officer / Adjointe...	2010-12-24 12:08:51 PM

Fw: BF: 10:00am Friday December 31, 2010, 10-127340 - 194 - Action Request - Follow-up to the December 21, 2010, internal meeting to discuss scheduling salvia divinorum under the Controlled Drugs and Substances Act and relativity with NHP regulations

Cyndi Vaughan

to:

Jocelyn Kula

2010-12-29 12:22 PM

Cc:

CSTD-OCS-DO, "Denis Arsenault", Paula Robert, SoniaH Lindblad1, Stephanie Szick, "Stephanie Chandler"

Show Details

Confirmation received that this is the template to use.

Thank you

Cyndi Vaughan

Director General's Office (DGO) / Bureau de la Directrice générale  
Controlled Substances and Tobacco Directorate (CSTD) / Direction des substances contrôlées et de la lutte au tabagisme (DSCLT)

HECS / SESC

Health Canada / Santé Canada

123 rue Slater Street / AL: 3509A

Tel: (613) 946-3596

cyndi.vaughan@hc-sc.gc.ca

----- Forwarded by Cyndi Vaughan/HC-SC/GC/CA on 2010-12-29 12:12 PM -----

From: Cyndi Vaughan/HC-SC/GC/CA

To: Jocelyn Kula/HC-SC/GC/CA@HWC

Cc: CSTD-OCS-DO, "Denis Arsenault" <denis.arsenault@hc-sc.gc.ca>, Paula Robert/HC-SC/GC/CA@HWC, SoniaH Lindblad1/HC-SC/GC/CA@HWC, Stephanie Szick/HC-SC/GC/CA@HWC, "Stephanie Chandler" <stephanie.chandler@hc-sc.gc.ca>

Date: 2010-12-29 10:41 AM

Subject: Re: BF: 10:00am Friday December 31, 2010, 10-127340 - 194 - Action Request - Follow-up to the December 21, 2010, internal meeting to discuss scheduling salvia divinorum under the Controlled Drugs and Substances Act and relativity with NHP regulations

Hi Jocelyn,

This is the note for PCO, and it will need to be a briefing note.

Thanks

Cyndi Vaughan

Director General's Office (DGO) / Bureau de la Directrice générale

002156



**Fw:**  
Jocelyn Kula to: Stephanie Chandler

2010-12-30 03:25 PM

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224  
----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2010-12-30 03:25 PM -----

From: Jocelyn Kula/HC-SC/GC/CA  
To: Cathy A Sabiston/HC-SC/GC/CA@HWC  
Cc: SoniaH Lindblad1/HC-SC/GC/CA@HWC, Stephanie Szick/HC-SC/GC/CA@HWC  
Date: 2010-12-21 10:32 AM  
Subject: Re:

---

### 1) Timelines:

NOI can go as soon as it is approved; typically the Canada Gazette office needs 6 business days with the content before it is printed but they have special deadlines over the holidays, i.e. cut off for January 1, 2011 edition is today and cut off for January 8, 2011 edition is December 29, 2011; CG I is printed every Saturday.....

Comment period for an NOI is typically 30 days and then we would need time to review all responses received (if any) and factor into our RIAS/ regs package.

Most important next step is to get triage statement completed and over to TB for review; we have not engaged them on this file as of yet.

Remaining steps are then to build rest of regs package, i.e., RIAS (based on scheduling IAS), memo to the Min, supp note (if we deem one necessary), etc. Note that we also have never flagged salvia in our drafting priorities so there would also have to be some negotiating with the drafting service if the Department really wants to move on this.

Bottom line is that the earliest we could probably be in CG I is June 2011.

### 2) NHPs

You have probably seen the exchanges between MO and HPFB last night and their response re. compliance. At the end of the day, this is an issue we will have with any plant that has psychoactive properties and is not yet regulated as a controlled substance, i.e., a plant that has hallucinogenic properties will always meet the definition of an NHP according to the NHP regs, and thus it would be wrong of HC not to state clearly that it is illegal for unauthorized NHPs to be sold in Canada. The problem is, and HPFB knows this, is that all of the product coming into Canada and being sold in Canada is not coming in as an NHP or being sold as any kind of health product, nor is it being sold as having hallucinogenic properties. Instead, it comes in as a consumer product, probably labelled as incense or room aromatizer, and people buy it and use it for a totally different purpose. And, this is why, despite all the language in our lines around potential compliance and enforcement actions under the *Food and Drugs Act*, HPFB has never prioritized action on Salvia. Also why I think we should move to some slightly softer language around NHP classification in our recent media responses (talked to Stephanie about this

yesterday), as to me, the whole NHP classification issue is really a bit of smoke and mirrors. Even if we were not recommending scheduling under the CDSA as we are now, I don't think that HPFB would be leaping out of the gate with an aggressive compliance and enforcement plan.....

I will bring a copy of the IAS with me for when we meet, as well as a copy of the updated NOI, media lines and QP. See you at 12:30.

Jocelyn

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

---

Cathy A Sabiston      Looks like salvia mtg will go ahead and I will att...      2010-12-21 09:07:59 AM

From: Cathy A Sabiston/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: SoniaH Lindblad1/HC-SC/GC/CA@HWC, Stephanie Szick/HC-SC/GC/CA@HWC  
Date: 2010-12-21 09:07 AM  
Subject: Re:

---

Looks like salvia mtg will go ahead and I will attend with you

What is the natural health product issue?

And what is timeline for noi and then cg1?

We shld probably meet around 12:40 at tunneys.

Thx. Cas



**Salvia triage statement draft v.1**  
Stephanie Chandler to: Denis Arsenault

2010-12-31 10:06 AM

---

Hi Denis,

First draft of the Salvia triage statement for your review (and possibly discussion?)



Salvia Triage\_Dec 22 2010.rtf

I have left a file with a hard copy of this document as well as the Salvia stakeholder docs I emailed yesterday in your inbox.

Regards,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca





## Triage Statement Form

V.1

### Section I: Overview

Security classification  
Protected B

#### Date received by RAS:

Title of the Regulatory Proposal: **Addition of *Salvia divinorum* and salvinorin A to Schedule III of the *Controlled Drugs and Substances Act (CDSA)***

Sponsoring Regulatory Organization(s): **Health Canada**

Statutory Authority: ***Controlled Drugs and Substances Act (CDSA)***

Approximate date of submission of regulatory proposal to RAS: **2011**

#### Issue

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Its leaves are generally chewed or smoked to obtain psychotropic effects. While uncertainty remains surrounding the health risks of *S. divinorum*, known effects are reported to be short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant. Neither *S. divinorum* nor its main active ingredient salvinorin A are currently included in any of the Schedules to the *Controlled Drugs and Substances Act (CDSA)*.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. *S. divinorum* is widely touted as a "legal" hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs. Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, 1.6% of Canadians aged 15 years and older reported having used *S. divinorum* at least once in their lifetime, and that youth aged 15-24 were much more likely to have used it than adults aged 25 years and older. The results from the Canadian 2008-2009 *Youth Smoking Survey* also show that 5% of 15 year olds have used *S. divinorum* in the past year. Moreover, the 2009 *Ontario Student Drug Use and Health Survey (OSDUHS)* indicated that 5.4% of Ontario students in grades 7-12 reported ever using *S. divinorum* and 4.4% of these students reported using this substance in the past year. Given its



unknown effects and pharmacological similarity to other substances included in Schedule III to the CDSA, such as LSD and psilocybin, Health Canada is concerned that the ready availability and use of *S. divinorum* poses a risk to the health and safety of Canadians, particularly youth.

While *S. divinorum* and salvinorin A are not currently included in any of the United Nations Drug Control Conventions, a number of countries have chosen to regulate one or both <sup>of these substances</sup> as controlled substances. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden have all placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. Some American states have also implemented laws restricting their use, sale and/or distribution.

## Objectives

Including *S. divinorum* and its main active ingredient salvinorin A in Schedule III to the *Controlled Drugs and Substances Act* (CDSA) would prohibit: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation).

Presently, products containing *S. divinorum* or salvinorin A that are marketed as hallucinogens are considered unauthorized natural health products and may be subject to compliance and enforcement actions under the *Food and Drugs Act* (FDA). However, most products containing these substances are not marketed in this way and therefore administrative regulations under the FDA cannot be applied or enforced. The control of *S. divinorum* and salvinorin A under the CDSA will enable law enforcement agencies to take action against suspected illegal activities involving these substances. Control measures for substances listed in the CDSA are more stringent than for substances regulated under the FDA. The CDSA also sets out penalties for illegal activities involving substances listed in its Schedules.

<sup>*S. divinorum* & salvinorin A</sup>  
Scheduling ~~these substances~~ under the CDSA will reduce the risks associated with the increased use and unknown effects of ~~*S. divinorum* and salvinorin A~~ <sup>these substances</sup>. In this way, the control of *S. divinorum* and salvinorin A under the CDSA will protect the health and safety of Canadians, particularly youth.

## Description

Health Canada is proposing to include the following substances in Schedule III to the CDSA:

- *Salvia divinorum*; and
- Salvinorin A

**Page(s) 002162 to\à 002173**

**Is(Are) exempted pursuant to section(s)  
est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**



Treasury Board of Canada  
Secrétariat

Secrétariat du Conseil du Trésor  
du Canada

*The regulatory organization should provide a rationale in writing if the regulatory organization wishes to obtain an exemption from RAS on some of the requirements listed above:*

*RAS should list any additional requirements for this proposal, such as policy cover, program funding, or other information:*

In the case of a MAR, RAS approves the use of the MARs process:

Yes  No

**Departmental signoff (Director):**

Name and title (print):

Date:

Name and address of departmental contact person(s):

**RAS signoff (analyst):**

Date:

The regulatory organization should send two signed copies of the final Triage Statement to RAS. RAS will then sign the two Triage Statements and return one copy to the regulatory organization.

Regulatory Affairs Sector  
Treasury Board of Canada Secretariat  
155 Queen Street  
Ottawa ON K1A 0R5  
Canada

### Salvia Stakeholders → NOI

#### BIAD

CSTD - RCMP

CSTD - Police

#### \_PD

All licensed dealers (except Industrial Hemp)

#### RPD

CSTD - RPD - Deans of Canadian Universities

CSTD - RPD - P/T Licensing Authorities - Registrars of P

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CSTD - RPD - Professional Associations - Pharmacy Association

" " " Medical Association

" " " Dental Association

" " " Veterinary Association

Canadian Psychiatric Association

Canadian Association of Naturopathic Doctors

Canadian Public Health Association

Natural Health Products Manufacturers of Canada

CSTD - RPD - Other Government Departments - Canada Border

CSTD - RPD - " " - Public Safety

Canadian mental health Association

" " " " " "

- draft email to ...  
- regions in the

# Group List Names for the Office of Controlled Substances in the Stakeholder Information Management System (SIMS)

## Business, Information and Authorization Division

- CSTD - RCMP
- CSTD - Police
- CSTD - Alberta Law Enforcement
- CSTD - British Columbia Law Enforcement
- CSTD - Manitoba Law Enforcement
- CSTD - New Brunswick Law Enforcement
- CSTD - Newfoundland and Labrador Law Enforcement
- CSTD - Northwest Territories Law Enforcement
- CSTD - Nova Scotia Law Enforcement
- CSTD - Nunavut Law Enforcement
- CSTD - Ontario Law Enforcement
- CSTD - Prince Edward Island Law Enforcement
- CSTD - Québec Law Enforcement
- CSTD - Saskatchewan Law Enforcement
- CSTD - Yukon Law Enforcement

## Licences and Permits Division

- CSTD - Class A Precursor Licensed Dealers
- CSTD - Class A Precursor Licensed Dealer - SPIC
- CSTD - Class A Precursor Licensed Dealer - RPIC
- CSTD - Class B Precursor Licensed Dealer - SPIC
- CSTD - Controlled Substances Licensed Dealers - QPIC
- CSTD - Industrial Hemp Licensed Dealers

? licensed dealers - controlled drugs?

## National Compliance and Exemption Division

- CSTD - NCED - Research Institutions
- CSTD - NCED - Provincial Licensing Bodies

- Trade Associations

Provincial Toxicology Centre  
research centres

## Regulatory Policy Division

- CSTD - RPD - Deans of Canadian Universities
- CSTD - RPD - P/T Licensing Authorities
- CSTD - RPD - P/T Licensing Authorities - Registrars of Pharmacy
- CSTD - RPD - P/T Licensing Authorities - Registrars of Physicians and Surgeons
- CSTD - RPD - P/T Licensing Authorities - Registrars of Dental Surgeons
- CSTD - RPD - P/T Licensing Authorities - Registrars of Veterinary Medicine
- CSTD - RPD - P/T Licensing Authorities - Registrars of Nursing
- CSTD - RPD - P/T Licensing Authorities - Registrars of Podiatry
- CSTD - RPD - P/T Licensing Authorities - Registrars of Midwives
- CSTD - RPD - P/T Licensing Authorities - Registrars of Naturopathy?
- CSTD - RPD - Professional Associations
- CSTD - RPD - Professional Associations - Pharmacy Associations
- CSTD - RPD - Professional Associations - Medical Associations
- CSTD - RPD - Professional Associations - Dental Associations
- CSTD - RPD - Professional Associations - Veterinary Associations
- CSTD - RPD - Professional Associations - Midwives Associations
- CSTD - RPD - Professional Associations - Nursing Associations
- CSTD - RPD - Professional Associations - Podiatry Associations
- CSTD - RPD - Professional Associations - Hospital Associations
- CSTD - RPD - Professional Associations - Other Health Professional Associations
- CSTD - RPD - P/T Deputy Ministers of Health
- CSTD - RPD - Trade Associations
- CSTD - RPD - Other Government Departments
- CSTD - RPD - Health Related NGO's

Deans of: Science  
Pharmacy  
Medicine  
Pharmacy  
vet + med.

health authority

CPHA  
psychiatric associations

CBSA, Public Safety

Canadian mental health Association

- CBSA, Public Safety

- F/P/T Committee on Substance Abuse?

- OCS Regions - NCED contact?

Canadian Centre on Substance Abuse

- International Regulatory Agencies

CAMH  
PHAC

- AHPD

- CSS

## HECSB SIMS Stakeholder Types and Sub-types FINAL April 7, 2010

This classification scheme describes stakeholder types and sub-types for HECSB SIMS. Please include in the Excel template **both** a stakeholder type and sub-type(s), where available, selected from this table. An organization can be assigned only one single stakeholder type, however multiple sub-types can be selected if they exist, and are applicable.

Stakeholder Types	Stakeholder Sub-types	Description
Academia/ Education and Research		Organizations involved in providing academic expertise, teaching and/or research, in a broad range of disciplines (e.g. physical sciences, social sciences) or vocations. They generally don't sell their technology or results of scientific research for a profit. In the case where it is profit driven, it needs to be classified as an Industry organization. The purpose of Health Canada's involvement with these organizations is essentially due to their expertise in respective fields.
<p><i>- Contact TBS-RAS analyst</i></p> <p><i>- approves triage statement</i></p>		<p>organizations with a focus on providing education. Academia is a collective term <u>institutions</u> and <u>scholars</u> engaged in <u>higher</u> Education is the process by which society accumulated <u>knowledge</u>, <u>values</u>, and <u>skills</u> together through institutions.</p> <p>, public schools, vocational schools</p>
<p><i>N001</i></p> <p><i>NHPD → Lisa<sup>M.</sup> Young</i></p> <p><i>- applicants</i></p>		<p><b>ation/Licensing/Standards:</b> Accreditation is the process of confirmation of competency, authority, or certification refers to the confirmation of an object, person or organization. This is provided by some form of external review, Organizations that issue credentials or certify to national standards are themselves formally recognized as accreditation bodies. Licensing organizations have the authority to issue a license or 'license' to another party as an agreement between those parties. Standards organizations are recognized authority to establish standards. e.g. Accreditation Cooperation, Standards</p>
<p><i>- sign up to be notified</i></p> <p><i>- central database</i></p>		
<p><i>- translated version needed.</i></p>		
<p><i>-</i></p>		
		<p><b>s/Boards: includes any non-profit organization with a primary focus on academia, education</b></p>
		<p>Association of Teachers, Canadian Research and Development Association, Association of Canadian University</p>

## HECSB SIMS Stakeholder Types and Sub-types FINAL April 7, 2010

This classification scheme describes stakeholder types and sub-types for HECSB SIMS. Please include in the Excel template **both** a stakeholder type and sub-type(s), where available, selected from this table. An organization can be assigned only one single stakeholder type, however multiple sub-types can be selected if they exist, and are applicable.

Stakeholder Types	Stakeholder Sub-types	Description
<b>Academia/ Education and Research</b>		<p>Organizations involved in providing academic expertise, teaching and/or research, in a broad range of disciplines (e.g. physical sciences, social sciences) or vocations. They generally don't sell their technology or results of scientific research for a profit. In the case where it is profit driven, it needs to be classified as an Industry organization. The purpose of Health Canada's involvement with these organizations is essentially due to their expertise in respective fields.</p>
	<b>Academia/ Education</b>	<p>o <b>Academia/Education:</b> organizations with a focus on providing academic expertise and/or education. Academia is a collective term for the <u>community of students and scholars</u> engaged in <u>higher education and research</u>. Education is the process by which society deliberately transmits its accumulated <u>knowledge, values, and skills</u> from one generation to another through institutions. e.g. universities, colleges, public schools, vocational schools</p>
	<b>Accreditation/ Certification/ Licensing/ Standards</b>	<p>o <b>Accreditation/Certification/Licensing/Standards:</b> Accreditation is a process in which certification of competency, authority, or credibility is presented. Certification refers to the confirmation of certain characteristics of an object, person or organization. This confirmation is often provided by some form of external review, education or assessment. Organizations that issue credentials or certify third parties against official standards are themselves formally accredited by accreditation bodies. Licensing organizations have authority to grant permission or 'license' to another party as an element of an agreement between those parties. Standards organizations have a recognized authority to establish standards. e.g. International Laboratory Accreditation Cooperation, Standards Council of Canada</p>
	<b>Associations/Societies/ Boards</b>	<p>o <b>Associations/Societies/Boards:</b> includes any non-profit organization that has a primary focus on academia, education and/or research e.g. Canadian Society of Teachers, Canadian Research and Institutional Planning Association, Association of Canadian University Planning Programs</p>



	<b>Research</b>	o <b>Research:</b> organizations (e.g. centers of excellence, institutes, etc) with a focus on research (e.g. scientific, applied, quantitative, qualitative), which could be in a broad range of disciplines. e.g. National Research Centre for Environmental Toxicology
<b>Blood/Cell, Tissue and Organ</b>	<b>Blood Industry</b>	o <b>Blood Industry:</b> For-profit activities related to blood components. e.g. Cangene Corporation
	<b>Blood Organizations</b>	o <b>Blood Organizations.:</b> Operates on not-for-profit basis and the business is related to blood components. e.g. Canadian Blood Services
	<b>Cell/Tissue/Organ Industry</b>	o <b>Cell/Tissue/Organ Industry:</b> Business line is related to cells, tissues and organs. e.g. Bone Bank Allograft
	<b>Cell/Tissue/Organ Organization</b>	o <b>Cell/Tissue/Organ Organization:</b> Not for profit organizations with a mandate related to cells, tissues and organs. e.g. Canadian Association of Eye and Tissue Bank.
<b>Community and Consumer Groups</b>		These are often non-profit organizations. Sub-types are based on their mission and segment/group of the population/community they represent. Multiple sub-types can be selected.
	<b>Aboriginal</b>	o <b>Aboriginal:</b> e.g. Congress of Aboriginal Peoples, Manitoba
	<b>Children</b>	o <b>Children:</b> e.g. INFACT Canada (Infant Feeding Action Coalition), day care/child care
	<b>Civil Societies/Unions</b>	o <b>Civil Societies/Unions:</b> Often non-governmental organizations and community groups that would want to become involved with collective action on shared visions beyond exercising right of vote on governance. When an interest group is not captured within the other sub-groups then they may be captured as civil societies. e.g. The Council of Canadians, Canadian Health Coalition, Democracy Watch, Family Services Canada. Labor & Union groups.
	<b>Consumer Organizations</b>	o <b>Consumer Organizations:</b> Represent the interests of consumers. e.g. Consumers Association of Canada, Consumers Council of Canada
	<b>Disabilities</b>	o <b>Disabilities:</b> The groups representing disabilities should not be considered as part of the <i>Patient and Prevention</i> type. e.g. Canadian Association of the Deaf, Canadian National Institute for the Blind, Canadian Paraplegic Association, Heart and Stroke Foundation
	<b>Environment/Ecology</b>	o <b>Environment/Ecology:</b> e.g. Sierra Club, Green Peace
	<b>Linguistic Minorities</b>	o <b>Linguistic Minorities:</b> Represent the interest of either the English or French community where it is the minority language in a given area or of a province.

		e.g. Association des universités de la francophonie canadienne
	<p><b>Multi-faith</b></p> <p><b>Multicultural</b></p> <p><b>Seniors</b></p> <p><b>Women</b></p> <p><b>Youth</b></p>	<p>o <b>Multi-faith:</b> e.g. Anglican Church of Canada, Maritime Sikh Society</p> <p>o <b>Multicultural:</b> e.g. Canadian Council on Multicultural Health</p> <p>o <b>Seniors:</b> e.g. Active Living Coalition for Older Adults</p> <p>o <b>Women:</b> e.g. National Council of Women of Canada, Women and Health Protection</p> <p>o <b>Youth:</b> e.g. Big Brothers Big Sisters of Canada, Girl Guides of Canada</p>
<b>Enforcement/ Fire and Rescue</b>	<p><b>Associations/Societies/ Boards</b></p> <p><b>Fire and Rescue</b></p> <p><b>Police</b></p> <p><b>Other</b></p>	<p>Enforcement is a term used to describe either an organization that enforces the laws of one or more governing bodies, or an organization that actively and directly assists in the enforcement of laws. In doing so, the enforcement organization assists the governing bodies to provide governance for their subjects and maintains social control.</p> <p>Sub-type selections include Associations/Societies/Boards , Fire and Rescue, Police, and Other</p> <p><b>Associations/Societies/Boards:</b> include any organization that has a primary focus on enforcement and/or fire and rescue. e.g. Canadian Association of Chiefs of Police</p> <p><b>Fire and Rescue</b> includes organizations that provide operations or services that usually involve the saving of <u>life</u>, or prevention of <u>injury</u> fire service. Fire and rescue services can fall within provincial/territorial, or municipal government responsibilities. e.g Fire Marshals, Fire Commissioners; Municipal: Fire Chiefs, Fire Departments ; Emergency Medical Services</p> <p><b>Police</b> includes those agencies that provide police services, usually of the <u>executive</u> branch of government, empowered to <u>enforce the law</u> and to ensure public and social order through the legitimized use of force. This includes also, RCMP—Royal Canadian Mounted Police—Canada's national police service and an agency of the Ministry of Public Safety Canada. e.g. Ontario Provincial Police, Ottawa Police, Royal Canadian Mounted Policy</p> <p><b>Other:</b> organizations that have a focus on enforcement and/or fire and rescue, that do not fit the description for the above sub-types.</p>
<b>Government</b>		Sub-type selections include four levels of Governments i.e. Federal, Provincial, Municipal and Territorial.

	<p><b>Federal</b></p> <p><b>Municipal</b></p> <p><b>Provincial</b></p> <p><b>Territorial</b></p>	<p><b>Federal:</b> e.g. United States Food and Drug Administration, Environment Canada, Canada Border Services Agency, Public Safety Canada</p> <p><b>Municipal:</b> e.g. City of Ottawa</p> <p><b>Provincial:</b> e.g. Ontario Ministry of Health and Long-Term Care</p> <p><b>Territorial:</b> e.g. Northwest Territories Department of Health</p>
<p><b>Industry</b></p>	<p><b>Agriculture</b></p> <p><b>Associations/Societies/Boards</b></p> <p><b>Biologics and Genetic Therapies and Radiopharmaceuticals</b></p> <p><b>Chemicals/Gas/Reagents</b></p> <p><b>Consultants</b></p> <p><b>Cosmetics and Personal Care Products</b></p>	<p>Overall Industry represents a large range of entities (e.g. companies, manufacturers, banks, associations supporting a specific stream of trade) with the common goal of generating profit for goods or services it provides. The range of entities can be extensive therefore the list of sub-types are intended to include more common products/commodities and industry establishment types encountered for Health Canada. If the sub-types are not applicable then it is recommended to select "Other goods and services".</p> <p>To optimize industry characterization multiple sub-types can be selected, for example commodity and establishment types.</p> <p>o <b>Agriculture:</b> e.g. CropLife Canada</p> <p>o <b>Associations/Societies/Boards:</b> Organizations, for-profit or not-for profit, that have a focus on supporting industry. e.g. Non-Prescription Drug Manufacturers Association of Canada, Canadian Chemical Producers Association, Canadian Horticultural Council</p> <p>o <b>Biologics and Genetic Therapies and Radiopharmaceuticals:</b> e.g. Confab Laboratories</p> <p>o <b>Chemicals/Gas/Reagents:</b> e.g. Dow Chemicals Ltd.</p> <p>o <b>Consultants:</b> are firms of professionals who provide advice in a particular area of expertise.</p> <p>o <b>Cosmetics and Personal Care Products:</b> Cosmetics are substances used to enhance or protect the appearance or odor of the human body. Personal Care Products are consumer products used for beautification and in personal hygiene. e.g. Avon Canada</p>
	<p><b>Consumer Products</b></p> <p><b>Distributors</b></p>	<p>o <b>Consumer Products:</b> are generally any tangible personal property that is used for personal, family or household purposes. e.g. Proctor &amp; Gamble Co., Mattel Inc.</p> <p>o <b>Distributors:</b> An establishment that sells primarily to retailers, other merchants or industrial, institutional, and commercial users, mainly for</p>

		<p>resale or business use. Includes wholesalers, distribution centers for retail chains and district offices.</p>
	<b>Drugs</b>	<p>o <b>Drugs:</b> e.g. Bayer HealthCare</p>
	<b>Education/Communications/Marketing</b>	<p>o <b>Education/Communications/Marketing:</b> an establishment involved in marketing, public relations or communications activities. e.g. Small World Media Group, Eden Advertising</p>
	<b>Environment</b>	<p>o <b>Environment:</b> e.g. for-profit organizations providing restoration/remediation services for contaminated land, consulting services, involved in removal/transport/disposal of environmental contaminants</p>
	<b>Food/Alcohol/Beverages/Food Additives/Nutrition</b>	<p>o <b>Food/Alcohol/Beverages/Food Additives/Nutrition:</b> It can include alcoholic beverages and water. e.g. McCain Foods Ltd.</p>
	<b>Importer/Exporter/Brokers</b>	<p>o <b>Importer/Exporter/Brokers:</b> An establishment primarily engaged in the importation of products for sale in Canada or the exportation of products manufactured in Canada. It includes firms/consultants/agents licensed by Canada customs authorities, which work on behalf of traders, for example, representing the importer/exporter when dealing with customs authorities.</p>
	<b>Manufacturers</b>	<p>o <b>Manufacturers:</b> An establishment primarily engaged in the manufacturing of products for use or sale. It is most commonly applied to industrial production, in which raw materials are transformed into finished goods on a large scale. Such finished goods may be used for manufacturing other, more complex products, or sold to wholesalers, who in turn sell them to retailers, who then sell them to end users- the "consumers. Also includes firms that package or re-label products under their own branding/logo.</p>
	<b>Medical Devices</b>	<p>o <b>Medical Devices:</b> e.g. Bayer Healthcare, Cook Canada, MedTronic Canada, 3M Canada</p>
	<b>Natural Health Products</b>	<p>o <b>Natural Health Products:</b> e.g. Asian Herbs and Nutritionals</p>
	<b>Other Goods and Services</b>	<p>o <b>Other Goods and Services:</b> those organizations not represented by any of the above sub-types. e.g. courier services, insurance companies</p>

	<p><b>Retailers</b></p> <p><b>Research and Development</b></p> <p><b>Tobacco</b></p> <p><b>Veterinary Drugs</b></p>	<p><b>o Retailers:</b> An establishment selling products directly to consumers. Includes vendors.</p> <p><b>o Research and Development:</b> An establishment, operating in a for-profit context, primarily engaged in creative work, undertaken on a systematic basis, in order to develop new products and/or services.</p> <p><b>o Tobacco:</b> e.g. Imperial Tobacco Group</p> <p><b>o Veterinary Drugs:</b> e.g. Schering-Plough Animal Health, Novartis Animal Health</p>
<p><b>Livestock Producers</b></p>	<p><b>Aquaculture</b></p> <p><b>Bees</b></p> <p><b>Cattle</b></p> <p><b>Eggs</b></p> <p><b>Goats</b></p> <p><b>Horses</b></p> <p><b>Milk</b></p> <p><b>Poultry</b></p> <p><b>Sheep</b></p> <p><b>Swine</b></p> <p><b>Other</b></p>	<p>Livestock Producers are in fact a category of Industry but are identified separately.</p>
<p><b>Media</b></p>		<p>Includes organizations that are designed to reach large audiences using tools such as newspapers, radio, TV etc. e.g. Canadian Health and Lifestyle Magazine, L'Actualité Médicale</p>
<p><b>Patient and Prevention Groups</b></p>		<p>Organizations that have activities related to supporting patients suffering from particular diseases; such as advocacy for research and treatment to eliminate disease; education and health promotion in order to prevent disease onset or early detection.</p> <p>There are large numbers of organizations representing different diseases. Many of the disease focused organizations are likely to undertake activities for both patient and healthy populations. The patient groups should not be mixed up with disability groups-which are included under 'Community and Consumer Groups' type.</p> <p>e.g. National Society of Disease Prevention, Canadian Cancer Society, Canadian Lung Association</p>

<p><b>Professionals Health</b></p>	<p><b>Associations/Societies/Boards</b></p> <p><b>Accreditation/Certification/Licensing/Standards</b></p> <p><b>Clinic/Hospitals/Health Centers</b></p> <p><b>Licensed Practitioners</b></p> <p><b>Other</b></p>	<p>Includes organizations/associations formed around members for their expertise in their respective fields of human and/or animal health, in order to deliver the services. Organizations in this case are dependent on the expertise of those who deliver the services.</p> <p>o <b>Associations/Societies/Boards:</b> e.g. Canadian Anesthesiologists Society, Canadian Association of Naturopathic Doctors, Canadian Nursing Association</p> <p>o <b>Accreditation/Certification/Licensing/Standards:</b> Accreditation is a process in which certification of competency, authority, or credibility is presented. Certification refers to the confirmation of certain characteristics of an object, person or organization. This confirmation is often provided by some form of external review, education or assessment. Organizations that issue credentials or certify third parties against official standards are themselves formally accredited by accreditation bodies. Licensing organizations have authority to grant permission or 'license' to another party as an element of an agreement between those parties. Standards organizations have a recognized authority to establish standards. e.g. World Health Organization (WHO), Royal College of Physicians and Surgeons, College of Veterinarians of Ontario, Pharmacy Examining Board of Canada</p> <p>o <b>Clinics/Hospitals/Health Centers:</b> e.g. Ottawa Civic Hospital</p> <p>o <b>Licensed Practitioners :</b> organization having a specialized type of licensed health practitioner e.g. podiatrist, chiropractor</p> <p>o <b>Other:</b> organizations that do not fit descriptions of the above sub-types.</p>
<p><b>Professionals -Non Health</b></p>	<p><b>Associations/Societies/Boards</b></p> <p><b>Accreditation/Certification/Licensing/Standards</b></p>	<p>Represents organizations formed around members for their expertise in their respective fields, other than human, animal and/or environmental health, in order to deliver the services. Organizations in this case are built around those professionals or vice versa.</p> <p>o <b>Associations/Societies/Boards:</b> Organizations with a focus on the interests of non-health professions. e.g. Canadian Law and Society Association</p> <p>o <b>Accreditation/Certification/Licensing/Standards:</b> Accreditation is a process in which certification of competency, authority, or credibility is presented. Certification refers to the confirmation of certain characteristics of an object, person or organization. This confirmation is often provided by some form of external review, education or assessment. Organizations that issue credentials or certify third parties against official standards are themselves formally accredited by accreditation bodies. Licensing organizations have authority to grant</p>

		permission or 'license' to another party as an element of an agreement between those parties. Standards organizations have a recognized authority to establish standards. e.g. Canadian Engineering Accreditation Board, International Standards Organization, International Electrotechnical Committee
	<b>Ethicists</b>	o <b>Ethicists:</b> e.g. Canadian Bioethics Society
	<b>Other</b>	o <b>Other:</b> e.g. Intersol Consulting Associates, law firms, lawyers, legal aid

**Page(s) 002186 to\à 002193**

**Is(Are) exempted pursuant to section(s)  
est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**19(1)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**



10-127340-194

## BRIEFING NOTE TO THE MINISTER'S OFFICE

### Regulatory Status of *Salvia divinorum* in Canada

#### ISSUE:

To respond to a request from the Privy Council Office (PCO) for more information regarding the current regulatory status of *Salvia divinorum* in Canada further to recent media attention surrounding this plant.

#### BACKGROUND:

*Salvia divinorum* is a species of sage belonging to the mint family. Both the plant *Salvia divinorum* and its main active ingredient salvinorin A are known to have both physical and mental effects which include hallucinations, out-of-body experiences, uncontrollable laughter, short-term memory loss and loss of consciousness.

Media interest surrounding *Salvia divinorum* is recurrent. Questions regarding this substance generally focus on its legality. Recently, a number of media reports have commented on a YouTube video which reportedly shows the young Hollywood celebrity Miley Cyrus smoking *Salvia divinorum*. There have also been several reports from scientific and media sources, indicating that *Salvia divinorum* has the potential for abuse, and is used by adolescents and young adults for its hallucinogenic properties.

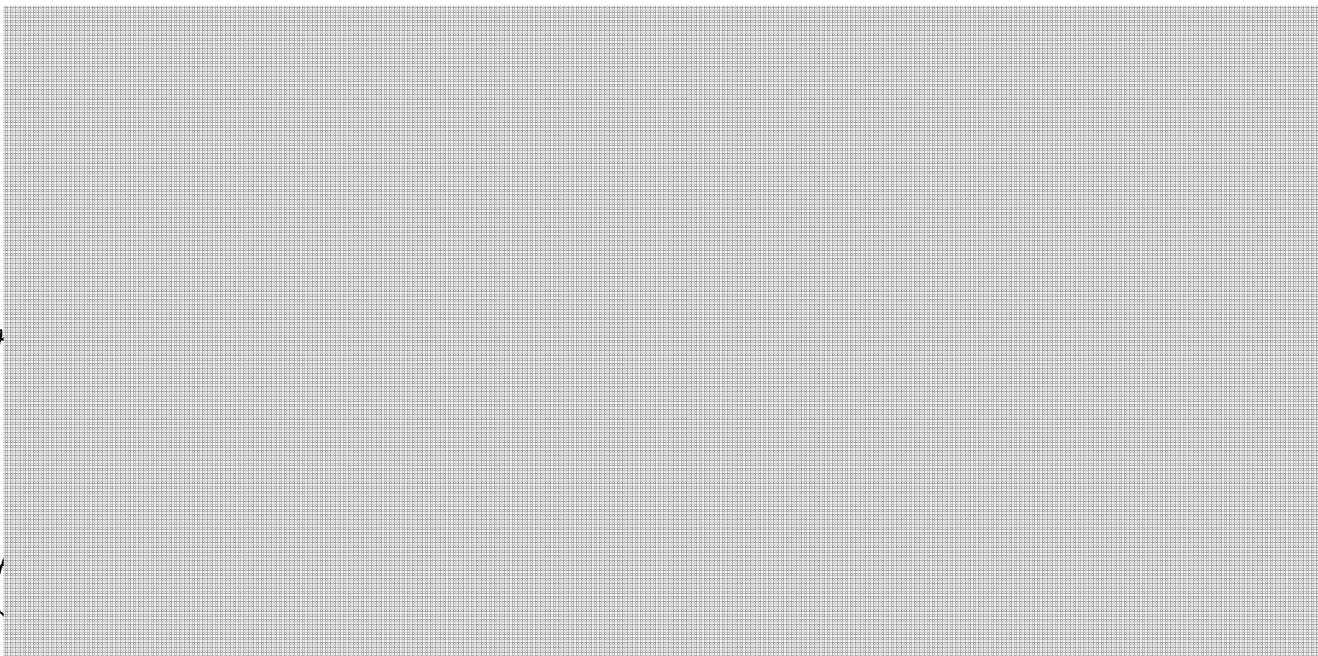
Results from the *Canadian Alcohol and Drug Use Monitoring Survey* (CADUMS) reveal that, in 2009, 1.6% of Canadians aged 15 years and older reported having used *S. divinorum* at least once in their lifetime, and that youth aged 15-24 were much more likely to have used it than adults aged 25 years and older. The results from the Canadian 2008-2009 *Youth Smoking Survey* also show that 5% of 15 year olds have used *S. divinorum* in the past year. Moreover, the 2009 *Ontario Student Drug Use and Health Survey* (OSDUHS) indicated that 5.4% of Ontario students in grades 7-12 reported ever using *S. divinorum* and 4.4% of these students reported using this substance in the past year.

#### CURRENT STATUS:

Neither *Salvia divinorum* nor its active ingredient salvinorin A are listed under the United Nations Drug Control Conventions; as a result, they do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to

these Conventions. Several countries (including Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) as well as some American states have placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A.

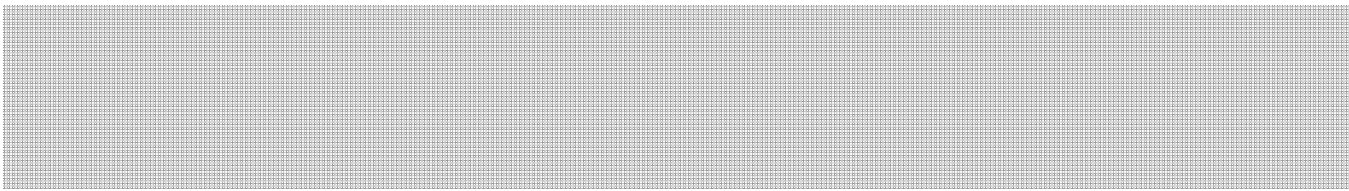
At present, the plant *Salvia divinorum* is not currently regulated under the *Controlled Drugs and Substances Act* (CDSA) and therefore the plant is not considered to be "banned", nor are activities with it considered to be illegal in Canada. Nevertheless, when specifically marketed for its hallucinogenic properties, *Salvia divinorum* meets the definition of a natural health product under the Natural Health Products Regulations. To date, however, Health Canada has not authorized for sale any natural health products which contain *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products containing *Salvia divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.



front

s.21(1)(a)  
s.21(1)(b)

**CONCLUSION:**



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Deputy Minister's Office

MECS# 10-127340-194

Branch Head: Paul Glover  
Telephone: 613-946-6701

Attachment

Appendix A - Draft Issue Analysis Summary

10-127340-194

## BRIEFING NOTE TO THE MINISTER'S OFFICE

### Regulatory Status of *Salvia divinorum* in Canada

#### ISSUE:

To provide information regarding the regulatory status of *Salvia divinorum* in Canada further to increased. The Privy Council Office has subsequently asked for an information note on *Salvia divinorum*.

#### BACKGROUND:

*Salvia divinorum* is a species of sage belonging to the mint family. While uncertainty remains surrounding the health risks of the plant *Salvia divinorum* and its main active ingredient salvinorin A, both physical and mental effects are reported to include hallucinations, out-of-body experiences, uncontrollable laughter, short-term memory loss and loss of consciousness.

Media interest surrounding *Salvia divinorum* is recurrent. Questions regarding this substance generally focus on its legality. Recently, a number of media reports have commented on a YouTube video which reportedly shows the young Hollywood celebrity Miley Cyrus smoking *Salvia divinorum*. There have also been several reports from scientific and media sources indicating that *Salvia divinorum* has the potential for abuse, and is being used by adolescents and young adults for its hallucinogenic properties.

#### CURRENT STATUS:

Results from the *Canadian Alcohol and Drug Use Monitoring Survey* (CADUMS) reveal that, in 2009, 1.6% of Canadians aged 15 years and older reported having used *S. divinorum* at least once in their lifetime, and that youth aged 15-24 were much more likely to have used it than adults aged 25 years and older. While 0.2% of respondents aged 15 years and older reported using *Salvia divinorum* in the past year, 0.7% reported using illicit hallucinogens in the past year. The results from the Canadian 2008-2009 *Youth Smoking Survey* also show that 5% of 15 year olds have used *S. divinorum* in the past year. In comparison, 6.9% indicated that they had used other hallucinogens in the last twelve months. Moreover, the 2009 *Ontario Student Drug Use and Health Survey* (OSDUHS) indicated that 5.4% of Ontario students in grades 7-12 reported ever using *S. divinorum* and 4.4% of these students reported using this substance in the past year. By way of comparison, 2.4% of students reported using lysergic acid diethylamide (LSD) in

- 2 -

their lifetime and 6.3% of students reported using other hallucinogens (not including LSD or phencyclidine (PCP)).

Neither *Salvia divinorum* nor its active ingredient salvinorin A are listed under the United Nations Drug Control Conventions. As a result, they do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions. Several countries, e.g. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden, as well as some individual American states, have however placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A.

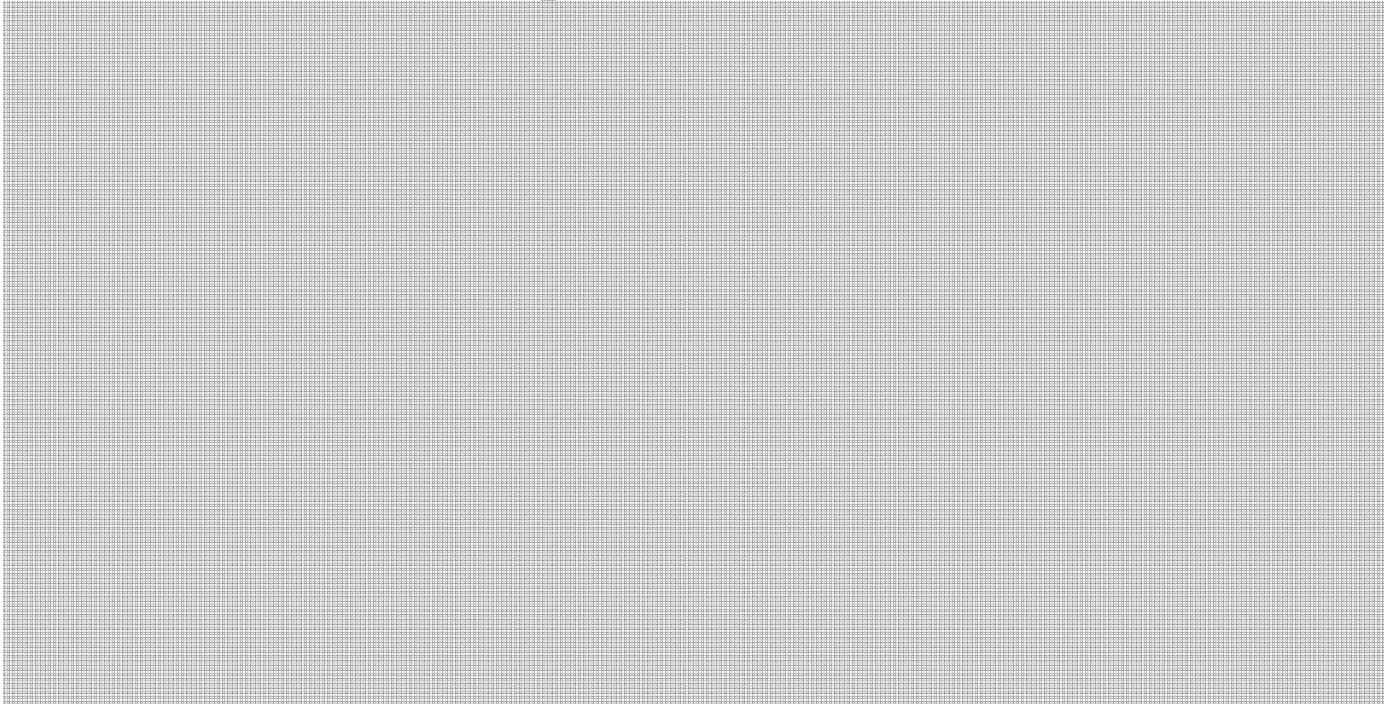
At present, the plant *Salvia divinorum* is not currently regulated under the CDSA and therefore the plant is not considered to be "banned", nor are activities with it considered to be illegal in Canada. Nevertheless, when specifically marketed for its hallucinogenic properties, *Salvia divinorum* meets the definition of a natural health product under the *Natural Health Products Regulations*. To date most *Salvia divinorum* products consumed for recreational purposes appear however to be sold as "incense" and Health Canada has not authorized for sale any natural health products which contain *Salvia divinorum* or salvinorin A as an ingredient.

While the sale of unauthorized natural health products containing *Salvia divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act* (FDA), the penalties applicable to incidences of unauthorized sale under the FDA are very low and would likely not deter a retailer from continuing to market unauthorized products.

It is because of this and the surveillance data indicating that there is an interest in *Salvia divinorum* among youth that the Controlled Substances and Tobacco Directorate (CSTD) is now proposing to add both substances to Schedule III to the *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth. This action will reduce the potential health and safety risks associated with the ready availability, increased use and unknown effects of these substances and will thus protect the health and safety of Canadians, particularly youth. The Issue Analysis Summary included in Appendix A further outlines the CSTD scheduling assessment of *Salvia divinorum*.

s.21(1)(a)  
s.21(1)(b)

#### CONCLUSION:



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Deputy Minister's Office

MECS# 10-127340-194

Branch Head: Paul Glover  
Telephone: 613-946-6701

Attachment

Appendix A - Draft Issue Analysis Summary

s.21(1)(a)

s.21(1)(b)

10-127340-194

## BRIEFING NOTE TO THE MINISTER'S OFFICE

### Regulatory Status of *Salvia divinorum* in Canada

#### ISSUE:

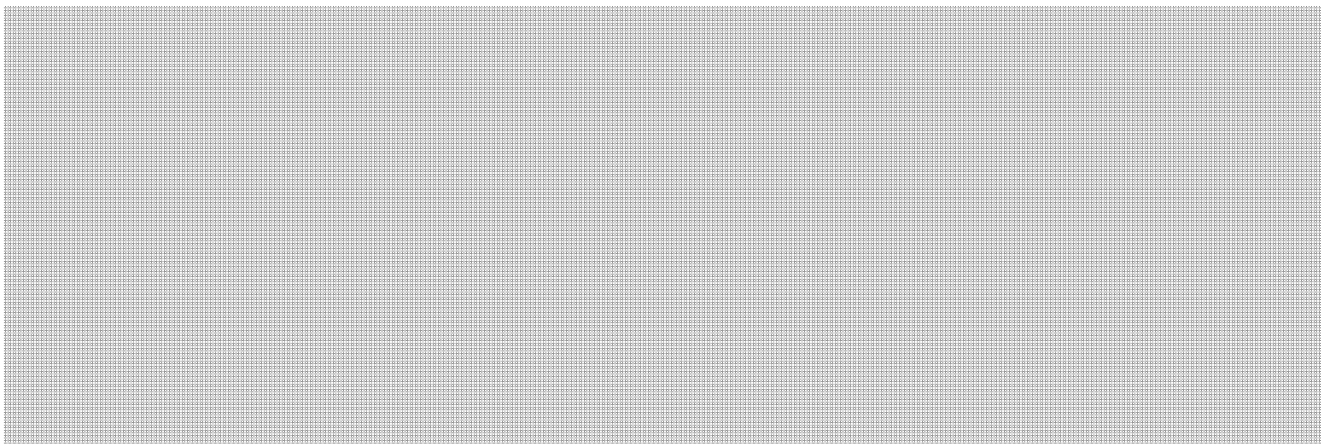
To respond to a request from the Privy Council Office (PCO) for more information regarding the current regulatory status of *Salvia divinorum* in Canada further to recent media attention surrounding this plant.

#### BACKGROUND:

*Salvia divinorum* is a species of sage belonging to the mint family. Both the plant *Salvia divinorum* and its main active ingredient salvinorin A are known to have physical and mental effects which include hallucinations, out-of-body experiences, uncontrollable laughter, short-term memory loss and loss of consciousness.

Media interest surrounding *Salvia divinorum* is recurrent. Questions regarding this substance generally focus on its legality. Recently, a number of media reports have commented on a YouTube video which reportedly shows the young Hollywood celebrity Miley Cyrus smoking *Salvia divinorum*. There have also been several reports from scientific and media sources, indicating that *Salvia divinorum* has the potential for abuse, and is used by adolescents and young adults for its hallucinogenic properties.

#### CURRENT STATUS:



Health Canada will inform stakeholders of its proposal by publishing a Notice to

.../2

-2-

Interested Parties (NOI) in *Canada Gazette*, Part I. The NOI will provide stakeholders and other interested parties with the opportunity to provide comments on the proposal to regulate *Salvia divinorum* and salvinorin A as controlled substances.

Neither *Salvia divinorum* nor its active ingredient salvinorin A are listed under the United Nations Drug Control Conventions; as a result, they do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions. Several countries (including Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden) as well as some American states have placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A.

Results from the *Canadian Alcohol and Drug Use Monitoring Survey* (CADUMS) reveal that, in 2009, 1.6% of Canadians aged 15 years and older reported having used *S. divinorum* at least once in their lifetime, and that youth aged 15-24 were much more likely to have used it than adults aged 25 years and older. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *S. divinorum* in the past year. Moreover, the *2009 Ontario Student Drug Use and Health Survey* (OSDUHS) indicated that 5.4% of Ontario students in grades 7-12 reported ever using *S. divinorum* and 4.4% of these students reported using this substance in the past year.

At present, the plant *Salvia divinorum* is not currently regulated under the CDSA and therefore the plant is not considered to be "banned", nor are activities with it considered to be illegal in Canada. Nevertheless, when specifically marketed for its hallucinogenic properties, *Salvia divinorum* meets the definition of a natural health product under the Natural Health Products Regulations. To date, however, Health Canada has not authorized for sale any natural health products which contain *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products containing *Salvia divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

#### CONCLUSION:

s.21(1)(a)  
s.21(1)(b)

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Deputy Minister's Office

002201



MECS# 10-127340-194

Branch Head: Paul Glover  
Telephone: 613-946-6701

Attachment

Appendix A - Draft Issue Analysis Summary

10-127340-194

## BRIEFING NOTE TO THE MINISTER'S OFFICE

### Regulatory Status of *Salvia divinorum* in Canada

#### ISSUE:

To provide information regarding the regulatory status of *Salvia divinorum* in Canada further to increased media attention. The Privy Council Office has subsequently asked for an information note on *Salvia divinorum*.

#### BACKGROUND:

*Salvia divinorum* is a species of sage belonging to the mint family. While uncertainty remains surrounding the health risks of the plant *Salvia divinorum* and its main active ingredient salvinorin A, physical and mental effects are reported to include hallucinations, out-of-body experiences, uncontrollable laughter, short-term memory loss and loss of consciousness.

Media interest surrounding *Salvia divinorum* is recurrent. Questions regarding this substance generally focus on its legality. Recently, a number of media reports have commented on a YouTube video which reportedly shows the young Hollywood celebrity Miley Cyrus smoking *Salvia divinorum*. There have also been several reports from scientific and media sources indicating that *Salvia divinorum* has the potential for abuse, and is being used by adolescents and young adults for its hallucinogenic properties.

#### CURRENT STATUS:

Results from the 2009 *Canadian Alcohol and Drug Use Monitoring Survey* (CADUMS) reveal that 1.6% of Canadians aged 15 years and older reported having used *Salvia divinorum* at least once in their lifetime, and that youth aged 15-24 were much more likely to have used it than adults aged 25 years and older. This equates to 0.2% of respondents aged 15 years and older having reported using *Salvia divinorum* in the past year, compared to 0.7% having reported using other illicit hallucinogens such as lysergic acid diethylamide (LSD) and phencyclidine. In addition, the results from the 2008-2009 *Youth Smoking Survey* also show that 5% of 15 year olds have used *Salvia divinorum*, compared to 6.9% who indicated that they had used other hallucinogens in the last twelve months. Moreover, the 2009 *Ontario Student Drug Use and Health Survey* (OSDUHS) indicated that 5.4% of Ontario students in grades 7-12 reported ever using *Salvia*

.../2

s.21(1)(a)

s.21(1)(b)

-2-

*divinorum* and 4.4% of those students reported using this substance in the past year. By way of comparison, only 2.4% of students reported using LSD in their lifetime while 6.3% of students reported using other hallucinogens (not including LSD or phencyclidine).

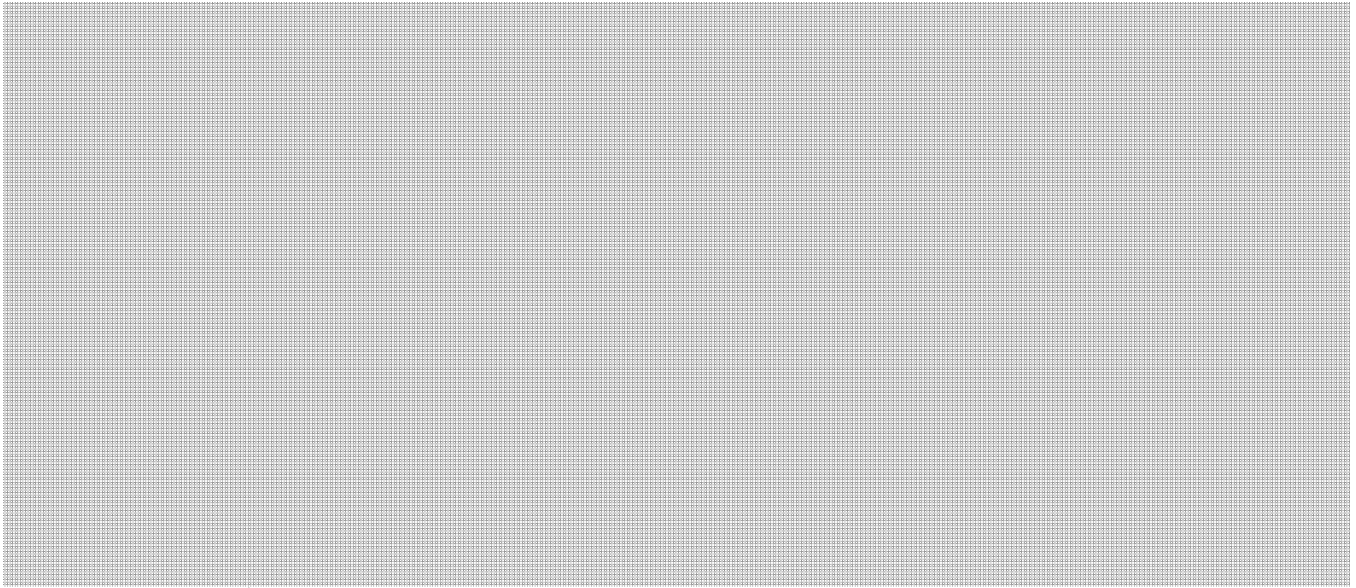
Neither *Salvia divinorum* nor its active ingredient salvinorin A are listed under the United Nations Drug Control Conventions. As a result, they do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions. Several countries, e.g. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden, as well as some individual American states, have however placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A.

At present, the plant *Salvia divinorum* is not currently regulated under the *Controlled Drugs and Substances Act* (CDSA) and therefore the plant is not considered to be "banned", nor are activities with it considered to be illegal in Canada. Nevertheless, when specifically marketed for its hallucinogenic properties, *Salvia divinorum* meets the definition of a natural health product under the *Natural Health Products Regulations*. To date most *Salvia divinorum* products consumed for recreational purposes appear however to be sold as "incense" and Health Canada has not authorized for sale any natural health products containing *Salvia divinorum* or salvinorin A as an ingredient.

While the sale of unauthorized natural health products containing *Salvia divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act* (FDA), the penalties applicable to incidences of unauthorized sale under the FDA are very low and would likely not deter a retailer from continuing to market unauthorized products.

It is because of this and the surveillance data indicating that there is an interest in *Salvia divinorum* among youth that the Controlled Substances and Tobacco Directorate (CSTD) is now proposing to add both substances to Schedule III to the CDSA. This action will reduce the potential health and safety risks associated with the ready availability, increased use and unknown effects of these substances and will thus protect the health and safety of Canadians, particularly youth. The Issue Analysis Summary included in Appendix A summarizes the CSTD scheduling assessment on *Salvia divinorum*.

## CONCLUSION:



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Deputy Minister's Office

MECS# 10-127340-194

Branch Head: Paul Glover  
Telephone: 613-946-6701

**s.21(1)(a)**  
**s.21(1)(b)**

Attachment

Appendix A - Draft Issue Analysis Summary

10-127340-194

## BRIEFING NOTE TO THE MINISTER'S OFFICE

### Regulatory Status of *Salvia divinorum* in Canada

#### ISSUE:

To provide information regarding the regulatory status of *Salvia divinorum* in Canada further to increased media attention. The Privy Council Office has subsequently asked for an information note on *Salvia divinorum*.

#### BACKGROUND:

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.../2

-2-

indicated that 5.4% of Ontario students in grades 7-12 reported ever using *Salvia divinorum* and 4.4% of those students reported using this substance in the past year. By way of comparison, only 2.4% of students reported using LSD in their lifetime while 6.3% of students reported using other hallucinogens (not including LSD or phencyclidine).

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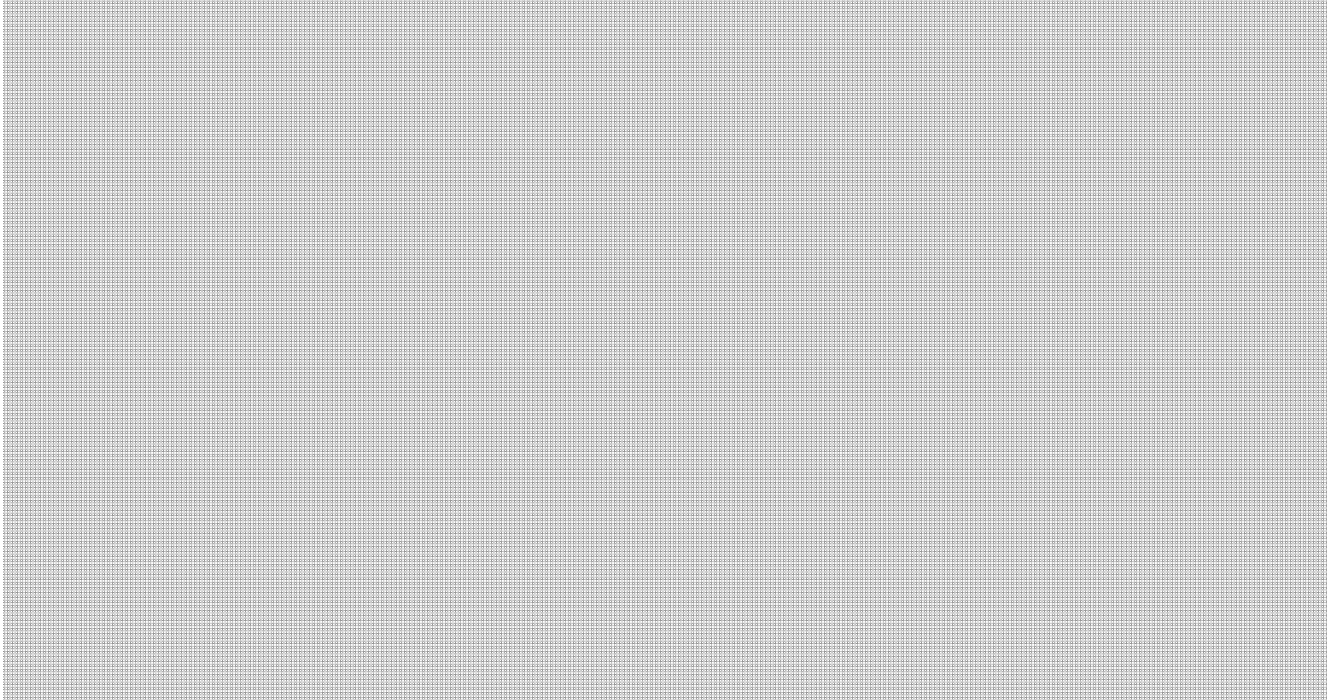
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It is because of this and the surveillance data indicating that there is an interest in *Salvia divinorum* among youth that the Controlled Substances and Tobacco Directorate (CSTD) is now proposing to add both substances to Schedule III to the CDSA. This action will reduce the potential health and safety risks associated with the ready availability, increased use and unknown effects of these substances and will thus protect the health and safety of Canadians, particularly youth. The Issue Analysis Summary included in Appendix A summarizes the CSTD scheduling assessment on *Salvia divinorum*.

.../3

**CONCLUSION:**



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Deputy Minister's Office

MECS# 10-127340-194

Branch Head: Paul Glover  
Telephone: 613-946-6701

Attachment

Appendix A - Draft Issue Analysis Summary



**Re: Fw: Updated Media Lines and Draft Notice of Intent for Salvia**

Jocelyn Kula to: Nicole Prentice

2011-01-04 11:03 AM

Cc: Stephanie Chandler, Christine Roush, stephanie.szick

Hi Nicole,

We did a briefing for MO on Salvia the week before the holidays, and are now working on a briefing note for MO/ PCO. As a result, DGO attention on the media lines and QP has redirected a bit. The briefing note is now with MO, and I can't say when we will get back to the media lines and QP etc. Soon though, as the note refers to an NOI being published in January, and of course, that means moving ahead with the lines and having the QP ready.

JK

---

Jocelyn Kula

Acting Director/ Directrice par intérim

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs

Health Canada/ Santé Canada

Tel: (613) 952-2177 Fax: (613) 946-4224

---

Nicole Prentice

Happy New Year Jocelyn and Stephanie, Just c...

2011-01-04 10:39:38 AM

From: Nicole Prentice/HC-SC/GC/CA

To: Stephanie Chandler/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC

Cc: Christine Roush/HC-SC/GC/CA@HWC

Date: 2011-01-04 10:39 AM

Subject: Re: Fw: Updated Media Lines and Draft Notice of Intent for Salvia

---

Happy New Year Jocelyn and Stephanie,

Just checking in on this item, are there any updates? Has Cathy reviewed and provided feedback?

Thanks.

**Nicole Prentice**

Junior Communications Officer | Agente junior des Communications

Regulatory Communications and Media Relations Division | Division des communications réglementaires et des relations avec les médias

Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la consultation et des communications

Health Canada | Santé Canada

Tel: 613.941.3107

Fax: 613.948.8085

---

Stephanie Chandler Hi Nicole and Christine, Sorry you weren't cc'e...

2010-12-10 09:07:59 AM

From: Stephanie Chandler/HC-SC/GC/CA

To: Christine Roush/HC-SC/GC/CA@HWC, Nicole Prentice/HC-SC/GC/CA@HWC

Cc: Jocelyn Kula/HC-SC/GC/CA@HWC

Date: 2010-12-10 09:07 AM



Subject: Fw: Updated Media Lines and Draft Notice of Intent for Salvia

---

Hi Nicole and Christine,

Sorry you weren't cc'ed on this... but the Salvia MLs and NOI have gone to DGO.

Regards,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca  
----- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2010-12-10 09:04 AM -----

From: Jocelyn Kula/HC-SC/GC/CA  
To: stephanie.szick@hc-sc.gc.ca  
Cc: CSTD-DGO, Stephanie Chandler/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2010-12-09 06:19 PM  
Subject: Updated Media Lines and Draft Notice of Intent for Salvia

---

Hi Stephanie,

Per previous instruction from Cathy and for Cathy's review and approval, please find attached a copy of the revised media lines for Salvia as well as our proposed Notice of Intent. We have worked with Comms on the media lines, and they are comfortable with us submitting them for Cathy's approval ourselves as we know that Cathy wanted to see both the media lines and the draft NOI at the same time. For this reason, we are not submitting the IYH for approval at this point; our thinking is that we would hold off on issuing that until the NOI was in print. We have already revised the text to be consistent however.

[attachment "Salvia Media Lines\_Dec 9\_OCS + CR.doc" deleted by Nicole Prentice/HC-SC/GC/CA] (with track changes)

[attachment "Salvia Media Lines\_Dec 9\_Clean.doc" deleted by Nicole Prentice/HC-SC/GC/CA] (clean version)

[attachment "DRAFT Salvia NOI\_Dec 8.wpd" deleted by Nicole Prentice/HC-SC/GC/CA]

Jocelyn

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224



**Note on Salvia**

Jocelyn Kula to: Ruth.Naylor  
Cc: stephanie.szick, Cathy A Sabiston  
Bcc: Stephanie Chandler

2011-01-05 04:51 PM

Hi Ruth,

Further to my phone message, please see the attached advance copy of our briefing note on Salvia.  
Happy to discuss at any point.



10-127340-194 ADMO approved.wpd

Regards  
Jocelyn

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
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Tel: (613) 952-2177 Fax: (613) 946-4224

10-127340-194

## BRIEFING NOTE TO THE MINISTER'S OFFICE

### Regulatory Status of *Salvia divinorum* in Canada

#### ISSUE:

To provide information regarding the regulatory status of *Salvia divinorum* in Canada.

#### BACKGROUND:

*Salvia divinorum* is a species of sage belonging to the mint family. While uncertainty remains surrounding the health risks of the plant *Salvia divinorum* and its main active ingredient salvinorin A, physical and mental effects are reported to include hallucinations, out-of-body experiences, uncontrollable laughter, short-term memory loss, and loss of consciousness.

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#### CURRENT STATUS:

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- 2 -

indicated that 5.4% of Ontario students in grades 7-12 reported ever using *Salvia divinorum* and 4.4% of those students reported using this substance in the past year. By way of comparison, only 2.4% of students reported using LSD in their lifetime while 6.3% of students reported using other hallucinogens (not including LSD or phencyclidine).

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At present, the plant *Salvia divinorum* is not regulated under the *Controlled Drugs and Substances Act* (CDSA) and therefore the plant is not considered to be "banned," nor are activities with it considered to be illegal in Canada. Nevertheless, when specifically marketed for its hallucinogenic properties, *Salvia divinorum* meets the definition of a natural health product under the *Natural Health Products Regulations*. Health Canada has not authorized for sale any natural health products containing *Salvia divinorum* or salvinorin A as an ingredient. However, to date most *Salvia divinorum* products consumed for recreational purposes appear to be sold as "incense."

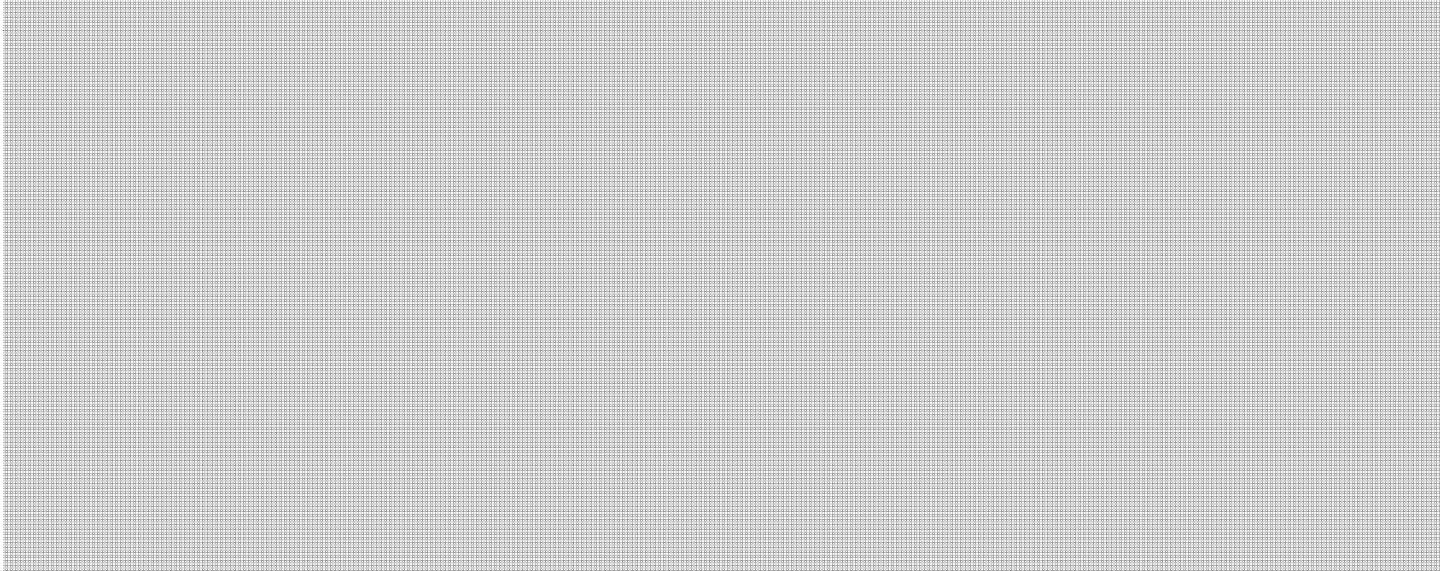
While the sale of unauthorized natural health products containing *Salvia divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act* (FDA), the penalties applicable to incidences of unauthorized sale under the FDA are very low and would likely not deter a retailer from continuing to market unauthorized products.

It is because of this and the surveillance data indicating that there is an interest in *Salvia divinorum* among youth that the Department is now proposing to add *Salvia divinorum* and salvinorin A to Schedule III to the CDSA. This action will reduce the potential health and safety risks associated with the ready availability, increased use and unknown effects of these substances and will thus protect the health and safety of Canadians, particularly youth. The Issue Analysis Summary included in Appendix A summarizes the scheduling assessment on *Salvia divinorum*.

- 3 -

**s.21(1)(a)**  
**s.21(1)(b)**

**CONCLUSION:**



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Deputy Minister's Office

MECS #10-127340-194

Branch Head: Paul Glover, ADM, HECSB  
Telephone: 613-946-6701

Attachment  
Appendix A - Draft Issue Analysis Summary

s.19(1)



**Fw: Salvia divinorum**

Jocelyn Kula to: [REDACTED]  
Cc: Stephanie Chandler, Denis Arsenault

2011-01-07 04:21 PM

From: Jocelyn Kula/HC-SC/GC/CA  
To: [REDACTED]  
Cc: Stephanie Chandler/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC

Hi [REDACTED]

I sent this message to you before the holiday period but have only just realized that you would not have received as I had your email address wrong.

Apologies, and hope 2011 has been good to you so far.

Jocelyn

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224  
----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2011-01-07 04:20 PM -----

From: Jocelyn Kula/HC-SC/GC/CA  
To: [REDACTED]  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2010-12-24 12:54 PM  
Subject: Salvia divinorum

Hi [REDACTED]

It is a long while since we have spoken I know, so trust that this message finds you well.

I am writing about *Salvia divinorum* and its active ingredient Salvinorin A, which are not yet regulated as controlled substances in Canada.

We are currently finalizing a comprehensive scheduling assessment of the substances, and would appreciate clarification of some information we came across on the National Institute of Drug Abuse (NIDA) website. Essentially, the page we found (I regrettably don't have the link at hand but can provide if you need it), seems to suggest that the DEA is considering classifying *S. divinorum* as a Schedule I drug. We would appreciate confirmation of this information as it was always my understanding that while the import and/or distribution of Salvia is illegal in some individual states, the DEA only considers it to be a substance of concern at this point in time. In this regard, any additional information regarding the federal control of these substances (actual or planned if you can share) which you can provide would be greatly appreciated. As you can imagine, there is an intense amount of interest in products containing salvia further to the appearance of the Miley Cyrus video on Youtube.

Best wishes of the season, and I look forward to hearing from you.

Jocelyn

---

Jocelyn Kula

Acting Director/ Directrice par intérim

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs

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Tel: (613) 952-2177 Fax: (613) 946-4224

**Re: Salvia - NOI posting in CG1** 

Christine Roush to: Jocelyn Kula

2011-01-13 08:16 PM

Cc: Denis Arseneault, Stephanie Chandler

Thanks for your note Jocelyn. I understand that the late Dec period was a busy time for all; however I would like to be part of the process going forward and look forward to receiving the products from Denis, with Cathy's request for changes. I'll brief up to Dave, et al on the process for posting an NOI and how comms will be supporting this move. We should also ensure that the messaging for this is consistent with the It's Your Health info, which I'm sure will need some tweaks.

Christine

Jocelyn Kula

----- Original Message -----

**From:** Jocelyn Kula

**Sent:** 2011-01-13 05:49 PM EST

**To:** Christine Roush

**Cc:** Denis Arseneault; Stephanie Chandler

**Subject:** Re: Salvia - NOI posting in CG1

Hi Christine

Typically for an NOI (note there are no rules for this...), we do media lines only, and we prepare an email to affected stakeholders advising them that the NOI has been posted. No comms plan or other comms docs.

For salvia, the package that went to Cathy for approval included:

- 1) draft NOI
- 2) media lines (which we prepared using the draft lines for the IYH as a base) and
- 3) revised QP (which is not required per se but Cathy wanted as there has been some interest from MO and PCO and so she wanted to be prepared for when the house reconvenes)

While I admit that we didn't get you to look at the products before they went to Cathy, she was champing at the bit for them after the briefing in MO before the holidays and so we rushed them, but then she didn't look at them right away because of all the furf with tobacco. She has now reviewed though and we just got comments back today and a request for revised docs for Monday.

As I am thinking that you should probably see the next versions before they go back to Cathy, I am asking Denis and Stephanie in RPD to liaise with you at some point so you can see where things are at. Note that Cathy has specifically directed that the key messages in the media lines mirror to some extent the main bullets in the QP.....

Re. timing, our latest 3 month report says publication in CGI for early February but of course this is all conditional on what if anything we hear back from MO re the note we had to do after the holidays/ from PCO who were also asked to do an information note for MO.

Please feel free to contact Denis if you have any further questions.

Jocelyn

---

Jocelyn Kula

Acting Director/ Directrice par intérim

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et



de la sécurité des consommateurs  
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Tel: (613) 952-2177 Fax: (613) 946-4224

Christine Roush      Hi Jocelyn, Further to your email in December, r...      2011-01-13 02:07:53 PM

From: Christine Roush/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC, stephanie.szick@hc-sc.gc.ca  
Date: 2011-01-13 02:07 PM  
Subject: Salvia - NOI posting in CG1

Hi Jocelyn,  
Further to your email in December, re: the NOI for Salvia - can you tell me what Communications products you will need to support the posting of the NOI in CGI, and when this is likely to happen? I have not been part of a NOI posting so I'm not sure what the process is for getting the message out to interested parties. thanks,

Christine Roush  
Senior Communications Advisor/

Jocelyn Kula      Hi Christine Sorry for the delayed reply. Just dis...      2010-11-04 08:18:49 AM

From: Jocelyn Kula/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC, CSTD-OCS-DO, stephanie.szick@hc-sc.gc.ca  
Date: 2010-11-04 08:18 AM  
Subject: Re: Fw: Approval - Salvia ML & IYH

Hi Christine

Sorry for the delayed reply. Just discussed Salvia with Cathy yesterday and now that there appears to be general departmental consensus re scheduling under the CDSA at the working level, she has agreed that we should begin to prepare an NOI for publication in CG I. We will use Salvia as an example when we brief Paul on the new proposed scheduling policy (PPR is scheduled for Dec 8 I believe), and of course, as soon as we put this in the 3 month table, we will likely have to do more briefings up the line as there has been quite a bit of interest in this file over time.

Bottom line, we can't go public with a doc that refers to the regulatory decision to schedule until after the NOI appears so Cathy won't be approving the IYH docs until then. One assumes that both the IYH and media lines will need tweaking re the scheduling decision in any case.

Out of the office today and tomorrow but back on Monday if you want to discuss further.

Hope this helps  
Jocelyn

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

Christine Roush

Hi Jocelyn - just wondering if I could get an upd...

2010-11-01 03:41:20 PM

From: Christine Roush/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2010-11-01 03:41 PM  
Subject: Fw: Approval - Salvia ML & IYH

---

Hi Jocelyn - just wondering if I could get an update on Salvia. Cathy indicated in her email below that she was not prepared to sign off on the Salvia ML and IYH article until after the working group meeting to finalize the scheduling decision. Has this meeting been held and were any decisions taken on the scheduling of Salvia?

Christine Roush  
Senior Communications Advisor/

From: Cathy A Sabiston/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC, Christine Roush/HC-SC/GC/CA@HWC  
Cc: CSTD-DGO, Nicole Prentice/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC  
Date: 2010-10-06 01:12 PM  
Subject: Re: Fw: Approval - Salvia ML & IYH

---

No. I'm decided :)  
Jocelyn Kula

----- Original Message -----

**From:** Jocelyn Kula  
**Sent:** 2010-10-06 12:33 PM EDT  
**To:** Christine Roush  
**Cc:** Cathy A Sabiston; CSTD-DGO; Nicole Prentice; Suzanne Desjardins  
**Subject:** Re: Fw: Approval - Salvia ML & IYH

Christine, the CSS-WG is meeting again on October 27, 2010.

Cathy- would you like Suzanne and I to arrange a short meeting with you to discuss the risks and benefits of proceeding with the IYH and related lines as is vs. waiting until after the CSS mtg?

JK

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224  
Christine Roush/HC-SC/GC/CA

Christine  
Roush/HC-SC/GC/CA  
2010-10-06 10:50 AM

To Cathy A Sabiston/HC-SC/GC/CA@HWC  
cc CSTD-DGO, Diane Allan/HC-SC/GC/CA@HWC, Jocelyn  
Kula/HC-SC/GC/CA@HWC, Nicole  
Prentice/HC-SC/GC/CA@HWC, Suzanne  
Desjardins/HC-SC/GC/CA@HWC

Subject Re: Fw: Approval - Salvia ML & IYH

Hi Cathy - I can certainly appreciate your comments below regarding the urgency of these products, given everything else on your plate at the moment; however, I would like you to know that HPFB is really pushing for the IYH article and MLs to be approved as soon as possible, since the department has previously not been able to say too much on the issue of Salvia. Now, we can say that Salvia is technically illegal because it hasn't been approved as a natural health product. Also, these products have been in the works for over a year now, and many, many, people have been involved in their development. It would therefore be discouraging to all if the products were yet again held up. I understand that OCS is still studying the issue to see whether Salvia should be added to the list of controlled substances, and our lines currently reflect this. I understand that Jocelyn and Suzanne are in agreement with the messaging in these products and that Jocelyn is now on board with the approach of posting the IYH article on HC's website. I don't know when the 2nd meeting is scheduled of the working group to finalize the decision on Salvia, but if it is months from now, I would suggest we move forward with these products now, as too much time has already been spent on getting them to this stage of readiness.

Christine Roush  
Senior Communications Advisor/

Cathy A Sabiston/HC-SC/GC/CA



Cathy A  
Sabiston/HC-SC/GC/CA  
2010-10-06 10:20 AM

To Nicole Prentice/HC-SC/GC/CA@HWC  
cc Christine Roush/HC-SC/GC/CA@HWC, CSTD-DGO, Diane Allan/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC  
Subject Re: Fw: Approval - Salvia ML & IYH

IT is not on my urgent list of things to do. Particularly since we haven't had the second working group meeting to finalize the scheduling decision. Who wants is anxious for this to be approved?

Fw: Approval - Salvia ML & IYH

**Fw: Approval - Salvia ML & IYH**

Nicole Prentice to: Cathy A Sabiston

2010-10-06 10:14 AM

Cc: CSTD-DGO, Suzanne Desjardins, Jocelyn Kula, Diane Allan, Christine Roush

Hi Cathy,

Can we get approval of the items below today?

002220

Thanks.

Nicole Prentice  
Junior Communications Officer | Agente junior des Communications  
Regulatory Communications and Media Relations Division | Division des communications réglementaires  
et des relations avec les médias  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la  
consultation et des communications  
Health Canada | Santé Canada  
Tel: 613.941.3107  
Fax: 613.948.8085

----- Forwarded by Nicole Prentice/HC-SC/GC/CA on 2010-10-06 10:13 AM -----



Nicole  
Prentice/HC-SC/GC/CA  
2010-10-01 10:18 AM

To Cathy A Sabiston/HC-SC/GC/CA  
cc CSTD-DGO, Suzanne Desjardins/HC-SC/GC/CA@HWC,  
Jocelyn Kula/HC-SC/GC/CA@HWC, Diane  
Allan/HC-SC/GC/CA@HWC, Christine  
Roush/HC-SC/GC/CA@HWC  
Subject Fw: Approval - Salvia ML & IYH

Hi Cathy,

Attached below is the IYH article and media lines on Salvia for your approval by Tuesday, October 5th  
COB. Jocelyn, Diane and Suzanne have reviewed and approved already.

Thank you kindly.

[attachment "Salvia Media Lines\_Sept30.doc" deleted by Cathy A Sabiston/HC-SC/GC/CA] [attachment  
"IYH Salvia divinorum\_v18 clean Oct 1.doc" deleted by Cathy A Sabiston/HC-SC/GC/CA] [attachment  
"Approval Slip - Salvia HECSB.doc" deleted by Cathy A Sabiston/HC-SC/GC/CA]

Nicole Prentice  
Junior Communications Officer | Agente junior des Communications  
Regulatory Communications and Media Relations Division | Division des communications réglementaires  
et des relations avec les médias  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la  
consultation et des communications  
Health Canada | Santé Canada  
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Fax: 613.948.8085

----- Forwarded by Nicole Prentice/HC-SC/GC/CA on 2010-10-01 10:08 AM -----



Suzanne  
Desjardins/HC-SC/GC/CA  
2010-09-30 04:22 PM

To Nicole Prentice/HC-SC/GC/CA@HWC  
cc Valence Nebie/HC-SC/GC/CA@HWC  
Subject Re: Fw: Approval - Salvia ML & IYH

Hi Nicole,

The same correction that was made to the second key message, should be made to the IYH under Legal Status of Savia...

Because of its their hallucinogenic properties...

Then approved

Thanks

Suzanne

Nicole Prentice/HC-SC/GC/CA



Nicole  
Prentice/HC-SC/GC/CA  
2010-09-30 02:38 PM

To Suzanne Desjardins/HC-SC/GC/CA@HWC  
cc Diane Allan/HC-SC/GC/CA@HWC, Jocelyn  
Kula/HC-SC/GC/CA@HWC, Valence  
Nebie/HC-SC/GC/CA@HWC  
Subject Fw: Approval - Salvia ML & IYH

Hi Suzanne,

Attached below is the IYH article and media lines on Saliva for your approval by Monday, October 4 COB. Jocelyn & Diane have reviewed and approved already.

Diane - Please note, we accepted all you changes, however, made an addition change to the first key message so it would read better.

Thanks in advance.

[attachment "IYH Salvia divinorum\_v18 clean Sept2010.doc" deleted by Suzanne Desjardins/HC-SC/GC/CA] [attachment "Salvia Media Lines\_Sept30.doc" deleted by Suzanne Desjardins/HC-SC/GC/CA]

Nicole Prentice  
Junior Communications Officer | Agente junior des Communications  
Regulatory Communications and Media Relations Division | Division des communications réglementaires  
et des relations avec les médias  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la  
consultation et des communications  
Health Canada | Santé Canada  
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----- Forwarded by Nicole Prentice/HC-SC/GC/CA on 2010-09-30 02:34 PM -----

Christine  
Roush/HC-SC/GC/CA  
2010-09-30 02:27 PM

To Nicole Prentice/HC-SC/GC/CA@HWC  
cc  
Subject Fw: Approval - Salvia ML & IYH

I made a change to the first key message. Was there anything else you were concerned about?

[attachment "MLs - S. divinorum-revcr\_Sept30.doc" deleted by Nicole Prentice/HC-SC/GC/CA]

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
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Tel/Tél : (613) 954-0712/Cell: (613) 219-7194  
Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca


----- Forwarded by Christine Roush/HC-SC/GC/CA on 2010-09-30 02:26 PM -----

**Diane Allan/HC-SC/GC/CA**

2010-09-29 09:39 AM

To Nicole Prentice/HC-SC/GC/CA@HWC

cc Christine Roush/HC-SC/GC/CA@HWC, CSTD-OCS-DO,  
Jocelyn Kula/HC-SC/GC/CA@HWC

Subject Re: Fw: Approval - Salvia ML & IYH 

Approved with a few minor changes to media lines.

[attachment "Salvia Media Lines\_v14 clean Sept2010.doc" deleted by Nicole Prentice/HC-SC/GC/CA]

Diane Allan

Director / Directrice  
Office of Controlled Substances / Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch / Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada / Santé Canada  
Tel: 613-952-2177  
Fax: 613-946-4224

Nicole Prentice/HC-SC/GC/CA



**Nicole  
Prentice/HC-SC/GC/CA**

2010-09-28 02:09 PM

To Diane Allan/HC-SC/GC/CA@HWC

cc Jocelyn Kula/HC-SC/GC/CA@HWC, Christine  
Roush/HC-SC/GC/CA@HWC, CSTD-OCS-DO  
Subject Fw: Approval - Salvia ML & IYH

Hi Diane,

Attached below is the IYH article and media lines on Salvia for your approval by Wednesday, September

29 COB. Jocelyn has reviewed and approved already.


Thanks in advance.

[attachment "IYH Salvia divinorum\_v18 clean Sept2010.doc" deleted by Nicole Prentice/HC-SC/GC/CA]  
[attachment "Salvia Media Lines\_v14 clean Sept2010.doc" deleted by Nicole Prentice/HC-SC/GC/CA]  
[attachment "Approval Slip - Salvia HECSB.doc" deleted by Nicole Prentice/HC-SC/GC/CA]

Nicole Prentice  
Junior Communications Officer | Agente junior de Communications  
Regulatory Communications and Media Relations Division | Division des communications réglementaires  
et des relations avec les médias  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la  
consultation et des communications  
Health Canada | Santé Canada  
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Fax: 613.948.8085

----- Forwarded by Nicole Prentice/HC-SC/GC/CA on 2010-09-28 02:04 PM -----

**Christine  
Roush/HC-SC/GC/CA**  
2010-09-28 01:55 PM

To Nicole Prentice/HC-SC/GC/CA@HWC  
cc Bronwyn Cline/HC-SC/GC/CA@HWC  
Subject Re: Approval - Salvia ML & IYH 

Nicole - could you please take care of approvals of this It's Your Health article. The article and approval slip are below. thx. Jocelyn Kula has already reviewed and approved.

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
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Tel/Tél : (613) 954-0712/Cell: (613) 219-7194  
Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca

Lisa MacKay/HC-SC/GC/CA

**Lisa MacKay/HC-SC/GC/CA**  
2010-09-28 01:40 PM

To Christine Roush/HC-SC/GC/CA@HWC, Bronwyn  
Cline/HC-SC/GC/CA@HWC  
cc Lisa MacKay/HC-SC/GC/CA@HWC  
Subject Approval - Salvia ML & IYH

Hello,

On to the next stage! Could you please send the documents around for approval and return them to me by

cob Tuesday, October 12.

Thank you

Lisa Mackay

It's Your Health Project Manager/Gestionnaire du projet Votre santé et vous

Strategic Communications and Ministerial Services Division / Division des communications stratégiques  
et des services ministériels

Public Affairs, Consultation and Communications Branch/ Direction générale des affaires publiques, de la  
consultation et des communications

Health Canada | Santé Canada

Tel 613.954.0105

Fax 613.952.8644

Lisa\_Mackay@hc-sc.gc.ca





**Re: Salvia NOI Stakeholders**   
Courtney Smith to: Stephanie Chandler

2011-01-13 11:19 AM

Hi Stephanie

As discussed, Martin Burt, George Mezher and Nicole Rougier work in the OGD programs unit in the CBSA.

Courtney Smith  
Border Integrity Specialist | Spécialiste, intégrité frontalière  
Border Integrity Unit | Unité d'intégrité frontalière  
Health Products and Food Branch Inspectorate | Inspectorat de la direction générale des produits de santé et des aliments  
Health Canada | Santé Canada  
B206 Graham Spry  
250 Lanark AL2002B  
Ottawa ON K1A 0K9  
Tel: 613-946-6863

Stephanie Chandler Thanks Courtney! I do have another question f... 2010-12-24 08:51:34 AM

From: Stephanie Chandler/HC-SC/GC/CA  
To: Courtney Smith/HC-SC/GC/CA@HWC  
Date: 2010-12-24 08:51 AM  
Subject: Re: Salvia NOI Stakeholders

Thanks Courtney!

I do have another question for you related to the NOI. We would like to make sure CBSA is aware once we publish it. Would your unit have the email for a person(s) who we could contact once it is published? No rush, if you could get back to me by the end of the first week of January that would be great. Enjoy your holidays!

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

Courtney Smith Hi Stephanie Just to let you know I will follow up... 2010-12-23 05:54:41 PM

**DRAFT V.8**

DEPARTMENT OF HEALTH

CONTROLLED DRUGS AND SUBSTANCES ACT

*Notice to interested parties - Proposal regarding the addition of Salvia divinorum and salvinorin A to Schedule III to the Controlled Drugs and Substances Act*

This notice provides interested stakeholders with the opportunity to provide comments on Health Canada's proposal to add the plant *Salvia divinorum* (*S. divinorum*) and its active ingredient salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA). Stakeholders may also identify themselves for inclusion in any future consultation.

*S. divinorum* is a species of sage belonging to the mint family. Its leaves are generally chewed or smoked to obtain psychotropic effects. While uncertainty remains surrounding the health risks of *S. divinorum*, known effects are reported to be short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant. Neither *S. divinorum* nor salvinorin A are currently included in any of the Schedules to the CDSA.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. *S. divinorum* is widely touted as a "legal" hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs.<sup>1</sup> Results from the *Canadian Alcohol and Drug Use Monitoring Survey* (CADUMS) reveal that, in 2009, 1.6% of Canadians aged 15 years and older reported having used *S. divinorum* at least once in their lifetime, and that youth aged 15-24 were much more likely to have used it than adults aged 25 years and older. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *S. divinorum* in the past year. Moreover, the 2009 *Ontario Student Drug Use and Health Survey* (OSDUHS) indicated that 5.4% of Ontario students in grades 7-12 reported ever using *S. divinorum* and 4.4% of these students reported using this substance in the past year. Given its unknown effects and pharmacological similarity to other substances included in Schedule III to the CDSA such as lysergic acid diethylamide (LSD) and psilocybin, Health Canada is concerned that the ready availability and use of *S. divinorum* poses a risk to the health and safety of Canadians, particularly youth.

While *S. divinorum* and salvinorin A are not currently included in any of the United Nations Drug Control Conventions, a number of countries have chosen to regulate one or both as controlled substances. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden have all placed controls on the import and/or sale of *S. divinorum*

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<sup>1</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.

and/or salvinorin A. Some American states have also implemented laws restricting their use, sale and/or distribution.

Including these substances within Schedule III to the CDSA would prohibit: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation). The control of *S. divinorum* and salvinorin A under the CDSA will enable law enforcement agencies to take action against suspected illegal activities involving these substances.

As this action is not intended to interfere with the use and availability of *S. divinorum* and/or salvinorin A for legitimate medical, scientific or industrial purposes, Health Canada is seeking information from stakeholders on whether there are any such uses in Canada. Information received in response to this notice will be instrumental in determining appropriate regulation under the CDSA.

The publication of this notice begins a 30-day comment period. There will be additional opportunities to provide comments as the federal regulatory process progresses.

If you are interested in this process or have comments on this proposal, please contact Stephanie Chandler, Regulatory Policy Division, Office of Controlled Substances, Address Locator: 3503D, 123 Slater St., Ottawa, Ontario, Canada, K1A 1B9, by fax at (613) 946-4224 or by email at [OCS\\_Policy\\_and\\_Regulatory\\_Affairs@hc-sc.gc.ca](mailto:OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca).

Cathy A. Sabiston  
Director General  
Controlled Substances and Tobacco Directorate

Date \_\_\_\_\_



**Fw: salvia "holding lines"**  
Jocelyn Kula to: Denis Arsenault  
Cc: Stephanie Chandler

2011-01-13 05:13 PM

For reference in the package of docs that I gave to Denis. Stephanie in DGO would like revised docs for Monday.

JK

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224  
----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2011-01-13 05:12 PM -----

From: Stephanie Szick/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Date: 2011-01-13 04:33 PM  
Subject: salvia "holding lines"

the original email below, with attached "clean version" with these messages per trail below.



Standard Holding Lines\_pre NOI.doc  
----- Forwarded by Stephanie Szick/HC-SC/GC/CA on 2011-01-13 04:31 PM -----

From: Jocelyn Kula/HC-SC/GC/CA  
To: Stephanie Szick/HC-SC/GC/CA@HWC  
Date: 2010-12-22 11:21 AM  
Subject: URGENT: Media query - CBC [REDACTED] - Salvia  
Sent by: Carmen Berube

s.19(1)

voila

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224  
----- Forwarded by Carmen Berube/HC-SC/GC/CA on 2010-12-22 11:21 AM -----

**Re: URGENT: Media query - CBC [REDACTED] - Salvia**

Jocelyn Kula to: Christine Roush

2010-12-17 05:22 PM

Nicole Prentice, Chantal Routhier-Garner, Denis Arsenault, Stephanie Chandler,

Cc: Suzanne Desjardins

Building on Suzanne's input. Approved for OCS:

**1) Is salvia legal to take in Canada? Is salvia legal to sell in Canada? Has Health Canada Approved the sale of the drug? Is it classified as a banned substance?**

~~A1) Health Canada does not recommend the use of products containing *S. divinorum* and/or salvinorin A because very little is known about these substances and their potential effects on the brain and/or body, and their impact on physical and mental functions.~~

~~To date, Health Canada has not licensed for sale any drug or Natural Health Product which contains salvia as an ingredient.~~

~~It is a contravention of the *Food and Drugs Act* and the *Natural Health Products Regulations* to sell Natural Health Products in Canada unless they have been reviewed by Health Canada and authorized for sale. NHPs authorized for sale will have a Natural Product Number (NPN), a Homeopathic Medicine Number (DIN-HM) or an Exemption Number (EN) on the label. The sale of unauthorized natural health products containing *S. divinorum* and/or salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.~~

~~Complaints about the sale of unauthorized products containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate by calling 1-800-267-9675.~~

The plant *Salvia divinorum* is not regulated under the *Controlled Drugs and Substances Act* (CDSA) and therefore the plant is not considered to be "banned" nor are activities with it considered to be illegal in Canada. However, as *Salvia divinorum* is a plant with hallucinogenic properties when consumed by humans, it meets the definition of a natural health product (NHP) under the *Natural Health Products Regulations* when marketed as a hallucinogen. To date, Health Canada has not licensed for sale any Natural Health Product which contains *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products containing *S. divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

Complaints about the sale of unauthorized products containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate by calling 1-800-267-9675.

**2) Given the negative effects of side effects, why doesn't HC stop the sale of salvia? If it is illegal then why is it readily available? Why isn't there a greater push to enforce (a ban) the substance?**

A2) Health Canada is currently assessing whether the regulation of *Salvia divinorum* and/or salvinorin A under the *Controlled Drugs and Substances Act* is warranted.

**3) Since when has Health Canada been studying salvia?**

A3) Health Canada is taking steps to address the lack of data regarding the use of and/or extent of abuse involving *Salvia divinorum*. Questions regarding the use of *Salvia divinorum* were have been included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. In addition, questions regarding the use of *Salvia divinorum* in the general population were have also been included in the 2009 Canadian Alcohol and Drug Use Monitoring Survey and the data released in July 2010. The data, however, will not likely be available until 2010. In the interim, Health Canada will continue to collect and consider information regarding *Salvia divinorum* as it becomes available. (URL: <http://www.hc-sc.gc.ca/hc-ps/drugs-drogues/stat/index-eng.php>)

**4) What are your reactions to the Saskatchewan radio DJ openly getting high off salvia on his radio show today?**

A4) Health Canada does not recommend the use of products containing *S. divinorum* and/or salvinorin A because very little is known about these substances and their potential effects on the brain and/or body, and their impact on physical and mental functions.

**5) How many complaints has Health Canada received about the substance?**

A5) Health Canada has not received any complaints about this substance. [Could also include the line from past media responses re the four adverse reactions, as long as you also include the caveat about how one can't extrapolate from this because the number is so small....]

**6) Has anyone died from taking the substance?**

A6) We are not aware of a death having occurred in Canada as an immediate consequence of the use of the drug.

s.19(1)

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

Suzanne Desjardins Hi Nicole, Please see my input in blue below. 2010-12-17 04:53:37 PM

From: Suzanne Desjardins/HC-SC/GC/CA  
To: Nicole Prentice/HC-SC/GC/CA@HWC  
Cc: Chantal Routhier-Garner/HC-SC/GC/CA@HWC, Christine Roush/HC-SC/GC/CA@HWC, CSTD-DGO, CSTD-OCS-DO, Denis Arsenault/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2010-12-17 04:53 PM  
Subject: Re: URGENT: Media query - CBC - Salvia

Hi Nicole,  
Please see my input in blue below.

Thanks  
Suzanne

Nicole Prentice Hi Jocelyn and Suzanne, Please see the media... 2010-12-17 04:09:27 PM

Nicole Prentice For your review...I know we need to send this to... 2010-12-17 03:25:14 PM

**1) Is salvia legal to take in Canada? Is salvia legal to sell in Canada? Has Health Canada Approved the sale of the drug? Is it classified as a banned substance?**

The plant *Salvia divinorum* is not regulated under the Controlled Drugs and Substances Act (CDSA) and therefore the plant is not considered to be "banned" nor are activities with it considered to be illegal in Canada. However, as *Salvia divinorum* is a plant with hallucinogenic properties when consumed by humans, it meets the definition of a natural health product (NHP) under the Natural Health Products Regulations when marketed as a hallucinogen. To date, Health Canada has not licensed for sale any Natural Health Product which contains *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products containing *S. divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the Food and Drugs Act.

Complaints about the sale of unauthorized products containing *S. divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate by calling 1-800-267-9675.

**2) Given the negative effects of side effects, why doesn't HC stop the sale of salvia? If it is illegal then why is it readily available? Why isn't there a greater push to enforce (ban) the substance?**

Health Canada is currently assessing whether the regulation of *Salvia divinorum* and/or salvinorin A under the Controlled Drugs and Substances Act is warranted.

**3) Since when has Health Canada been studying salvia?**

Health Canada is taking steps to address the lack of data regarding the use of and/or extent of abuse involving *Salvia divinorum*.

Questions regarding the use of *Salvia divinorum* were included in the 2008-2009 Youth Smoking Survey and the 2009 Ontario Student Drug Use and Health Survey. In addition, questions regarding the use of *Salvia divinorum* in the general population were also been included in the 2009 Canadian Alcohol and Drug Use Monitoring Survey and the data released in July 2010 (URL: <http://www.hc-sc.gc.ca/hc-ps/drugs-drogues/stat/index-eng.php>)

**4) What are your reactions to the Saskatchewan radio DJ openly getting high off salvia on his radio show today?**

Health Canada does not recommend the use of products containing *S. divinorum* and/or salvinorin A because little is known about this substance and its potential effects on the brain and/or body, and its impact on physical and mental functions.

**5) How many complaints has Health Canada received about the substance?**

Health Canada has not received any complaints about this substance.

**6) Has anyone died from taking the substance?**

We are not aware of a death having occurred in Canada as an immediate consequence of the use of the drug.



**Fw: Salvia**

Jocelyn Kula to: Stephanie Chandler, Denis Arsenault

2011-01-14 10:35 AM

for the file pls

---

Jocelyn Kula

Acting Director/ Directrice par intérim

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs

Health Canada/ Santé Canada

Tel: (613) 952-2177 Fax: (613) 946-4224

----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2011-01-14 10:35 AM -----

From: Stephanie Szick/HC-SC/GC/CA  
To: Cathy A Sabiston/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC  
Date: 2011-01-12 12:19 PM  
Subject: Salvia

---

Per below from Jesse - the memo did indeed land in MO afterall -- on Jan. 5.

She will flag with DMO that PCO is sending their note to PMO this week and ask if MO has  
comments/concerns to advise as soon as possible.

Jocelyn -- let us know when you receive the PCO version.

Thanks,S

----- Forwarded by Stephanie Szick/HC-SC/GC/CA on 2011-01-12 12:16 PM -----

From: Jesse Arnup-Blondin/HC-SC/GC/CA  
To: Stephanie Szick/HC-SC/GC/CA@HWC  
Date: 2011-01-12 11:58 AM  
Subject: Re: Issues Mgmt Table - Salvia

---

Turns out - it has gone to MO. It just wasn't routed properly in MECS - it was sent by email on the 5th.

MO has not come back with any questions or concerns at it has been a week. As you know the briefing  
note was not "for approval", so we won't get a response from MO. I can try to do a signal check through  
DMO, but we may not have any luck getting a clear answer. I think our best bet would be to do a "PCO is  
sending their note to PMO this week - speak now, or it goes".

Does that work for you?





**Fw: Note on Salvia**

Jocelyn Kula to: Stephanie Chandler, Denis Arsenault

2011-01-14 10:36 AM

not sure if I forwarded to you or not

---

Jocelyn Kula

Acting Director/ Directrice par intérim

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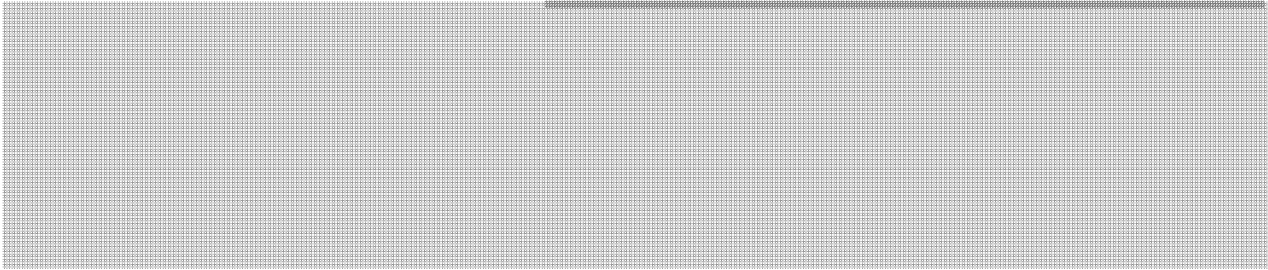
----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2011-01-14 10:36 AM -----

**s.21(1)(a)**

From: "Naylor, Ruth" <Ruth.Naylor@pco-bcp.gc.ca>  
To: "Jocelyn Kula" <jocelyn.kula@hc-sc.gc.ca>  
Date: 2011-01-12 03:17 PM  
Subject: RE: Note on Salvia

---

Thanks Jocelyn. Not comfortable sharing as 



If you had any specific concerns, I would be happy to answer those. Let me know....Thanks – Ruth

---

Ruth Naylor

Social Development Policy | Politique du développement social

Privy Council Office | Bureau du Conseil privé

[ruth.naylor@pco-bcp.gc.ca](mailto:ruth.naylor@pco-bcp.gc.ca)

Telephone | Téléphone 613-957-5531

**From:** Jocelyn Kula [mailto:jocelyn.kula@hc-sc.gc.ca]

**Sent:** January 12, 2011 1:45 PM

**To:** Naylor, Ruth

**Subject:** Re: Note on Salvia

Hi Ruth,

No word from MinO and our package for the NOI is on its way in the approvals process. Is there any chance you can share a copy of your note?

Jocelyn

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé  
environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

"Naylor, Ruth" ---2011-01-12 09:09:56 AM---Good morning Jocelyn! Our note is set to go up today, so I wondered if there is any update? Have you

From: "Naylor, Ruth" <Ruth.Naylor@pco-bcp.gc.ca>  
To: <jocelyn.kula@hc-sc.gc.ca>  
Date: 2011-01-12 09:09 AM  
Subject: Re: Note on Salvia

---

Good morning Jocelyn! Our note is set to go up today, so I wondered if there is any update? Have you heard anything from your MinO? Thanks - Ruth

**From:** Jocelyn Kula <jocelyn.kula@hc-sc.gc.ca>  
**To:** Naylor, Ruth  
**Sent:** Wed Jan 05 17:40:20 2011  
**Subject:** Re: Note on Salvia

Yes we have media lines but at this point they are focused on imminent NOI. The IYH is ready to go but again, is pending publication of the NOI as thinking was that there was no point in going out with original text that suggested no scheduling action (because when IYH was first developed we had not concluded scheduling assessment) when shortly thereafter, we would be going out with the NOI stating that we are pursuing scheduling. The plan is still to do the IYH, but only once the NOI is out there and we are "on our way" to scheduling.

Let me know if you want to see the media lines.

Jocelyn

---

Jocelyn Kula  
Acting Director/ Directrice par intérim

Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la  
santé environnementale et de la sécurité des consommateurs  
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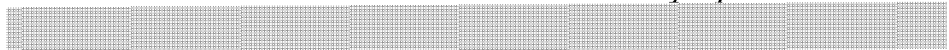
"Naylor, Ruth" ---2011-01-05 05:33:22 PM---Thanks Jocelyn. I am out of the  
office right now, but will take a look at this tomorrow. I was wond

From: "Naylor, Ruth" <Ruth.Naylor@pco-bcp.gc.ca>  
To: <jocelyn.kula@hc-sc.gc.ca>  
Date: 2011-01-05 05:33 PM  
Subject: Re: Note on Salvia

s.21(1)(a)

---

Thanks Jocelyn. I am out of the office right now, but  
will take a look at this tomorrow. I was wondering  
whether HC had finalized media lines and posted  
information about salvia in "It's Your Health", as was  
mentioned in the issue summary you shared with me?

 Thanks -  
Ruth

----- Original Message -----

From: Jocelyn Kula <jocelyn.kula@hc-sc.gc.ca>  
To: Naylor, Ruth  
Cc: stephanie.szick@hc-sc.gc.ca  
<stephanie.szick@hc-sc.gc.ca>; Cathy A Sabiston  
<cathy.a.sabiston@hc-sc.gc.ca>  
Sent: Wed Jan 05 16:51:55 2011  
Subject: Note on Salvia

Hi Ruth,

Further to my phone message, please see the attached  
advance copy of our  
briefing note on Salvia. Happy to discuss at any  
point.

Regards  
Jocelyn

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances  
contrôlées  
Healthy Environments and Consumer Safety Branch/  
Direction générale de la  
santé environnementale et de la sécurité des  
consommateurs  
Health Canada/ Santé Canada  
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**Fw: Salvia - NOI posting in CG1**

Denis Arsenault to: Jocelyn Kula

Cc: Stephanie Chandler

2011-01-14 10:55 AM

Hi Jocelyn,

Just reviewed the MLs and suggested to Stephanie some changes in line with our conversation yesterday (see attached).

Would you like us to send this version to Christine, or the version that Stephanie handed to you via hard copy - just to ensure there is no confusion!



Salvia Media Lines\_Jan 14 2011 (2).doc

Denis

Denis Arsenault, A/Manager / Gestionnaire p.i.

Regulatory Policy Division /

Division des politiques réglementaires,

Office of Controlled Substances /

Bureau des substances contrôlées,

Health Canada / Santé Canada

Tel/Tél: (613) 957-6828

Fax / Télécopieur : (613) 946-4224

E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca

---- Forwarded by Denis Arsenault/HC-SC/GC/CA on 2011-01-14 10:51 AM ----

From: Christine Roush/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2011-01-14 10:20 AM  
Subject: Re: Salvia - NOI posting in CG1

Denis/Jocelyn - can someone pls send me the revised MLs **before 11:00 today** as I'm told Salvia may be discussed at the MO briefing today at 11:00 on MMAP, and Dave Stephens, who will be attending, has requested a copy of the lines. thx.

Christine Roush  
Senior Communications Advisor/

Jocelyn Kula Hi Christine Typically for an NOI (note there are... 2011-01-13 05:49:35 PM

From: Jocelyn Kula/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2011-01-13 05:49 PM  
Subject: Re: Salvia - NOI posting in CG1

Hi Christine

Typically for an NOI (note there are no rules for this...), we do media lines only, and we prepare an email to affected stakeholders advising them that the NOI has been posted. No comms plan or other comms

docs.

For salvia, the package that went to Cathy for approval included:

- 1) draft NOI
- 2) media lines (which we prepared using the draft lines for the IYH as a base) and
- 3) revised QP (which is not required per se but Cathy wanted as there has been some interest from MO and PCO and so she wanted to be prepared for when the house reconvenes)

While I admit that we didn't get you to look at the products before they went to Cathy, she was champing at the bit for them after the briefing in MO before the holidays and so we rushed them, but then she didn't look at them right away because of all the furf with tobacco. She has now reviewed though and we just got comments back today and a request for revised docs for Monday.

As I am thinking that you should probably see the next versions before they go back to Cathy, I am asking Denis and Stephanie in RPD to liaise with you at some point so you can see where things are at. Note that Cathy has specifically directed that the key messages in the media lines mirror to some extent the main bullets in the QP.....

Re. timing, our latest 3 month report says publication in CGI for early February but of course this is all conditional on what if anything we hear back from MO re the note we had to do after the holidays/ from PCO who were also asked to do an information note for MO.

Please feel free to contact Denis if you have any further questions.

Jocelyn

---

Jocelyn Kula

Acting Director/ Directrice par intérim

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs

Health Canada/ Santé Canada

Tel: (613) 952-2177 Fax: (613) 946-4224

Christine Roush	Hi Jocelyn, Further to your email in December, r...	2011-01-13 02:07:53 PM
Jocelyn Kula	Hi Christine Sorry for the delayed reply. Just dis...	2010-11-04 08:18:49 AM
Christine Roush	Hi Jocelyn - just wondering if I could get an upd...	2010-11-01 03:41:20 PM

DRAFT 15  
January 14, 2010

### Media Lines *Salvia divinorum*

#### Issue

There is ongoing media interest regarding the availability of *Salvia divinorum* in Canada as well as reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has concluded that *Salvia divinorum* and its main active ingredient salvinorin A should be regulated under the *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth.

#### Key Messages:

- Health Canada is proposing to regulate both *Salvia divinorum* and its main active ingredient salvinorin A under Schedule III to the *Controlled Drugs and Substances Act* (CDSA).
- In February 2011, Health Canada published a *Notice to Interested Parties* (NOI) in *Canada Gazette*, Part I. The NOI is intended to give Canadians the opportunity to provide comments on the proposal to regulate *Salvia divinorum* and salvinorin A as controlled substances.
- The inclusion of *Salvia divinorum* and salvinorin A in Schedule III to the CDSA will make possession, trafficking, importation, exportation, and production (or cultivation) illegal unless authorized by regulation.

#### Supplementary Messages:

- Canadians should not use products containing *Salvia divinorum* and/or salvinorin A because very little is known about these substances and their potential effects on the brain and body.
- The plant *Salvia divinorum* is not regulated under the CDSA and therefore it is not considered to be "banned", nor are activities with it considered to be illegal in Canada. However, as *Salvia divinorum* is a plant with hallucinogenic properties when consumed by humans, it meets the definition of a natural health product (NHP) under the *Natural Health Products Regulations* when marketed as a hallucinogen. To date, Health Canada has not authorized for sale any natural health products which contain *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products containing *Salvia divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

#### Questions and Answers:

- Deleted:** 4
- Deleted:** December 22
- Deleted:** 0
- Deleted:** and
- Deleted:** has concluded its assessment of *Salvia divinorum* and its main active ingredient salvinorin A and
- Deleted:** substances
- Deleted:** CDSA in order to protect the health and safety of Canadians, particularly youth
- Formatted:** Font: Italic
- Deleted:** The inclusion of *Salvia divinorum* and salvinorin A in Schedule III to the CDSA will reduce the potential health and safety risks associated with the ready availability, increased use and unknown effects of these substances. Further to the regulation of these substances under the CDSA, the following activities would be prohibited unless authorized by regulation: possession, trafficking, possession for the purposes of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation).
- Deleted:** Health Canada will inform stakeholders of its proposal by publishing a *Notice to Interested Parties* (NOI) in *Canada Gazette*, Part I. The NOI will provide stakeholders and other interested parties with the opportunity to provide comments on the proposal to regulate (... [1])
- Deleted:** /or
- Deleted:** and their impact on physical and mental functions
- Deleted:** the plant
- Formatted:** Font: Times New Roman, 12 pt
- Formatted:** Font: Times New Roman, 12 pt, Italic
- Formatted:** Font: Times New Roman, 12 pt
- Formatted:** Font: Times New Roman, 12 pt, Italic
- Formatted:** Font: Times New Roman, 12 pt
- Deleted:** Nevertheless, when specifically marketed for its (... [2])
- Deleted:** however,

**Q1 – Are *Salvia divinorum* and/or salvinorin A controlled internationally? How are these substances regulated in other countries?**

A1 - Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions; as a result, they do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

The move to include *Salvia divinorum* and salvinorin A in Schedule III to the CDSA is consistent with actions taken by several countries (e.g. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Some individual U.S. states have implemented laws restricting their use, sale and/or distribution.

**Q2 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum* as a controlled substance. What does that involve and what stage is it at?**

A2 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada recently concluded its assessment of *Salvia divinorum* and salvinorin A against the aforementioned factors and proposes to include both substances in Schedule III to the CDSA. The regulation of these products will reduce the potential risks to the health and safety of Canadians associated with their ready availability, increased use and unknown effects. The scheduling of *Salvia divinorum* and salvinorin A will also eliminate the current perception that these substances are a safe alternative to other illegal drugs.

Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *Salvia divinorum* at least once in their lifetime, and that youth aged 15-24 were much more likely to have used it than adults aged 25 years and older. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *Salvia divinorum* in the past year. The 2009 *Ontario Student Drug Use and Health Survey (OSDUHS)* indicated that 5.4% of Ontario students in grades 7-12 reported ever using *Salvia divinorum* and 4.4% of these students reported using this substance in the past year.

**Q3 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why isn't it illegal?**



A3 – Health Canada proposes to include *Salvia divinorum* and salvinorin A under Schedule III to the CDSA. Further to the regulation of these substances under the CDSA, the following activities may be prohibited unless authorized by regulation: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation). Law enforcement agencies will then be able to take action against suspected illegal activities involving these substances.

In the interim, as *Salvia divinorum* is a plant with hallucinogenic properties, it meets the definition of a natural health product under the *Natural Health Products Regulations* (NHPR) when marketed as a hallucinogen. The sale of such unauthorized products containing *Salvia divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*.

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**Q4 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A4 – Once *Salvia divinorum* and salvinorin A are included in Schedule III to the CDSA, law enforcement will be able to take appropriate action in response to suspected illegal activities with these substances.

In the interim, *S. divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. Complaints about the illegal sale of drugs containing *Salvia divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

***If pressed on whether Health Canada has issued any kind of warning to Canadians about *Salvia divinorum****

A - Health Canada is developing an It's Your Health article about *Salvia divinorum* to help inform the general public about the risks associated with the use of this plant.

Deleted: on

**Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

Data from the 2008-2009 Youth Smoking Survey indicates that:

- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;
- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year;  
and.
- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using Salvia in their lifetime (0.2% in the past year); and
- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that:

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;
- 5.4% of students (grades 7-12) ever used *Salvia divinorum*; and
- the use of *Salvia divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

**Prepared by:** Stephanie Chandler and Denis Arsenault, OCS, CSTD

**Input by:** Lisa Mackay IYH/PACCB, Suzanne Desjardins HECSB/ODARS, Hanan Abramovici HECSB/ODARS, Bruna Brands HECSB/ODARS, Jocelyn Kula, HECSB/OCS, Robin Marles HPFB/NHPD, Maggie Graham HPFB/NHPD, Stephanie Collins HPFB/NHPD, Mano Murty HPFB/MHPD, Robert Leitch HPFB/MHPD, Shahid Perwaiz HPFB/MHPD, Collin Pinto, HPFB/HPFBI

**Approved by:**

Robin Marles, Director, Bureau of Clinical Trials, NHPD (pending)  
Lindsay Blaney, Director, Policy and Regulatory Affairs, NHPD (pending)  
Duc Vu, Director, Marketed Biologics, Biotechnology and Natural Health Products  
Bureau, MHPD (pending)  
Kim Dayman-Rutkas, Director, HPFBI (pending)  
Diane Allan, Director, OCS, CSTD, HECS (approved, Sept 29, 2010)  
Suzanne Desjardins, Director, ODARS, CSTD, HECS approved, Sept 30, 2010)  
Cathy Sabiston, DG, CSTD, HECS (pending)  
Chris Turner, DG, MHPD (pending)  
Nancy Richards, DG, NHPD (pending)  
Diana Douthwaite, DG, HPFBI (pending)  
Ken Polk, Communications Executive, HPFB (pending)  
Jean Tessier, Senior Media Relations, PACCB (pending)  
Warren Braun, Director, Strategic Communications, PACCB (pending)  
Peter Yendall, Director, Public Affairs, PACCB (pending)  
HECS Legal (pending)  
HPFB Legal (pending)  
Paul Glover, ADM, HECSB (pending)

Meena Ballantyne, ADM, HPFB (pending)  
Anne Lamar, ADM, PACCB (pending)  
DMO (pending)  
MO (pending)  
PCO (pending)

Page 1: [1] Deleted

STCHANDL

2011-01-14 10:30:00 AM

Health Canada will inform stakeholders of its proposal by publishing a *Notice to Interested Parties* (NOI) in *Canada Gazette*, Part I. The NOI will provide stakeholders and other interested parties with the opportunity to provide comments on the proposal to regulate *Salvia divinorum* and salvinorin A as controlled substances.

Page 1: [2] Deleted

STCHANDL

2011-01-14 10:33:00 AM

Nevertheless, when specifically marketed for its hallucinogenic properties, *Salvia divinorum* meets the definition of a natural health product under the *Natural Health Products Regulations*.



**Fw: Salvia - NOI posting in CG1**  
Denis Arsenault to: Jocelyn Kula  
Cc: Stephanie Chandler

2011-01-14 10:26 AM

Hi Jocelyn,

FYI - Stephanie is revising the lines now per Cathy's comments and our conversation yesterday.

Denis

Denis Arsenault, A/Manager / Gestionnaire p.i.  
Regulatory Policy Division /  
Division des politiques réglementaires,  
Office of Controlled Substances /  
Bureau des substances contrôlées,  
Health Canada / Santé Canada  
Tel/Tél: (613) 957-6828  
Fax / Télécopieur : (613) 946-4224  
E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca

----- Forwarded by Denis Arsenault/HC-SC/GC/CA on 2011-01-14 10:26 AM -----

From: Christine Roush/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2011-01-14 10:20 AM  
Subject: Re: Salvia - NOI posting in CG1

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Christine Roush  
Senior Communications Advisor/

Jocelyn Kula                      Hi Christine Typically for an NOI (note there are...                      2011-01-13 05:49:35 PM

From: Jocelyn Kula/HC-SC/GC/CA  
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Hi Christine

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For salvia, the package that went to Cathy for approval included:

- 1) draft NOI
- 2) media lines (which we prepared using the draft lines for the IYH as a base) and
- 3) revised QP (which is not required per se but Cathy wanted as there has been some interest from MO and PCO and so she wanted to be prepared for when the house reconvenes)

**Re: Salvia - NOI posting in CG1**

Dave Stephens to: Christine Roush, Stephanie Chandler  
Cc: Jocelyn Kula, Denis Arsenault

2011-01-14 11:43 AM

They weren't discussed. But we now have direction to issue a NR.  
Christine Roush

----- Original Message -----

**From:** Christine Roush  
**Sent:** 2011-01-14 11:41 AM EST  
**To:** Stephanie Chandler  
**Cc:** Jocelyn Kula; Denis Arsenault; Dave Stephens  
**Subject:** Re: Salvia - NOI posting in CG1

Thanks Stephanie for providing the draft lines below - my point being that if Jocelyn was bringing a copy of the lines to the MO meeting, that my communications executive should also have a copy of the lines in hand too for that meeting.

Christine Roush  
Senior Communications Advisor/

Stephanie Chandler Hi Christine, As I stated previously, the revised... 2011-01-14 11:35:31 AM

**From:** Stephanie Chandler/HC-SC/GC/CA  
**To:** Christine Roush/HC-SC/GC/CA@HWC  
**Cc:** Jocelyn Kula/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, Dave Stephens/HC-SC/GC/CA@HWC  
**Date:** 2011-01-14 11:35 AM  
**Subject:** Re: Salvia - NOI posting in CG1

Hi Christine,

As I stated previously, the revised media lines have not been approved by OCS (Denis has also not reviewed), and therefore I doubt Jocelyn would share them with MO, but rather has a copy for her own information. Attached below is the version Jocelyn has, however I'm fairly certain it will be updated again before she approves them.

[attachment "Salvia Media Lines\_Jan 14 2011.doc" deleted by Dave Stephens/HC-SC/GC/CA]

Sorry for any confusion,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

Christine Roush Hi Stephanie - I would like to remind you that m... 2011-01-14 11:27:35 AM

From: Christine Roush/HC-SC/GC/CA  
To: Stephanie Chandler/HC-SC/GC/CA@HWC  
Cc: Jocelyn Kula/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, Dave Stephens/HC-SC/GC/CA@HWC  
Date: 2011-01-14 11:27 AM  
Subject: Re: Salvia - NOI posting in CG1

---

Hi Stephanie - I would like to remind you that media lines are a communications product and as such, the responsibility of PACCB to produce and obtain necessary approvals. Since Communications has not seen the revised MLs on Salvia, I'm hoping it is not Jocelyn's intent to share them with MO during today's briefing. I would appreciate it if you could share a draft copy with me at your soonest,

Thanks,

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
Health Canada/Santé Canada  
Tel/Tél : (613) 954-0712/Cell: (613) 219-7194  
Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca

---

Stephanie Chandler    Hi Christine, My apologies for the late reply.    2011-01-14 11:14:50 AM

From: Stephanie Chandler/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Cc: Jocelyn Kula/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2011-01-14 11:14 AM  
Subject: Re: Salvia - NOI posting in CG1

---

Hi Christine,

My apologies for the late reply.

As Jocelyn did not have a chance to review the media lines that were revised this morning, she has brought a copy with her to the meeting with MO which she is also attending.

Regards,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

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Christine Roush    Denis/Jocelyn - can someone pls send me the r...    2011-01-14 10:20:42 AM

From: Christine Roush/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2011-01-14 10:20 AM  
Subject: Re: Salvia - NOI posting in CG1

---

Denis/Jocelyn - can someone pls send me the revised MLs **before 11:00 today** as I'm told Salvia may be discussed at the MO briefing today at 11:00 on MMAP, and Dave Stephens, who will be attending, has requested a copy of the lines. thx.

Christine Roush  
Senior Communications Advisor/

Jocelyn Kula	Hi Christine Typically for an NOI (note there are...	2011-01-13 05:49:35 PM
Christine Roush	Hi Jocelyn, Further to your email in December, r...	2011-01-13 02:07:53 PM
Jocelyn Kula	Hi Christine Sorry for the delayed reply. Just dis...	2010-11-04 08:18:49 AM
Christine Roush	Hi Jocelyn - just wondering if I could get an upd...	2010-11-01 03:41:20 PM



**Re: Salvia - NOI posting in CG1** 

Jocelyn Kula to: Christine Roush, Stephanie Chandler

2011-01-14 12:09 PM

Cc: Denis Arsenault, Dave Stephens

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No need to worry Christine. Dave and I did not have time to consult Paul about whether he would raise Salvia or not and so I saw no benefit to sharing lines which I have not even read with Dave, when they most certainly were not going to be tabled at the meeting.

As it turns out, the discussion was very brief and really centered around Paul getting confirmation that we could proceed with the NOI.

Rest assured, no one, least of all I, is trying to usurp the comms approval process!

I will try and touch base with you re the lines (when I have read them) at the end of the day

JK

Sent by blackberry

Jocelyn Kula

A/ Director/ Directrice par interim

Office of Controlled Substances/ Bureau des substances contrôllées

Christine Roush

----- Original Message -----

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**Sent:** 2011-01-14 11:41 AM EST

**To:** Stephanie Chandler

**Cc:** Jocelyn Kula; Denis Arsenault; Dave Stephens

**Subject:** Re: Salvia - NOI posting in CG1

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Senior Communications Advisor/

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**Date:** 2011-01-14 11:35 AM  
**Subject:** Re: Salvia - NOI posting in CG1

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[attachment "Salvia Media Lines\_Jan 14 2011.doc" deleted by Jocelyn Kula/HC-SC/GC/CA]

Sorry for any confusion,

002250

**DIRECTORATE: CONTROLLED SUBSTANCES AND TOBACCO DIRECTORATE**

CURRENT PRIORITIES OF THE DIRECTORATE (TITLE AND DESCRIPTION)	RPS PRIORITY LEVEL	RATIONALE (INCLUDE CRITERIA FROM APPENDIX A AND FURTHER EXPLANATION)	ESTIMATED DRAFTING RESOURCES (TIME AND PEOPLE) REQUIRED (AS DISCUSSED WITH DRAFTERS)	CONSIDERATIONS (TIMING - AIMING FOR A SPECIAL DATE? DIRECTORATE WORKLOAD - AVAILABILITY OF POLICY ANALYSTS?)
<p><b>Scheduling of <i>Salvia divinorum</i> and Salvinorin A under the CDSA – <i>Salvia divinorum</i> is a species of sage belonging to the mint family. While uncertainty remains surrounding the health risks of the plant <i>Salvia divinorum</i> and its main active ingredient salvinorin A, physical and mental effects are reported to include hallucinations, out-of-body experiences, uncontrollable laughter, short-term memory loss, and loss of consciousness. There have been several reports from scientific and media sources indicating that <i>Salvia divinorum</i> has the potential for abuse, and is being used by adolescents and young adults for its hallucinogenic properties. Health Canada is proposing to add both <i>Salvia divinorum</i> and salvinorin A to the Schedules to the CDSA in order to reduce the potential health and safety risks associated with the ready availability, increased use and unknown effects of these substances.</b></p>				

- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year; and.
- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using *Salvia* in their lifetime (0.2% in the past year); and
- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that:

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;
- 5.4% of students (grades 7-12) ever used *Salvia divinorum*; and
- the use of *Salvia divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

**Prepared by:** Stephanie Chandler and Denis Arseneault, OCS, CSTD

**Input by:** Lisa Mackay, IYH/PACCB, Suzanne Desjardins, HECSB/ODARS, Hanan Abramovici, HECSB/ODARS, Bruna Brands, HECSB/ODARS, Jocelyn Kula, HECSB/OCS, Robin Marles, HPPFB/NHPD, Maggie Graham, HPPFB/NHPD, Stephanie Collins, HPPFB/NHPD, Mano Murty, HPPFB/MHPD, Robert Leitch, HPPFB/MHPD, Shahid Perwaiz, HPPFB/MHPD, Collin Pinto, HPPFB/HPFBI

**Approved by:**

- ~~Robin Marles, Director, Bureau of Clinical Trials, NHPD (pending)~~
- ~~Lindsay Blaney, Director, Policy and Regulatory Affairs, NHPD (pending)~~
- ~~Duc Vu, Director, Marketed Biologics, Biotechnology and Natural Health Products Bureau, MHPD (pending)~~
- ~~Kim Dayman Rutkas, Director, HPFBI (pending)~~
- ~~Diane Allan, Director, OCS, CSTD, HECS (approved, Sept 29, 2010)~~
- ~~Suzanne Desjardins, Director, ODARS, CSTD, HECS approved, Sept 30, 2010~~
- Cathy Sabiston, DG, CSTD, HECS (pending)
- ~~Chris Turner, DG, MHPD (pending)~~
- ~~Nancy Richards, DG, NHPD (pending)~~
- ~~Diana Douthwaite, DG, HPFBI (pending)~~
- ~~Ken Polk, Communications Executive, HPPFB (pending)~~
- ~~Jean Tessier, Senior Media Relations, PACCB (pending)~~
- ~~Warren Braun, Director, Strategic Communications, PACCB (pending)~~
- ~~Peter Yendall, Director, Public Affairs, PACCB (pending)~~
- HECS Legal (pending)
- ~~HPFB Legal (pending)~~
- Paul Glover, ADM, HECSB (pending)
- ~~Meena Ballantyne, ADM, HPPFB (pending)~~
- Anne Lamar, ADM, PACCB (pending)

one line NHPD

JZ

Dave Stephens  
Director Comm PAA CB

DG →

HPPFB  
her advice?

DMO (pending)  
MO (pending)  
PCO (pending)

DRAFT 15, 2011  
January 14, 2010

### Media Lines *Salvia divinorum*

#### Issue

There is ongoing media interest regarding the availability of *Salvia divinorum* in Canada as well as reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has concluded that *Salvia divinorum* and its main active ingredient salvinorin A should be regulated under the *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth.

#### Key Messages:

- Health Canada is proposing to regulate both *Salvia divinorum* and its main active ingredient salvinorin A, under Schedule III to the CDSA in order to protect the health and safety of Canadians, particularly youth.
- Health Canada will publish a *Notice to Interested Parties* (NOI) in *Canada Gazette, Part I* in February 2011. The NOI will give people the opportunity to provide comments on the proposal to regulate *Salvia divinorum* and salvinorin A as controlled substances.
- The inclusion of *Salvia divinorum* and salvinorin A in Schedule III to the CDSA will reduce the potential health and safety risks associated with the ready availability, increased use and unknown effects of these substances. Once *Salvia divinorum* and salvinorin A are regulated as controlled substances, the following activities would be prohibited unless authorized by regulation: possession, trafficking, possession for the purposes of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation).

#### Supplementary Messages:

- Canadians should not use products containing *Salvia divinorum* and/or salvinorin A because very little is known about these substances and their potential effects on the brain and body.
- The plant *Salvia divinorum* is not regulated under the CDSA and therefore it is not considered to be "banned", nor are activities with it considered to be illegal in Canada. However, as *Salvia divinorum* is a plant with hallucinogenic properties when consumed by humans, it meets the definition of a natural health product (NHP) under the *Natural Health Products Regulations* when marketed as a hallucinogen. To date, Health Canada has not authorized for sale any natural health products which contain *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products containing *Salvia*

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*divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

#### Questions and Answers:

##### **Q1 – Are *Salvia divinorum* and/or salvinorin A controlled internationally? How are these substances regulated in other countries?**

A1 - Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions; as a result, they do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

The move to include *Salvia divinorum* and salvinorin A in Schedule III to the CDSA is consistent with actions taken by several countries (Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Some individual U.S. states have implemented laws restricting their use, sale and/or distribution.

##### **Q2 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum* as a controlled substance. What does that involve and what stage is it at?**

A2 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada recently concluded its assessment of *Salvia divinorum* and salvinorin A against the aforementioned factors and proposes to include both substances in Schedule III to the CDSA. The regulation of these products will reduce the potential risks to the health and safety of Canadians associated with their ready availability, increased use and unknown effects. The scheduling of *Salvia divinorum* and salvinorin A will also eliminate the current perception that these substances are a safe alternative to other illegal drugs.

Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *Salvia divinorum* at least once in their lifetime, and that youth aged 15-24 were much more likely to have used it than adults aged 25 years and older. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *Salvia divinorum* in the past year. The 2009 *Ontario Student Drug Use and Health Survey (OSDUHS)* indicated that 5.4% of Ontario

students in grades 7-12 reported ever using *Salvia divinorum* and 4.4% of these students reported using this substance in the past year.

**Q3 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why isn't it illegal?**

A3 – Health Canada proposes to include *Salvia divinorum* and salvinorin A under Schedule III to the CDSA. Further to the regulation of these substances under the CDSA, the following activities may be prohibited unless authorized by regulation: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation). Law enforcement agencies will then be able to take action against suspected illegal activities involving these substances.

In the interim, as *Salvia divinorum* is a plant with hallucinogenic properties, it meets the definition of a natural health product under the *Natural Health Products Regulations* (NHPR) when marketed as a hallucinogen. The sale of such unauthorized products containing *Salvia divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*.

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**Q4 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A4 – Once *Salvia divinorum* and salvinorin A are included in Schedule III to the CDSA, law enforcement will be able to take appropriate action in response to suspected illegal activities with these substances.

In the interim, *S. divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. Complaints about the illegal sale of drugs containing *Salvia divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

***If pressed on whether Health Canada has issued any kind of warning to Canadians about *Salvia divinorum****

A - Health Canada is developing an It's Your Health article for the departmental website about *Salvia divinorum* to help inform the general public about the risks associated with the use of this plant.

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**Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

Data from the 2008-2009 Youth Smoking Survey indicates that:

- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;
- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year; and.
- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using Salvia in their lifetime (0.2% in the past year); and
- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that:

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;
- 5.4% of students (grades 7-12) ever used *Salvia divinorum*; and
- the use of *Salvia divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

**Prepared by:** Stephanie Chandler and Denis Arsenault, OCS, CSTD

**Input by:** Lisa Mackay IYH/PACCB, Suzanne Desjardins HECSB/ODARS, Hanan Abramovici HECSB/ODARS, Bruna Brands HECSB/ODARS, Jocelyn Kula, HECSB/OCS, Robin Marles HPFB/NHPD, Maggie Graham HPFB/NHPD, Stephanie Collins HPFB/NHPD, Mano Murty HPFB/MHPD, Robert Leitch HPFB/MHPD, Shahid Perwaiz HPFB/MHPD, Collin Pinto, HPFB/HPFBI

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Anne Lamar, ADM, PACCB (pending)  
DMO (pending)  
MO (pending)  
PCO (pending)

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STCHANDL

2011-01-14 10:33:00 AM

Nevertheless, when specifically marketed for its hallucinogenic properties, *Salvia divinorum* meets the definition of a natural health product under the *Natural Health Products Regulations*.

DRAFT 15, 2011  
January 14, 2010

### Media Lines *Salvia divinorum*

#### Issue

There is ongoing media interest regarding the availability of *Salvia divinorum* in Canada as well as reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has concluded that *Salvia divinorum* and its main active ingredient salvinorin A should be regulated under the *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth.

#### Key Messages:

- Health Canada is proposing to regulate both *Salvia divinorum* and its main active ingredient salvinorin A under Schedule III to the CDSA in order to protect the health and safety of Canadians, particularly youth. *Controlled Drugs and Substances Act.*
- Health Canada will publish a *Notice to Interested Parties* (NOI) in *Canada Gazette, Part I* in February 2011. The NOI will give people the opportunity to provide comments on the proposal to regulate *Salvia divinorum* and salvinorin A as controlled substances.
- The inclusion of *Salvia divinorum* and salvinorin A in Schedule III to the CDSA will reduce the potential health and safety risks associated with the ready availability, increased use and unknown effects of these substances. Once *Salvia divinorum* and salvinorin A are regulated as controlled substances, the following activities would be prohibited unless authorized by regulation: possession, trafficking, possession for the purposes of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation).

would prohibit, unless

#### Supplementary Messages:

- Canadians should not use products containing *Salvia divinorum* and/or salvinorin A because very little is known about these substances and their potential effects on the brain and body.
- The plant *Salvia divinorum* is not regulated under the CDSA and therefore it is not considered to be "banned", nor are activities with it considered to be illegal in Canada. However, as *Salvia divinorum* is a plant with hallucinogenic properties when consumed by humans, it meets the definition of a natural health product (NHP) under the *Natural Health Products Regulations*, when marketed as a hallucinogen. To date, Health Canada has not authorized for sale any natural health products which contain *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products containing *Salvia*

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- Potential for abuse and risk of addiction associated with the substance;
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Health Canada recently concluded its assessment of *Salvia divinorum* and salvinorin A against the aforementioned factors and proposes to include both substances in Schedule III to the CDSA. The regulation of these products will reduce the potential risks to the health and safety of Canadians associated with their ready availability, increased use and unknown effects. The scheduling of *Salvia divinorum* and salvinorin A will also eliminate the current perception that these substances are a safe alternative to other illegal drugs.

Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *Salvia divinorum* at least once in their lifetime, and that youth aged 15-24 were much more likely to have used it than adults aged 25 years and older. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *Salvia divinorum* in the past year. The 2009 *Ontario Student Drug Use and Health Survey (OSDUHS)* indicated that 5.4% of Ontario

students in grades 7-12 reported ever using *Salvia divinorum* and 4.4% of these students reported using this substance in the past year.

**Q3 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why isn't it illegal?**

A3 – Health Canada proposes to include *Salvia divinorum* and salvinorin A under Schedule III to the CDSA. Further to the regulation of these substances under the CDSA, the following activities may be prohibited unless authorized by regulation: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation). Law enforcement agencies will then be able to take action against suspected illegal activities involving these substances.

In the interim, as *Salvia divinorum* is a plant with hallucinogenic properties, it meets the definition of a natural health product under the *Natural Health Products Regulations* (NHPR) when marketed as a hallucinogen. The sale of such unauthorized products containing *Salvia divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*.

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**Q4 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

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In the interim, *S. divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. Complaints about the illegal sale of drugs containing *Salvia divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

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A - Health Canada is developing an It's Your Health article for the departmental website about *Salvia divinorum* to help inform the general public about the risks associated with the use of this plant.

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**Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

Data from the 2008-2009 Youth Smoking Survey indicates that:

- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;
- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year; and
- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using *Salvia* in their lifetime (0.2% in the past year); and
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Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that:

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**Input by:** Lisa Mackay IYH/PACCB, Suzanne Desjardins HECSB/ODARS, Hanan Abramovici HECSB/ODARS, Bruna Brands HECSB/ODARS, Jocelyn Kula, HECSB/OCS, Robin Marles HPFB/NHPD, Maggie Graham HPFB/NHPD, Stephanie Collins HPFB/NHPD, Mano Murty HPFB/MHPD, Robert Leitch HPFB/MHPD, Shahid Perwaiz HPFB/MHPD, Collin Pinto, HPFB/HPFBI

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PCO (pending)

Nevertheless, when specifically marketed for its hallucinogenic properties, *Salvia divinorum* meets the definition of a natural health product under the *Natural Health Products Regulations*.



Version 2

DRAFT 15, 2011  
January 14, 2010

### Media Lines *Salvia divinorum*

#### Issue

There is ongoing media interest regarding the availability of *Salvia divinorum* in Canada as well as reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has concluded that *Salvia divinorum* and its main active ingredient salvinorin A should be regulated under the *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth.

#### Key Messages:

- Health Canada is proposing to regulate both *Salvia divinorum* and its main active ingredient salvinorin A under Schedule III to the *Controlled Drugs and Substances Act* (CDSA).
- Health Canada will publish a *Notice to Interested Parties (NOI)* in *Canada Gazette, Part I* in February 2011. The NOI will give people the opportunity to provide comments on the proposal to regulate *Salvia divinorum* and salvinorin A as controlled substances.
- The inclusion of *Salvia divinorum* and salvinorin A in Schedule III to the CDSA would prohibit, unless authorized by regulation: possession, trafficking, possession for the purposes of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation).

#### Supplementary Messages:

- Canadians should not use products containing *Salvia divinorum* and/or salvinorin A because very little is known about these substances and their potential effects on the brain and body.
- The plant *Salvia divinorum* is not regulated under the CDSA and therefore it is not considered to be "banned", nor are activities with it considered to be illegal in Canada. However, as *Salvia divinorum* is a plant with hallucinogenic properties when consumed by humans, it meets the definition of a natural health product (NHP) under the *Natural Health Products Regulations* when marketed as a hallucinogen. To date, Health Canada has not authorized for sale any natural health products which contain *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products containing *Salvia divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

#### Questions and Answers:

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**Q1 – Are *Salvia divinorum* and/or salvinorin A controlled internationally? How are these substances regulated in other countries?**

A1 - Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions; as a result, they do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

The move to include *Salvia divinorum* and salvinorin A in Schedule III to the CDSA is consistent with actions taken by several countries (Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Some individual U.S. states have implemented laws restricting their use, sale and/or distribution.

**Q2 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum* as a controlled substance. What does that involve and what stage is it at?**

A2 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
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Health Canada recently concluded its assessment of *Salvia divinorum* and salvinorin A against the aforementioned factors and proposes to include both substances in Schedule III to the CDSA. The regulation of these products will reduce the potential risks to the health and safety of Canadians associated with their ready availability, increased use and unknown effects. The scheduling of *Salvia divinorum* and salvinorin A will also eliminate the current perception that these substances are a safe alternative to other illegal drugs.

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**Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

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**Page 1: [1] Deleted**                      **STHANDL**                      **2011-01-14 10:30:00 AM**  
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DRAFT 15, 2011  
January 14, 2010

Media Lines  
Salvia divinorum  
(Post Issuance of NOI)

OK by me  
pls fix and send to Christine  
pls ask her to let us know if she has issues that can be

considered approved for OCS  
but need to go back to cat with NO package  
Does she want

**Issue**

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**Key Messages:**

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Paul Glover, ADM, HECSB (pending)  
Meena Ballantyne, ADM, HPFB (pending)  
Anne Lamar, ADM, PACCB (pending)  
DMO (pending)  
MO (pending)  
PCO (pending)

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Page 1: [1] Deleted STCHANDL 2011-01-14 10:30:00 AM

Health Canada will inform stakeholders of its proposal by publishing a *Notice to Interested Parties* (NOI) in *Canada Gazette*, Part I. The NOI will provide stakeholders and other interested parties with the opportunity to provide comments on the proposal to regulate *Salvia divinorum* and salvinorin A as controlled substances.

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Page 1: [2] Deleted STCHANDL 2011-01-14 10:33:00 AM

Nevertheless, when specifically marketed for its hallucinogenic properties, *Salvia divinorum* meets the definition of a natural health product under the *Natural Health Products Regulations*.

DRAFT 15, 2011  
January 14, 2010

### Media Lines *Salvia divinorum*

#### Issue

There is ongoing media interest regarding the availability of *Salvia divinorum* in Canada as well as reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has concluded that *Salvia divinorum* and its main active ingredient salvinorin A should be regulated under the *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth.

#### Key Messages:

- Health Canada is proposing to regulate both *Salvia divinorum* and its main active ingredient salvinorin A under Schedule III to the *Controlled Drugs and Substances Act* (CDSA).
- In February 2011, Health Canada published a *Notice to Interested Parties (NOI)* in *Canada Gazette, Part I*. The NOI is intended to give Canadians the opportunity to provide comments on the proposal to regulate *Salvia divinorum* and salvinorin A as controlled substances.
- The inclusion of *Salvia divinorum* and salvinorin A in Schedule III to the CDSA will make possession, trafficking, importation, exportation, and production (or cultivation) illegal unless authorized by regulation.

#### Supplementary Messages:

- Canadians should not use products containing *Salvia divinorum* and/or salvinorin A because very little is known about these substances and their potential effects on the brain and body.
- The plant *Salvia divinorum* is not regulated under the CDSA and therefore it is not considered to be "banned", nor are activities with it considered to be illegal in Canada. However, as *Salvia divinorum* is a plant with hallucinogenic properties when consumed by humans, it meets the definition of a natural health product (NHP) under the *Natural Health Products Regulations* when marketed as a hallucinogen. To date, Health Canada has not authorized for sale any natural health products which contain *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products containing *Salvia divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

#### Questions and Answers:

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**Q1 – Are *Salvia divinorum* and/or salvinorin A controlled internationally? How are these substances regulated in other countries?**

A1 - Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions; as a result, they do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

The move to include *Salvia divinorum* and salvinorin A in Schedule III to the CDSA is consistent with actions taken by several countries (e.g. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Some individual U.S. states have implemented laws restricting their use, sale and/or distribution.

**Q2 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum* as a controlled substance. What does that involve and what stage is it at?**

A2 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada recently concluded its assessment of *Salvia divinorum* and salvinorin A against the aforementioned factors and proposes to include both substances in Schedule III to the CDSA. The regulation of these products will reduce the potential risks to the health and safety of Canadians associated with their ready availability, increased use and unknown effects. The scheduling of *Salvia divinorum* and salvinorin A will also eliminate the current perception that these substances are a safe alternative to other illegal drugs.

Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *Salvia divinorum* at least once in their lifetime, and that youth aged 15-24 were much more likely to have used it than adults aged 25 years and older. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *Salvia divinorum* in the past year. The 2009 *Ontario Student Drug Use and Health Survey (OSDUHS)* indicated that 5.4% of Ontario students in grades 7-12 reported ever using *Salvia divinorum* and 4.4% of these students reported using this substance in the past year.

**Q3 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why isn't it illegal?**

A3 – Health Canada proposes to include *Salvia divinorum* and salvinorin A under Schedule III to the CDSA. Further to the regulation of these substances under the CDSA, the following activities may be prohibited unless authorized by regulation: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation). Law enforcement agencies will then be able to take action against suspected illegal activities involving these substances.

In the interim, as *Salvia divinorum* is a plant with hallucinogenic properties, it meets the definition of a natural health product under the *Natural Health Products Regulations* (NHPR) when marketed as a hallucinogen. The sale of such unauthorized products containing *Salvia divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*.

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**Q4 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A4 – Once *Salvia divinorum* and salvinorin A are included in Schedule III to the CDSA, law enforcement will be able to take appropriate action in response to suspected illegal activities with these substances.

In the interim, *S. divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. Complaints about the illegal sale of drugs containing *Salvia divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

***If pressed on whether Health Canada has issued any kind of warning to Canadians about *Salvia divinorum****

A - Health Canada is developing an It's Your Health article about *Salvia divinorum* to help inform the general public about the risks associated with the use of this plant.

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### **Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

Data from the 2008-2009 Youth Smoking Survey indicates that:

- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;
- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year; and
- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using Salvia in their lifetime (0.2% in the past year); and
- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that:

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;
- 5.4% of students (grades 7-12) ever used *Salvia divinorum*; and
- the use of *Salvia divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

**Prepared by:** Stephanie Chandler and Denis Arsenault, OCS, CSTD

**Input by:** Lisa Mackay IYH/PACCB, Suzanne Desjardins HECSB/ODARS, Hanan Abramovici HECSB/ODARS, Bruna Brands HECSB/ODARS, Jocelyn Kula, HECSB/OCS, Robin Marles HPFB/NHPD, Maggie Graham HPFB/NHPD, Stephanie Collins HPFB/NHPD, Mano Murty HPFB/MHPD, Robert Leitch HPFB/MHPD, Shahid Perwaiz HPFB/MHPD, Collin Pinto, HPFB/HPFBI

**Approved by:**

Robin Marles, Director, Bureau of Clinical Trials, NHPD (pending)  
Lindsay Blaney, Director, Policy and Regulatory Affairs, NHPD (pending)  
Duc Vu, Director, Marketed Biologics, Biotechnology and Natural Health Products  
Bureau, MHPD (pending)  
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Diane Allan, Director, OCS, CSTD, HECS (approved, Sept 29, 2010)  
Suzanne Desjardins, Director, ODARS, CSTD, HECS approved, Sept 30, 2010)  
Cathy Sabiston, DG, CSTD, HECS (pending)  
Chris Turner, DG, MHPD (pending)  
Nancy Richards, DG, NHPD (pending)  
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Jean Tessier, Senior Media Relations, PACCB (pending)  
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HECS Legal (pending)  
HPFB Legal (pending)  
Paul Glover, ADM, HECSB (pending)



Meena Ballantyne, ADM, HPFB (pending)  
Anne Lamar, ADM, PACCB (pending)  
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PCO (pending)

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STHANDL

2011-01-14 10:30:00 AM

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2011-01-14 10:33:00 AM

Nevertheless, when specifically marketed for its hallucinogenic properties, *Salvia divinorum* meets the definition of a natural health product under the *Natural Health Products Regulations*.

## QUESTION PERIOD NOTE

### NOTE POUR LA PÉRIODE DE QUESTIONS

Date:	January 14, 2011
Classification :	HECS PROTECTED - SESC PROTÉGÉ

---

#### SUBJECT - SUJET

English:

**DRUGS - SALVIA DIVINORUM**

Français:

**DROGUES - SALVIA DIVINORUM**

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#### SYNOPSIS - SOMMAIRE

English:

Media interest in Salvia divinorum is recurrent. Questions around this substance generally focus on its legality. Recently, a number of media reports have commented on a YouTube video which reportedly shows the young Hollywood celebrity Miley Cyrus smoking Salvia divinorum. There have also been several reports from scientific and media sources, indicating that Salvia divinorum has the potential for abuse, and is used by adolescents and young adults for its hallucinogenic properties.

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#### ANTICIPATED QUESTION - QUESTION PRÉVUE

English:

What is Health Canada doing to protect Canadians from the potential adverse effects associated with the use of Salvia divinorum?

Français:

Quelles mesures Santé Canada prend-il pour protéger les Canadiens contre les effets indésirables possibles liés à l'utilisation de la Salvia divinorum?

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English:

- Health Canada is proposing to regulate both *Salvia* and its main active ingredient salvinorin A under Schedule III to the *Controlled Drugs and Substances Act* (CDSA).
- In February 2011, Health Canada published a *Notice to Interested Parties* in *Canada Gazette*, Part I. The NOI is intended to give Canadians the opportunity to provide comments on the proposal to regulate these two substances.
- The inclusion of *Salvia* in Schedule III to the CDSA will make possession, trafficking, importation, exportation, and production (cultivation) illegal unless authorized by regulation.

Français:

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## **BACKGROUND - CONTEXTE**

English:

### **BACKGROUND / CONTEXTE**

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, diviner's sage, magic mint, and puff. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs.

Both the plant *S. divinorum* and its main active ingredient salvinorin A are known to have physical and mental effects which are often described as unpleasant, including:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter

- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

International Control of *S. divinorum*

Neither *Salvia divinorum* nor its main active ingredient salvinorin A are listed under the United Nations Drug Control Conventions; as a result, they do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions. The move to include *Salvia divinorum* and salvinorin A in Schedule III to the CDSA is consistent with actions taken by several countries (e.g. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Some individual U.S. states have implemented laws restricting their use, sale and/or distribution.

Current Situation in Canada

Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted, namely:

- International requirements and trends in control and/or scheduling;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e. therapeutic, scientific, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada recently concluded its assessment of *S. divinorum* and its main active ingredient salvinorin A against the aforementioned factors and now proposes to include both substances in Schedule III to the CDSA.

The plant *Salvia divinorum* is not regulated under the *Controlled Drugs and Substances Act* (CDSA) and therefore the plant is not considered to be "banned" nor are activities with it considered to be illegal in Canada. However, as *Salvia divinorum* is a plant with hallucinogenic properties when consumed by humans, it meets the definition of a natural health product (NHP) under the *Natural Health Products Regulations* when marketed as a hallucinogen. To date, Health Canada has not licensed for sale any Natural Health Product which contains *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products containing *Salvia divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

**ATTACHMENTS / PIÈCE(S)-JOINTE(S)**

Contact/Personne ressource : Denis Arsenault/HC-SC/GC/CA	Tel. no./No de tél. 613-957-6828	Approved by/ Approuvé par Paul Glover, ADM (HECS/SESC)	Tel. no./No. de tél. 946-6701
	Mobile/ Cellulaire: 613-296-4239	Title/ Titre:	Mobile/ Cellulaire:
Alternate/ Secondaire: Jocelyn Kula	Telephone/ Téléphone: 613-952-2177		
	Mobile/ Cellulaire: 613-797-2103		

**Date Prepared/Préparé le :** 2010-09-07

**Prepared by/Préparé par :** Stephanie Chandler **Phone/ No de tél. :** 613-946-0124

**Office/Bureau :** CSTD - Office of Controlled Substances

**Date Contact Signed/  
Signature de la personne  
ressource :**  **Contact Signed - Signé**

**D.G. Verification/  
Vérification par le D.E. :** Cathy Sabiston  **D.G. Approved / Approuvé D.E.**

**Date D.G. Verified/  
Date vérifié par le D.E. :**

**Programme :** Controlled Substances and Tobacco Directorate

**ADM Approved/ Approbation  
par le SMA :** Paul Glover  
(946-6701)

**Branch/ Direction générale :** HECS/SESC

**Department/ Ministère :** Health Canada / Santé Canada

**DRAFT V.8**

DEPARTMENT OF HEALTH

CONTROLLED DRUGS AND SUBSTANCES ACT

*Notice to interested parties - Proposal regarding the addition of Salvia divinorum and salvinorin A to Schedule III to the Controlled Drugs and Substances Act*

This notice provides interested stakeholders with the opportunity to provide comments on Health Canada's proposal to add the plant *Salvia divinorum* (*S. divinorum*) and its active ingredient salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA). Stakeholders may also identify themselves for inclusion in any future consultation.

*S. divinorum* is a species of sage belonging to the mint family. Its leaves are generally chewed or smoked to obtain psychotropic effects. While uncertainty remains surrounding the health risks of *S. divinorum*, known effects are reported to be short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant. Neither *S. divinorum* nor salvinorin A are currently included in any of the Schedules to the CDSA.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. *S. divinorum* is widely touted as a "legal" hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs.<sup>1</sup> Results from the *Canadian Alcohol and Drug Use Monitoring Survey* (CADUMS) reveal that, in 2009, 1.6% of Canadians aged 15 years and older reported having used *S. divinorum* at least once in their lifetime, and that youth aged 15-24 were much more likely to have used it than adults aged 25 years and older. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *S. divinorum* in the past year. Moreover, the 2009 *Ontario Student Drug Use and Health Survey* (OSDUHS) indicated that 5.4% of Ontario students in grades 7-12 reported ever using *S. divinorum* and 4.4% of these students reported using this substance in the past year. Given its unknown effects and pharmacological similarity to other substances included in Schedule III to the CDSA such as lysergic acid diethylamide (LSD) and psilocybin, Health Canada is concerned that the ready availability and use of *S. divinorum* poses a risk to the health and safety of Canadians, particularly youth.

While *S. divinorum* and salvinorin A are not currently included in any of the United Nations Drug Control Conventions, a number of countries have chosen to regulate one or both as controlled substances. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden have all placed controls on the import and/or sale of *S. divinorum*

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<sup>1</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.

and/or salvinorin A. Some American states have also implemented laws restricting their use, sale and/or distribution.

Including these substances within Schedule III to the CDSA would prohibit: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation). The control of *S. divinorum* and salvinorin A under the CDSA will enable law enforcement agencies to take action against suspected illegal activities involving these substances.

As this action is not intended to interfere with the use and availability of *S. divinorum* and/or salvinorin A for legitimate medical, scientific or industrial purposes, Health Canada is seeking information from stakeholders on whether there are any such uses in Canada. Information received in response to this notice will be instrumental in determining appropriate regulation under the CDSA.

The publication of this notice begins a 30-day comment period. There will be additional opportunities to provide comments as the federal regulatory process progresses.

If you are interested in this process or have comments on this proposal, please contact Stephanie Chandler, Regulatory Policy Division, Office of Controlled Substances, Address Locator: 3503D, 123 Slater St., Ottawa, Ontario, Canada, K1A 1B9, by fax at (613) 946-4224 or by email at [OCS\\_Policy\\_and\\_Regulatory\\_Affairs@hc-sc.gc.ca](mailto:OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca).

Cathy A. Sabiston  
Director General  
Controlled Substances and Tobacco Directorate

Date \_\_\_\_\_



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DRAFT V.8

DEPARTMENT OF HEALTH

CONTROLLED DRUGS AND SUBSTANCES ACT

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regulation

Including these substances within Schedule III to the CDSA would prohibit: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation). The ~~control~~ of *S. divinorum* and salvinorin A under the CDSA will enable law enforcement agencies to take action against suspected illegal activities involving these substances.

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Cathy A. Sabiston  
Director General  
Controlled Substances and Tobacco Directorate

Date \_\_\_\_\_

Minors only

**QUESTION PERIOD NOTE**  
**NOTE POUR LA PÉRIODE DE**  
**QUESTIONS**

Date:	January 14, 2011
Classification :	HECS PROTECTED - SESC PROTÉGÉ

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**SUBJECT - SUJET**

English:

**DRUGS - SALVIA DIVINORUM**

Français:

**DROGUES - SALVIA DIVINORUM**

---

**SYNOPSIS - SOMMAIRE**

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Media interest in Salvia divinorum is recurrent. Questions around this substance generally focus on its legality. Recently, a number of media reports have commented on a YouTube video which reportedly shows the young Hollywood celebrity Miley Cyrus smoking Salvia divinorum. There have also been several reports from scientific and media sources, indicating that Salvia divinorum has the potential for abuse, and is used by adolescents and young adults for its hallucinogenic properties.

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**ANTICIPATED QUESTION - QUESTION PRÉVUE**

English:

What is Health Canada doing to protect Canadians from the potential adverse effects associated with the use of Salvia divinorum?

Français:

Quelles mesures Santé Canada prend-il pour protéger les Canadiens contre les effets indésirables possibles liés à l'utilisation de la Salvia divinorum?

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English:

- Health Canada is proposing to regulate both *Salvia* and its main active ingredient salvinorin A under Schedule III to the *Controlled Drugs and Substances Act* (CDSA).
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- The inclusion of *Salvia* in Schedule III to the CDSA will make possession, trafficking, importation, exportation, and production (cultivation) illegal unless authorized by regulation.

Français:

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## **BACKGROUND - CONTEXTE**

English:

### **BACKGROUND / CONTEXTE**

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, diviner's sage, magic mint, and puff. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs.

Both the plant *S. divinorum* and its main active ingredient salvinorin A are known to have physical and mental effects which are often described as unpleasant, including:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter

- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

*also*

International Control of *S. divinorum*

Neither *Salvia divinorum* nor its main active ingredient salvinorin A are listed under the United Nations Drug Control Conventions; as a result, they do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions. The move to include *Salvia divinorum* and salvinorin A in Schedule III to the CDSA is consistent with actions taken by several countries (e.g. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Some individual U.S. states have implemented laws restricting their use, sale and/or distribution.

Current Situation in Canada

Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted, namely:

- International requirements and trends in control and/or scheduling;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e. therapeutic, scientific, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada recently concluded its assessment of *S. divinorum* and its main active ingredient salvinorin A against the aforementioned factors and now proposes to include both substances in Schedule III to the CDSA.

The plant *Salvia divinorum* is not regulated under the *Controlled Drugs and Substances Act* (CDSA) and therefore the plant is not considered to be "banned" nor are activities with it considered to be illegal in Canada. However, as *Salvia divinorum* is a plant with hallucinogenic properties when consumed by humans, it meets the definition of a natural health product (NHP) under the *Natural Health Products Regulations* when marketed as a hallucinogen. To date, Health Canada has not licensed for sale any Natural Health Product which contains *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products containing *Salvia divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

**ATTACHMENTS / PIÈCE(S)-JOINTE(S)**

Contact/Personne ressource : Denis Arsenault/HC-SC/GC/CA	Tel. no./No de tél. 613-957-6828	Approved by/ Approuvé par Paul Glover, ADM (HECS/SESC)	Tel. no./No. de tél. 946-6701
	Mobile/ Cellulaire: 613-296-4239	Title/ Titre:	Mobile/ Cellulaire:
Alternate/ Secondaire: Jocelyn Kula	Telephone/ Téléphone: 613-952-2177		
	Mobile/ Cellulaire: 613-797-2103		

**Date Prepared/Préparé le :** 2010-09-07  
**Prepared by/Préparé par :** Stephanie Chandler **Phone/ No de tél. :** 613-946-0124  
**Office/Bureau :** CSTD - Office of Controlled Substances

**Date Contact Signed/  
Signature de la personne  
ressource :**

**Contact Signed - Signé**

**D.G. Verification/  
Vérification par le D.E. :**

Cathy Sabiston

**D.G. Approved / Approuvé D.E.**

**Date D.G. Verified/  
Date vérifié par le D.E. :**

**Programme :** Controlled Substances and Tobacco Directorate

**ADM Approved/ Approbation  
par le SMA :** Paul Glover  
(946-6701)

**Branch/ Direction générale :** HECS/SESC

**Department/ Ministère :** Health Canada / Santé Canada

# QUESTION PERIOD NOTE NOTE POUR LA PÉRIODE DE QUESTIONS

Date:	January 14, 2011
Classification:	HECS PROTECTED - SESC PROTÉGÉ

## SUBJECT - SUJET

English:

**DRUGS - SALVIA DIVINORUM**

Français:

**DROGUES - SALVIA DIVINORUM**

## SYNOPSIS - SOMMAIRE

English:

Media interest in Salvia divinorum is recurrent. Questions around this substance generally focus on its legality. Recently, a number of media reports have commented on a YouTube video which reportedly shows the young ~~Hollywood~~ celebrity Miley Cyrus smoking Salvia divinorum. There have also been several reports from scientific and media sources, indicating that Salvia divinorum has the potential for abuse, and is used by adolescents and young adults for its hallucinogenic properties.

*Shld refer to surveillance info*

*fix*

*HC has evidence show secret that*

## ANTICIPATED QUESTION - QUESTION PRÉVUE

English:

What is Health Canada doing to protect <sup>young</sup> Canadians from the potential adverse effects associated with the use of Salvia divinorum?

Français:

Quelles mesures Santé Canada prend-il pour protéger les Canadiens contre les effets indésirables possibles liés à l'utilisation de la Salvia divinorum?

Why?  
to protect Canadian youth

English:

- Health Canada is proposing to regulate ~~both Salvia and its main active ingredient salvinorin A~~ under Schedule III to the Controlled Drugs and Substances Act (CDSA).
- In ~~February 2011~~, Health Canada <sup>has</sup> published a Notice to Interested Parties in Canada Gazette, Part I, The ~~NOI~~ is to ~~intended to~~ give Canadians the opportunity to provide comments on the proposal to regulate ~~these two~~ Salvia substances.
- The inclusion of Salvia in ~~Schedule III to the CDSA~~ <sup>regulation</sup> will make possession, trafficking, importation, exportation, and production (~~cultivation~~) illegal unless authorized by regulation.

Français:

Add to background [ W The regulation of Salvia, ~~will enable~~ law enforcement ~~to be able to~~ will be able to take action against ~~suspected~~ illegal activities involving this substance.

BACKGROUND - CONTEXTE

English:

BACKGROUND / CONTEXTE

Salvia divinorum (S. divinorum) is a species of sage belonging to the mint family. Some street names for S. divinorum include: Sally D, Lady Sally, Maria pastora, diviner's sage, magic mint, and puff. Certain websites are also promoting the use of S. divinorum as a "legal" alternative to street drugs.

Both the plant S. divinorum and its main active ingredient salvinorin A are known to have physical and mental effects which are often described as unpleasant, including:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter

③ Reg sub = no possess drug & law enf can take action

② Recent surveys indicate ~~and~~ youth are trying this substance which <sup>is bad</sup> is dangerous to their health.



- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

International Control of *S. divinorum*

Neither *Salvia divinorum* nor its main active ingredient salvinorin A are listed under the United Nations Drug Control Conventions; as a result, they do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions. The move to include *Salvia divinorum* and salvinorin A in Schedule III to the CDSA is consistent with actions taken by several countries (e.g. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Some individual U.S. states have also implemented laws restricting their use, sale and/or distribution.

Current Situation in Canada

Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted, namely:

- International requirements and trends in control and/or scheduling;
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- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada recently concluded its assessment of *S. divinorum* and its main active ingredient salvinorin A against the aforementioned factors and now proposes to include both substances in Schedule III to the CDSA.

The plant *Salvia divinorum* is not regulated under the *Controlled Drugs and Substances Act* (CDSA) and therefore the plant is not considered to be "banned" nor are activities with it considered to be illegal in Canada. However, as *Salvia divinorum* is a plant with hallucinogenic properties when consumed by humans, it meets the definition of a natural health product (NHP) under the *Natural Health Products Regulations* when marketed as a hallucinogen. To date, Health Canada has not licensed for sale any natural health product which contains *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products containing *Salvia divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

**ATTACHMENTS / PIÈCE(S)-JOINTE(S)**

Contact/Personne ressource : Denis Arsenault/HC-SC/GC/CA	Tel. no./No de tél. 613-957-6828	Approved by/ Approuvé par Paul Glover, ADM (HECS/SESC)	Tel. no./No. de tél. 946-6701
	Mobile/ Cellulaire: 613-296-4239	Title/ Titre:	Mobile/ Cellulaire:
Alternate/ Secondaire: Jocelyn Kula	Telephone/ Téléphone: 613-952-2177		
	Mobile/ Cellulaire: 613-797-2103		

**Date Prepared/Préparé le :** 2010-09-07  
**Prepared by/Préparé par :** Stephanie Chandler **Phone/ No de tél. :** 613-946-0124  
**Office/Bureau :** CSTD - Office of Controlled Substances

**Date Contact Signed/  
Signature de la personne  
ressource :**

Contact Signed - Signé

**D.G. Verification/  
Vérification par le D.E. :**

Cathy Sabiston

D.G. Approved / Approuvé D.E.


**Date D.G. Verified/  
Date vérifié par le D.E. :**

**Programme :** Controlled Substances and Tobacco Directorate

**ADM Approved/ Approbation  
par le SMA :** Paul Glover  
(946-6701)

**Branch/ Direction générale :** HECS/SESC

**Department/ Ministère :** Health Canada / Santé Canada

  
DRAFT V.9

DEPARTMENT OF HEALTH

CONTROLLED DRUGS AND SUBSTANCES ACT

*Notice to interested parties - Proposal regarding the addition of Salvia divinorum and salvinorin A to Schedule III to the Controlled Drugs and Substances Act*

This notice provides interested stakeholders with the opportunity to provide comments on Health Canada's proposal to add the plant *Salvia divinorum* (*S. divinorum*) and its main active ingredient salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA). Stakeholders may also identify themselves for inclusion in any future consultation.

*S. divinorum* is a species of sage belonging to the mint family. Its leaves are generally chewed or smoked to obtain psychotropic effects. While uncertainty remains surrounding the health risks of *S. divinorum*, known effects are reported to be short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant. Neither *S. divinorum* nor salvinorin A are currently included in any of the Schedules to the CDSA.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. *S. divinorum* is widely touted as a "legal" hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs.<sup>1</sup> Results from the *Canadian Alcohol and Drug Use Monitoring Survey* (CADUMS) reveal that, in 2009, 1.6% of Canadians aged 15 years and older reported having used *S. divinorum* at least once in their lifetime, and that youth aged 15-24 were much more likely to have used it than adults aged 25 years and older. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *S. divinorum* in the past year. Moreover, the *2009 Ontario Student Drug Use and Health Survey* (OSDUHS) indicated that 5.4% of Ontario students in grades 7-12 reported ever using *S. divinorum* and 4.4% of these students reported using this substance in the past year. Given its unknown effects and pharmacological similarity to other substances included in Schedule III to the CDSA such as lysergic acid diethylamide (LSD) and psilocybin, Health Canada is concerned that the ready availability and use of *S. divinorum* poses a risk to the health and safety of Canadians, particularly youth.

While *S. divinorum* and salvinorin A are not currently included in any of the United Nations Drug Control Conventions, a number of countries have chosen to regulate one or both as controlled substances. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden have all placed controls on the import and/or sale of *S. divinorum*

---

<sup>1</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.

and/or salvinorin A. Some American states have also implemented laws restricting their use, sale and/or distribution.

Including these substances within Schedule III to the CDSA would prohibit: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation). The regulation of *S. divinorum* and salvinorin A under the CDSA will also enable law enforcement agencies to take action against suspected illegal activities involving these substances.

As this action is not intended to interfere with the use and availability of *S. divinorum* and/or salvinorin A for legitimate medical, scientific or industrial purposes, Health Canada is seeking information from stakeholders on whether there are any such uses in Canada. Information received in response to this notice will be instrumental in determining appropriate regulation under the CDSA.

The publication of this notice begins a 30-day comment period. There will be additional opportunities to provide comments as the federal regulatory process progresses.

If you are interested in this process or have comments on this proposal, please contact Stephanie Chandler, Regulatory Policy Division, Office of Controlled Substances, Address Locator: 3503D, 123 Slater St., Ottawa, Ontario, Canada, K1A 1B9, by fax at (613) 946-4224 or by email at [OCS\\_Policy\\_and\\_Regulatory\\_Affairs@hc-sc.gc.ca](mailto:OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca).

Cathy A. Sabiston  
Director General  
Controlled Substances and Tobacco Directorate

Date \_\_\_\_\_

## ÉBAUCHE V.9

MINISTÈRE DE LA SANTÉ

### LOI RÉGLEMENTANT CERTAINES DROGUES ET AUTRES SUBSTANCES

*Avis aux parties intéressées - Proposition concernant l'ajout de Salvia divinorum et de salvinorine A à l'annexe III de la Loi réglementant certaines drogues et autres substances*

Cet avis informe les parties intéressées de la possibilité de commenter la proposition de Santé Canada d'ajouter la plante *Salvia divinorum* (*S. divinorum*) et son principal ingrédient actif, la salvinorine A, à l'annexe III de la *Loi réglementant certaines drogues et autres substances* (LRCDAS). Les parties intéressées ont aussi l'occasion d'ajouter leur nom pour toute consultation future.

*S. divinorum* est une espèce de sauge appartenant à la famille des menthes. Généralement, ses feuilles sont mâchées ou fumées pour obtenir des effets psychotropes. Alors qu'une incertitude subsiste quant aux risques pour la santé découlant de la consommation de *S. divinorum*, les effets de cette consommation sont connus pour être brefs et comprennent des hallucinations, une dysphorie, des expériences hors du corps, l'inconscience et une perte de mémoire à court terme. Les effets, qui varient d'une personne à l'autre, sont également souvent décrits comme déplaisants. Ni la *S. divinorum* ni la salvinorine A ne sont incluses dans les annexes de la LRCDAS.

extra-corporel

actuellement (?) *yes*

Des rapports ont récemment été publiés, indiquant que des adolescents et des jeunes adultes canadiens consomment de la *S. divinorum* pour sa capacité à produire des hallucinations. *S. divinorum* est largement vantée comme un hallucinogène "légal" sur Internet et a aussi été signalée comme l'un des produits à base d'herbes médicinales les plus courants utilisés comme option/aux drogues illicites.<sup>1</sup> Les conclusions tirées de l'*Enquête de surveillance canadienne de la consommation d'alcool et de drogues* (ESCCAD) révèlent que, en 2009, 1,6 % des Canadiens âgés de 15 ans ou plus ont déclaré avoir consommé de la *S. divinorum* au moins une fois dans leur vie, et que les jeunes âgés de 15 à 24 ans étaient beaucoup plus nombreux à en avoir consommé que les adultes âgés de 25 ans ou plus. Les résultats de l'*Enquête sur le tabagisme chez les jeunes* de 2008-2009 au Canada montrent également que 5 % des jeunes de 15 ans ont consommé de la *S. divinorum* au cours de la dernière année. De plus, le *Sondage sur la consommation de drogues et la santé des élèves de l'Ontario* (SCDSEO) de 2009 indique que

alternative

<sup>1</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. Oct 2005, vol. 39, no<sup>o</sup>10, pp. 1634-1639.

5,4 % des élèves de l'Ontario des classes scolaires 7 à 12 ont déclaré avoir déjà consommé de la *S. divinorum* et que 4,4 % de ces élèves ont indiqué avoir consommé cette substance au cours de la dernière année. Étant donné ses effets inconnus, ainsi que sa similarité pharmacologique avec d'autres substances comprises dans l'annexe III de la LRCDas, comme l'acide lysergique diéthylamide (LSD) et la psilocybine, Santé Canada craint que la disponibilité immédiate et la consommation de *S. divinorum* ne posent un risque pour la santé et la sécurité des Canadiens, en particulier pour celles des jeunes.

Alors que la *S. divinorum* et la salvinorine A ne sont actuellement comprises dans aucune des Conventions de l'ONU sur le contrôle des drogues, de nombreux pays ont choisi de réglementer une de ces substances, ou les deux, comme substance contrôlée. L'Australie, la Belgique, le designé Danemark, la Finlande, l'Allemagne, l'Italie, le Japon, la Corée du Sud, l'Espagne et la Suède ont tous établi des contrôles sur les importations ou la vente, ou les deux, de *S. divinorum* et/ou de salvinorine A. Certains États américains ont aussi mis en oeuvre des lois restreignant son utilisation, sa vente et/ou sa distribution.

Le fait d'ajouter ces substances à l'annexe III de la LRCDas en interdirait la possession, le commerce, la possession aux fins de commerce, l'importation, l'exportation, la possession aux fins d'exportation et la production (ou la culture). La réglementation de la *S. divinorum* et de la salvinorine A conformément à la LRCDas permettrait également aux organismes d'application de la loi de prendre des mesures contre les activités illégales présumées liées à ces substances.

Étant donné que cette mesure ne vise pas à interférer avec l'utilisation et la disponibilité de la *S. divinorum* et/ou de la salvinorine A à des fins médicales, scientifiques ou industrielles légitimes, Santé Canada sollicite de l'information aux <sup>parties</sup> parties intéressées sur les possibilités de ces types d'utilisation au Canada. L'information reçue en réponse à cet avis sera déterminante dans la rédaction d'un règlement approprié conformément à la LRCDas.


La publication de cet avis entame une période de commentaires de 30 jours. Il y aura des occasions supplémentaires de fournir des commentaires au fur et à mesure que progresse le processus de réglementation fédéral.

Si vous êtes intéressé par ce processus ou que vous avez des commentaires sur cette proposition, veuillez communiquer avec Stephanie Chandler de la Division de la politique réglementaire, du Bureau des substances contrôlées, situé au : 3503D, 123, rue Slater, Ottawa (Ontario), Canada, K1A 1B9, par télécopieur au (613) 946-4224 ou par courriel au [OCS\\_Policy\\_and\\_Regulatory\\_Affairs@hc-sc.gc.ca](mailto:OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca).

Cathy A. Sabiston  
Directrice générale  
Direction des substances contrôlées et de la lutte au tabagisme

Date \_\_\_\_\_



**Re: Revised Salvia Media Lines**   
Christine Roush to: Stephanie Chandler

2011-01-17 01:29 PM

History: This message has been forwarded.

Stephanie - I will try and look at them before my 3 to 5pm meeting today. I'm dealing with an urgent MO request at the moment, so no guarantees I'll be able to send them back to you today. If not, then early tomorrow am.

Christine Roush  
Senior Communications Advisor/

Stephanie Chandler Hi Christine, Just wondering what sort of timeli... 2011-01-17 01:13:56 PM

From: Stephanie Chandler/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Cc: Jocelyn Kula/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, Nicole Prentice/HC-SC/GC/CA@HWC  
Date: 2011-01-17 01:13 PM  
Subject: Re: Revised Salvia Media Lines

Hi Christine,

Just wondering what sort of timelines you have regarding reviewing the Salvia media lines. The DGO is still looking to see the entire Salvia package (MLs, NOI and QP Note) today. Would it be possible to have the media lines today given the lack of timing info for the news release at this point?

Thanks,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

Jocelyn Kula Hi Christine, The notion of a News Release cam... 2011-01-14 04:30:38 PM

From: Jocelyn Kula/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Cc: Stephanie Chandler/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, Nicole Prentice/HC-SC/GC/CA@HWC  
Date: 2011-01-14 04:30 PM  
Subject: Re: Revised Salvia Media Lines

Hi Christine,

The notion of a News Release came out of left field, as I have to be honest and say that I don't think we have ever done an NR to go with an NOI. NOIs are usually pretty low key affair. In this regard, am not sure what further guidance we can provide at this point other than perhaps you can start drafting

something in line with the key messages in the media lines. Not sure about the reference to timing as it didn't really come up in MO this morning.....Paul just confirmed there were no issues with us proceeding to do the NOI and that Cathy will be signing off/ MO did not need to see the text etc. I think we actually say January for the NOI in our last 3 month report, so maybe we should look at what publication cut off dates match with that timeframe, ie., late Jan/ early Feb and work backwards from there?

Jocelyn

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

---

Christine Roush      Stephanie - I'm told that at today's briefing MO a...      2011-01-14 04:12:23 PM

From: Christine Roush/HC-SC/GC/CA  
To: Stephanie Chandler/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Nicole Prentice/HC-SC/GC/CA@HWC  
Date: 2011-01-14 04:12 PM  
Subject: Re: Revised Salvia Media Lines

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**Stephanie** - I'm told that at today's briefing MO asked for a News Release to announce the NOI, so I'll need to discuss this with you before working on the media lines. I'm also told that this won't be announced for another couple of weeks. So I don't think I'll be able to send the MLs to you by Monday. Let me know if you have any more information on the request to do a NR. thx.

Christine Roush  
Senior Communications Advisor/

---

Stephanie Chandler      Hi Christine, Please find attached the revised...      2011-01-14 01:51:41 PM

From: Stephanie Chandler/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Cc: Nicole Prentice/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC  
Date: 2011-01-14 01:51 PM  
Subject: Revised Salvia Media Lines

Hi Christine,

Please find attached the revised Salvia media lines which have been approved by OCS. CSTD DGO has requested that the media lines, along with the revised NOI and QP Note be sent back to the DGO on Monday. Please advise as to how you would like to handle this step in the approval process so that all the Salvia products can reach Cathy together.

[attachment "Salvia Media Lines\_Jan 14 2011 (2).doc" deleted by Christine Roush/HC-SC/GC/CA]

Thanks,

Stephanie



Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: [stephanie.chandler@hc-sc.gc.ca](mailto:stephanie.chandler@hc-sc.gc.ca)

**DRAFT V.8**

DEPARTMENT OF HEALTH

CONTROLLED DRUGS AND SUBSTANCES ACT

*Notice to interested parties - Proposal regarding the addition of Salvia divinorum and salvinorin A to Schedule III to the Controlled Drugs and Substances Act*

This notice provides interested stakeholders with the opportunity to provide comments on Health Canada's proposal to add the plant *Salvia divinorum* (*S. divinorum*) and its active ingredient salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA). Stakeholders may also identify themselves for inclusion in any future consultation.

*S. divinorum* is a species of sage belonging to the mint family. Its leaves are generally chewed or smoked to obtain psychotropic effects. While uncertainty remains surrounding the health risks of *S. divinorum*, known effects are reported to be short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant. Neither *S. divinorum* nor salvinorin A are currently included in any of the Schedules to the CDSA.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. *S. divinorum* is widely touted as a "legal" hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs.<sup>1</sup> Results from the *Canadian Alcohol and Drug Use Monitoring Survey* (CADUMS) reveal that, in 2009, 1.6% of Canadians aged 15 years and older reported having used *S. divinorum* at least once in their lifetime, and that youth aged 15-24 were much more likely to have used it than adults aged 25 years and older. The results from the Canadian 2008-2009 *Youth Smoking Survey* also show that 5% of 15 year olds have used *S. divinorum* in the past year. Moreover, the 2009 *Ontario Student Drug Use and Health Survey* (OSDUHS) indicated that 5.4% of Ontario students in grades 7-12 reported ever using *S. divinorum* and 4.4% of these students reported using this substance in the past year. Given its unknown effects and pharmacological similarity to other substances included in Schedule III to the CDSA such as lysergic acid diethylamide (LSD) and psilocybin, Health Canada is concerned that the ready availability and use of *S. divinorum* poses a risk to the health and safety of Canadians, particularly youth.

While *S. divinorum* and salvinorin A are not currently included in any of the United Nations Drug Control Conventions, a number of countries have chosen to regulate one or both as controlled substances. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden have all placed controls on the import and/or sale of *S. divinorum*

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<sup>1</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.

and/or salvinorin A. Some American states have also implemented laws restricting their use, sale and/or distribution.

Including these substances within Schedule III to the CDSA would prohibit: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation). The regulation of *S. divinorum* and salvinorin A under the CDSA will enable law enforcement agencies to take action against suspected illegal activities involving these substances.

As this action is not intended to interfere with the use and availability of *S. divinorum* and/or salvinorin A for legitimate medical, scientific or industrial purposes, Health Canada is seeking information from stakeholders on whether there are any such uses in Canada. Information received in response to this notice will be instrumental in determining appropriate regulation under the CDSA.

The publication of this notice begins a 30-day comment period. There will be additional opportunities to provide comments as the federal regulatory process progresses.

If you are interested in this process or have comments on this proposal, please contact Stephanie Chandler, Regulatory Policy Division, Office of Controlled Substances, Address Locator: 3503D, 123 Slater St., Ottawa, Ontario, Canada, K1A 1B9, by fax at (613) 946-4224 or by email at [OCS\\_Policy\\_and\\_Regulatory\\_Affairs@hc-sc.gc.ca](mailto:OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca).

Cathy A. Sabiston  
Director General  
Controlled Substances and Tobacco Directorate

Date \_\_\_\_\_



**Re: Fw: Revised Salvia NOI and QP Note**   
Stephanie Szick to: Jocelyn Kula  
Cc: CSTD-DGO, Denis Arsenault, Stephanie Chandler

2011-01-18 11:42 AM

Thanks Jocelyn

I will bring to Cathy's attention with a note that comms products will follow under separate cover from Christine Roush (media lines, news release)

Depending on how the day proceeds, she may not have reviewed these in time for your bilat - will do our best to get them in front of her.

Stephanie Szick  
Director General's Office / Bureau du directeur général  
Controlled Substances & Tobacco Directorate (CSTD) /  
Direction des substances contrôlées et de la lutte au tabagisme (DSCLT)  
Health Canada / Santé Canada  
Tel / Tél: (613) 948-8651

Jocelyn Kula

Per discussion. I will cc you on a message to C...

2011-01-18 11:02:09 AM

From: Jocelyn Kula/HC-SC/GC/CA  
To: stephanie.szick@hc-sc.gc.ca  
Cc: CSTD-DGO, Stephanie Chandler/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2011-01-18 11:02 AM  
Subject: Fw: Revised Salvia NOI and QP Note

Per discussion. I will cc you on a message to Christine re media lines and NR.


Jocelyn

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2011-01-18 10:56 AM -----

From: Stephanie Chandler/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2011-01-17 03:21 PM  
Subject: Revised Salvia NOI and QP Note

Hi Jocelyn,

I have revised the Salvia NOI and QP Note (available here: ) as requested. Hope to get the media lines back from Christine Roush if not today then early tomorrow.

[attachment "DRAFT Salvia NOI\_Jan 14.wpd" deleted by Stephanie Szick/HC-SC/GC/CA]

Regards,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: [stephanie.chandler@hc-sc.gc.ca](mailto:stephanie.chandler@hc-sc.gc.ca)

DRAFT 15  
January 18, 2011

**Media Lines**  
*Salvia divinorum*

**Issue**

There is ongoing media interest regarding the availability of *Salvia divinorum* in Canada as well as reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has concluded that *Salvia divinorum* and its main active ingredient salvinorin A should be regulated under the *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth.

**Key Messages:**

- Health Canada is proposing to regulate both *Salvia divinorum* and its main active ingredient salvinorin A under Schedule III to the *Controlled Drugs and Substances Act* (CDSA).
- As a first step, Health Canada has published a *Notice to Interested Parties* (NOI) in *Canada Gazette, Part I* on January 29, 2011. The NOI is intended to give Canadians the opportunity to provide comments on the proposal to regulate *Salvia divinorum* and salvinorin A as controlled substances.
- The inclusion of *Salvia divinorum* and salvinorin A in Schedule III to the CDSA will make possession, trafficking, importation, exportation, and production (or cultivation) illegal unless authorized by regulation.

**Supplementary Messages:**

- Canadians should not use products containing *Salvia divinorum* and/or salvinorin A because very little is known about these substances and their potential effects on the brain and body.
- The plant *Salvia divinorum* is not regulated under the CDSA and therefore it is not considered to be "banned", nor are activities with it considered to be illegal in Canada.
- However, as *Salvia divinorum* is a plant with hallucinogenic properties when consumed by humans, it meets the definition of a natural health product (NHP) under the *Natural Health Products Regulations* when marketed as a hallucinogen.
- To date, Health Canada has not authorized for sale any natural health products which contain *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products containing *Salvia divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

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## Questions and Answers:

### Q1 – What is involved in regulating *Salvia divinorum* as a controlled substance and what stage is it at?

A1 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada recently concluded its assessment of *Salvia divinorum* and salvinorin A against the aforementioned factors and proposes to include both substances in Schedule III to the CDSA. The regulation of these products will reduce the potential risks to the health and safety of Canadians associated with their ready availability, with their increased use and their unknown effects. The scheduling of *Salvia divinorum* and salvinorin A will also eliminate the current perception that these substances are a safe alternative to other illegal drugs.

### Q2 – Are *Salvia divinorum* and/or salvinorin A controlled internationally? How are these substances regulated in other countries?

A2 - Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions; as a result, they do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

The move to include *Salvia divinorum* and salvinorin A in Schedule III to the CDSA is consistent with actions taken by several countries (e.g., Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Some individual U.S. states have implemented laws restricting their use, sale and/or distribution.

### Q3 – Is there any research on the use of *Salvia divinorum* in Canada?

A3 - Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *Salvia divinorum* at least once in their lifetime, and that youth aged 15-24 were much more likely to have used it than adults aged 25 years and older. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *Salvia divinorum* in the past year. The 2009 *Ontario Student Drug Use and Health Survey (OSDUHS)* indicated that 5.4% of Ontario

**Deleted:** Q1 – Are *Salvia divinorum* and/or salvinorin A controlled internationally? How are these substances regulated in other countries?¶

¶ A1 - Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions; as a result, they do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.¶

¶ The move to include *Salvia divinorum* and salvinorin A in Schedule III to the CDSA is consistent with actions taken by several countries (e.g. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Some individual U.S. states have implemented laws restricting their use, sale and/or distribution.¶

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students in grades 7-12 reported ever using *Salvia divinorum* and 4.4% of these students reported using this substance in the past year.

**Q4 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why isn't it illegal?**

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**A4 – Health Canada proposes to include *Salvia divinorum* and salvinorin A under Schedule III to the CDSA. Further to the regulation of these substances under the CDSA, the following activities may be prohibited unless authorized by regulation: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation). Law enforcement agencies will then be able to take action against suspected illegal activities involving these substances.**

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In the interim, as *Salvia divinorum* is a plant with hallucinogenic properties, it meets the definition of a natural health product under the *Natural Health Products Regulations* (NHPR) when marketed as a hallucinogen. The sale of such unauthorized products containing *Salvia divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*.

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**Q5 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

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**A5 – Once *Salvia divinorum* and salvinorin A are included in Schedule III to the CDSA, law enforcement will be able to take appropriate action in response to suspected illegal activities with these substances.**

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In the interim, *S. divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. Complaints about the illegal sale of drugs containing *Salvia divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

**Q6 - Has Health Canada issued any kind of warning to Canadians about *Salvia divinorum*?**

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**A6 - Health Canada is developing an *It's Your Health* article about *Salvia divinorum* to help inform the general public about the risks associated with the use of this plant.**

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**Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

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If pressed on whether Health Canada has issued any kind of warning to Canadians about *Salvia divinorum*¶

¶  
A - Health Canada is developing an *It's Your Health* article

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The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

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The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

Data from the 2008-2009 Youth Smoking Survey indicates that:

- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;
- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year; and
- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using Salvia in their lifetime (0.2% in the past year); and
- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that:

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;
- 5.4% of students (grades 7-12) ever used *Salvia divinorum*; and
- the use of *Salvia divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

**Prepared by:** Stephanie Chandler and Denis Arseneault, OCS, CSTD

**Input by:** Lisa Mackay IYH/PACCB, Suzanne Desjardins HECSB/ODARS, Hanan Abramovici HECSB/ODARS, Bruna Brands HECSB/ODARS, Jocelyn Kula, HECSB/OCS, Robin Marles HPFB/NHPD, Maggie Graham HPFB/NHPD, Stephanie Collins HPFB/NHPD, Mano Murty HPFB/MHPD, Robert Leitch HPFB/MHPD, Shahid Perwaiz HPFB/MHPD, Collin Pinto, HPFB/HPFBI

**Approved by:**

Robin Marles, Director, Bureau of Clinical Trials, NHPD (pending)  
Lindsay Blaney, Director, Policy and Regulatory Affairs, NHPD (pending)  
Duc Vu, Director, Marketed Biologics, Biotechnology and Natural Health Products  
Bureau, MHPD (pending)  
Kim Dayman-Rutkas, Director, HPFBI (pending)  
Diane Allan, Director, OCS, CSTD, HECS (approved, Sept 29, 2010)  
Suzanne Desjardins, Director, ODARS, CSTD, HECS approved, Sept 30, 2010)  
Cathy Sabiston, DG, CSTD, HECS (pending)  
Chris Turner, DG, MHPD (pending)  
Nancy Richards, DG, NHPD (pending)  
Diana Dowthwaite, DG, HPFBI (pending)  
Ken Polk, Communications Executive, HPFB (pending)  
Jean Tessier, Senior Media Relations, PACCB (pending)

Warren Braun, Director, Strategic Communications, PACCB (pending)

Peter Yendall, Director, Public Affairs, PACCB (pending)

HECS Legal (pending)

HPFB Legal (pending)

Paul Glover, ADM, HECSB (pending)

Meena Ballantyne, ADM, HPFB (pending)

Anne Lamar, ADM, PACCB (pending)

DMO (pending)

MO (pending)

PCO (pending)

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The inclusion of <i>Salvia divinorum</i> and salvinorin A in Schedule III to the CDSA will reduce the potential health and safety risks associated with the ready availability, increased use and unknown effects of these substances. Further to the regulation of these substances under the CDSA, the following activities would be prohibited unless authorized by regulation: possession, trafficking, possession for the purposes of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation).		
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Health Canada will inform stakeholders of its proposal by publishing a <i>Notice to Interested Parties</i> (NOI) in <i>Canada Gazette</i> , Part I. The NOI will provide stakeholders and other interested parties with the opportunity to provide comments on the proposal to regulate <i>Salvia divinorum</i> and salvinorin A as controlled substances.		
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, and their impact on physical and mental functions		
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Nevertheless, when specifically marketed for its hallucinogenic properties, <i>Salvia divinorum</i> meets the definition of a natural health product under the <i>Natural Health Products Regulations</i> .		
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**QUESTION PERIOD NOTE**  
**NOTE POUR LA PÉRIODE DE QUESTIONS**

Date:	January 18, 2011
Classification :	HECS PROTECTED - SESC PROTÉGÉ

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**SUBJECT - SUJET**

English:

**DRUGS - SALVIA DIVINORUM**

Français:

**DROGUES - SALVIA DIVINORUM**

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**SYNOPSIS - SOMMAIRE**

English:

Media interest in Salvia divinorum is recurrent. Questions around this substance generally focus on its legality. Recently, a number of media reports have commented on a YouTube video which reportedly shows the young celebrity Miley Cyrus smoking Salvia divinorum. Canadian surveillance data indicates that this substance is being used by adolescents and young adults for its hallucinogenic properties, and there have also been several reports from scientific sources indicating that Salvia divinorum has the potential for abuse.

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**ANTICIPATED QUESTION - QUESTION PRÉVUE**

English:

What is Health Canada doing to protect young Canadians from the potential adverse effects associated with the use of Salvia divinorum?

Français:

Quelles mesures Santé Canada prend-il pour protéger les jeunes Canadiens contre les effets indésirables possibles liés à l'utilisation de la Salvia divinorum?

---

English:

- Health Canada is proposing to regulate Salvia under the *Controlled Drugs and Substances Act* in order to protect the health and safety of Canadians, particularly youth.
- Health Canada has published a *Notice to Interested Parties* in *Canada Gazette*, Part I, to give Canadians the opportunity to provide comments on its proposal to regulate Salvia.
- The regulation of Salvia will make possession, trafficking, importation, exportation, and production illegal unless authorized by regulation.

Français:

---

## **BACKGROUND - CONTEXTE**

English:

### **BACKGROUND / CONTEXTE**

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, diviner's sage, magic mint, and puff. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs.

Both the plant *S. divinorum* and its main active ingredient salvinorin A are known to have physical and mental effects which are often described as unpleasant, including:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination

- slurred speech and awkward sentence patterns

Recent surveys indicate that Canadian youth are trying this substance which could be dangerous to their health. Results from the *Canadian Alcohol and Drug Use Monitoring Survey* (CADUMS) reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *Salvia divinorum* at least once in their lifetime, and that youth aged 15-24 were much more likely to have used it than adults aged 25 years and older. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *Salvia divinorum* in the past year. The *2009 Ontario Student Drug Use and Health Survey* (OSDUHS) indicated that 5.4% of Ontario students in grades 7-12 reported ever using *Salvia divinorum* and 4.4% of these students reported using this substance in the past year.

#### International Control of *S. divinorum*

Neither *Salvia divinorum* nor its main active ingredient salvinorin A are listed under the United Nations Drug Control Conventions; as a result, they do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions. The move to include *Salvia divinorum* and salvinorin A in Schedule III to the CDSA is consistent with actions taken by several countries (e.g. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Some individual U.S. states have also implemented laws restricting their use, sale and/or distribution.

#### Current Situation in Canada

Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted, namely:

- International requirements and trends in control and/or scheduling;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e. therapeutic, scientific, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada recently concluded its assessment of *S. divinorum* and its main active ingredient salvinorin A against the aforementioned factors and now proposes to include both substances in Schedule III to the CDSA.

The regulation of *Salvia divinorum* will allow law enforcement to take action against illegal activities involving this substance. The possession, trafficking, importation, exportation and production of *Salvia divinorum* and salvinorin A will be illegal unless authorized by regulation.

The plant *Salvia divinorum* is not currently regulated under the *Controlled Drugs and Substances Act* (CDSA) and therefore the plant is not considered to be "banned" nor are activities with it considered to be illegal in Canada. However, as *Salvia divinorum* is a plant with hallucinogenic properties when consumed by humans, it meets the definition of a natural health product (NHP) under the *Natural Health Products Regulations* when marketed as a hallucinogen. To date, Health Canada has not licensed for sale any natural health product which contains *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products containing *Salvia divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

ATTACHMENTS / PIÈCE(S)-JOINTE(S)

Contact/Personne ressource : Denis Arsenault/HC-SC/GC/CA	Tel. no./No de tél. 613-957-6828	Approved by/ Approuvé par Paul Glover, ADM (HECS/SESC)	Tel. no./No. de tél. 946-6701
	Mobile/ Cellulaire: 613-296-4239	Title/ Titre:	Mobile/ Cellulaire:
Alternate/ Secondaire: Jocelyn Kula	Telephone/ Téléphone: 613-952-2177		
	Mobile/ Cellulaire: 613-797-2103		

**Date Prepared/Préparé le :** 2010-09-07

**Prepared by/Préparé par :** Stephanie Chandler **Phone/ No de tél. :** 613-946-0124

**Office/Bureau :** CSTD - Office of Controlled Substances

**Date Contact Signed/  
Signature de la personne  
ressource :**

**Contact Signed - Signé**

**D.G. Verification/  
Vérification par le D.E. :**

Cathy Sabiston

**D.G. Approved / Approuvé D.E.**

**Date D.G. Verified/  
Date vérifié par le D.E. :**

**Programme :** Controlled Substances and Tobacco Directorate

**ADM Approved/ Approbation  
par le SMA :** Paul Glover  
(946-6701)

**Branch/ Direction générale :** HECS/SESC

**Department/ Ministère :** Health Canada / Santé Canada



**Re: Salvia NOI**

Christine Roush to: Stephanie Chandler

2011-01-18 03:12 PM

Cc: Denis Arsenault, Jocelyn Kula, Nicole Prentice, Jeannine Ritchot,  
Dave Stephens

Thanks for the copy of the NOI. I am just reviewing the MLs now - and these can go forward to Cathy for her approval after I finish my review, but the NR will have to wait until after I have revised the medical marihuana comms products, since the NR won't be posted until Friday Jan 28th. I will try and get the NR to you by Thursday, but I need to know if any of your partners, RCMP, etc, will be quoted in the release. I assume you have given your partners a head's up on this? At the same time, Dave Stephens, my Comms Exec., is giving MO a head's up of the posting/NR dates to see if they have any problems with the timing. We will let you know if they do.

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
Health Canada/Santé Canada  
Tel/Tél : (613) 954-0712/Cell: (613) 219-7194  
Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca

Stephanie Chandler Hi Christine, With regards to our earlier conver...

2011-01-18 02:53:10 PM

From: Stephanie Chandler/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Cc: Nicole Prentice/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Denis  
Arsenault/HC-SC/GC/CA@HWC  
Date: 2011-01-18 02:53 PM  
Subject: Salvia NOI

Hi Christine,

With regards to our earlier conversation, I have spoken to Jocelyn who will get in touch with DGO with regards to timelines/priorities. In the mean time, as discussed, we are intending to submit the Salvia NOI on Fri Jan 21st for publication in CGI on Sat. Jan 29th. I have attached the current draft of the NOI below for your information when drafting the NR. I believe this document contains all of the info you will need, however if you do need any additional information, please let me know.

[attachment "DRAFT Salvia NOI\_Jan 18.wpd" deleted by Christine Roush/HC-SC/GC/CA]

Thanks,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada



Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: [stephanie.chandler@hc-sc.gc.ca](mailto:stephanie.chandler@hc-sc.gc.ca)



**Re: Salvia NOI** 

Christine Roush to: Stephanie Chandler  
Cc: Denis Arsenault, Jocelyn Kula, Nicole Prentice

2011-01-18 03:36 PM

History:

This message has been replied to and forwarded.

Hi Stephanie,

I have reviewed the MLs and made some changes in blue. Could you please provide a better answer to the question below -as it currently doesn't answer the question, which is about the process involved in listing - (i.e., we have finished our assessment, and are posting to CG1 for comment - but what comes after this, and how much time is involved and when are we likely to have it listed. Also, could you please update the approval totem at the end of the document listing who needs to approve these lines from HECS and HPFB. Please return them to me by 10:00 am tomorrow for one final review. Thanks.



Salvia Media Lines\_Jan 18 2011 (1).doc

**Q1 – What is involved in regulating *Salvia divinorum* as a controlled substance and what stage is it at?**

A1 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada recently concluded its assessment of *Salvia divinorum* and salvinorin A against the aforementioned factors and proposes to include both substances in Schedule III to the CDSA. The regulation of these products will reduce the potential risks to the health and safety of Canadians associated with their ready availability, with their increased use and their unknown effects. The scheduling of *Salvia divinorum* and salvinorin A will also eliminate the current perception that these substances are a safe alternative to other illegal drugs.

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
Health Canada/Santé Canada  
Tel/Tél : (613) 954-0712/Cell: (613) 219-7194  
Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca

Stephanie Chandler Hi Christine, With regards to our earlier conver...

2011-01-18 02:53:10 PM

From: Stephanie Chandler/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Cc: Nicole Prentice/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Denis  
Arsenault/HC-SC/GC/CA@HWC  
Date: 2011-01-18 02:53 PM  
Subject: Salvia NOI

---

Hi Christine,

With regards to our earlier conversation, I have spoken to Jocelyn who will get in touch with DGO with regards to timelines/priorities. In the mean time, as discussed, we are intending to submit the Salvia NOI on Fri Jan 21st for publication in CGI on Sat. Jan 29th. I have attached the current draft of the NOI below for your information when drafting the NR. I believe this document contains all of the info you will need, however if you do need any additional information, please let me know.

[attachment "DRAFT Salvia NOI\_Jan 18.wpd" deleted by Christine Roush/HC-SC/GC/CA]

Thanks,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
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Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
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E-Mail: stephanie.chandler@hc-sc.gc.ca

DRAFT 15  
January 18, 2011

### Media Lines *Salvia divinorum*

#### Issue

There is ongoing media interest regarding the availability of *Salvia divinorum* in Canada as well as Canadian surveillance data suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has concluded that *Salvia divinorum* and its main active ingredient salvinorin A should be regulated under the *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth.

#### Key Messages:

- Health Canada is proposing to regulate both *Salvia divinorum* and its main active ingredient salvinorin A under Schedule III to the *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth.
- As a first step, Health Canada has published a *Notice to Interested Parties* (NOI) in *Canada Gazette*, Part I on January 29, 2011. The NOI is intended to give Canadians the opportunity to provide comments on the proposal to regulate *Salvia divinorum* and salvinorin A as controlled substances.
- The inclusion of *Salvia divinorum* and salvinorin A in Schedule III to the CDSA will make possession, trafficking, importation, exportation, and production (or cultivation) illegal unless authorized by regulation.

#### Supplementary Messages:

- Canadians should not use products containing *Salvia divinorum* and/or salvinorin A because very little is known about these substances and their potential effects on the brain and body.
- The plant *Salvia divinorum* is not regulated under the CDSA and therefore it is not considered to be "banned", nor are activities with it considered to be illegal in Canada.
- However, as *Salvia divinorum* is a plant with hallucinogenic properties when consumed by humans, it meets the definition of a natural health product (NHP) under the *Natural Health Products Regulations* when marketed as a hallucinogen.
- To date, Health Canada has not authorized for sale any natural health products which contain *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products containing *Salvia divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

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Questions and Answers:

**Q1 – What is involved in regulating *Salvia divinorum* as a controlled substance and what stage is it at?**

A1 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada recently concluded its assessment of *Salvia divinorum* and salvinorin A against the aforementioned factors and proposes to include both substances in Schedule III to the CDSA. The first step in the process of regulating a substance under the CDSA is the publication of a *Notice to Interested Parties* (NOI) in *Canada Gazette*, Part I. Any comments received will be considered during the preparation of a regulatory proposal. There will be additional opportunities for comment as the federal regulatory process progresses.

The regulation of these products will reduce the potential risks to the health and safety of Canadians associated with their ready availability, with their increased use and their unknown effects. The scheduling of *Salvia divinorum* and salvinorin A will also eliminate the current perception that these substances are a safe alternative to other illegal drugs.

**Q2 – Are *Salvia divinorum* and/or salvinorin A controlled internationally? How are these substances regulated in other countries?**

A2 - Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions; as a result, they do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

The move to include *Salvia divinorum* and salvinorin A in Schedule III to the CDSA is consistent with actions taken by several countries (e.g., Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Some individual U.S. states have implemented laws restricting their use, sale and/or distribution.

**Q3 – Is there any research on the use of *Salvia divinorum* in Canada?**

**Deleted:** Q1 – Are *Salvia divinorum* and/or salvinorin A controlled internationally? How are these substances regulated in other countries?¶

A1 - Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions; as a result, they do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.¶

The move to include *Salvia divinorum* and salvinorin A in Schedule III to the CDSA is consistent with actions taken by several countries (e.g. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Some individual U.S. states have implemented laws restricting their use, sale and/or distribution.¶

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A3 - Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *Salvia divinorum* at least once in their lifetime, and that youth aged 15-24 were much more likely to have used it than adults aged 25 years and older. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *Salvia divinorum* in the past year. The 2009 *Ontario Student Drug Use and Health Survey (OSDUHS)* indicated that 5.4% of Ontario students in grades 7-12 reported ever using *Salvia divinorum* and 4.4% of these students reported using this substance in the past year.

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Q4 - If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why isn't it illegal?

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A4 - Health Canada proposes to include *Salvia divinorum* and salvininorin A under Schedule III to the CDSA. Further to the regulation of these substances under the CDSA, the following activities will be illegal unless authorized by regulation: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation). Law enforcement agencies will also be able to take action against suspected illegal activities involving these substances.

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As a plant with hallucinogenic properties, however, *Salvia divinorum* meets the definition of a natural health product under the *Natural Health Products Regulations (NHPR)* when marketed as a hallucinogen. To date, Health Canada has not authorized for sale any natural health products which contain *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products may be subject to compliance and enforcement action under the *Food and Drugs Act*.

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Q5 - What will Health Canada do if it finds products containing *Salvia divinorum* on the market?

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A5 - Once *Salvia divinorum* and salvininorin A are included in Schedule III to the CDSA, law enforcement will be able to take appropriate action in response to suspected illegal activities with these substances.

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Currently however, *Salvia divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. Complaints about the illegal sale of drugs containing *Salvia divinorum* and/or salvininorin A can be referred to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

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If pressed on whether Health Canada has issued any kind of warning to Canadians about *Salvia divinorum*¶

¶ A - Health Canada is developing an It's Your Health article

Q6 - Has Health Canada issued any kind of warning to Canadians about *Salvia divinorum*?

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A6 - Health Canada is developing an *It's Your Health* article about *Salvia divinorum* to help inform the general public about the risks associated with the use of this plant.

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**Background**

unauthorized

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

Data from the 2008-2009 Youth Smoking Survey indicates that:

- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;
- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year; and.
- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using *Salvia* in their lifetime (0.2% in the past year); and
- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that:

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;
- 5.4% of students (grades 7-12) ever used *Salvia divinorum*; and
- the use of *Salvia divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

**Prepared by:** Stephanie Chandler and Denis Arsenault, OCS, CSTD

**Input by:** Lisa Mackay IYH/PACCB, Suzanne Desjardins HECSB/ODARS, Hanan Abramovici HECSB/ODARS, Bruna Brands HECSB/ODARS, Jocelyn Kula, HECSB/OCS, Robin Marles HPFB/NHPD, Maggie Graham HPFB/NHPD, Stephanie Collins HPFB/NHPD, Mano Murty HPFB/MHPD, Robert Leitch HPFB/MHPD, Shahid Perwaiz HPFB/MHPD, Collin Pinto, HPFB/HPFBI

**Approved by:**

Robin Marles, Director, Bureau of Clinical Trials, NHPD (pending)  
Lindsay Blaney, Director, Policy and Regulatory Affairs, NHPD (pending)  
Duc Vu, Director, Marketed Biologics, Biotechnology and Natural Health Products  
Bureau, MHPD (pending)  
Kim Dayman-Rutkas, Director, HPFBI (pending)  
Jocelyn Kula, A/Director, OCS, CSTD, HECS (pending)

**Deleted:** Diane Allan

**Deleted:** approved, Sept 29, 2010

Suzanne Desjardins, Director, ODARS, CSTD, HECS (approved, Sept 30, 2010)  
Cathy Sabiston, DG, CSTD, HECS (pending)  
Chris Turner, DG, MHPD (pending)  
Nancy Richards, DG, NHPD (pending)  
Diana Dowthwaite, DG, HPFBI (pending)  
Ken Polk, Communications Executive, HPFB (pending)  
Jean Tessier, Senior Media Relations, PACCB (pending)  
Warren Braun, Director, Strategic Communications, PACCB (pending)  
Peter Yendall, Director, Public Affairs, PACCB (pending)  
HECS Legal (pending)  
HPFB Legal (pending)  
Paul Glover, ADM, HECSB (pending)  
Meena Ballantyne, ADM, HPFB (pending)  
Anne Lamar, ADM, PACCB (pending)  
DMO (pending)  
MO (pending)  
PCO (pending)



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The inclusion of <i>Salvia divinorum</i> and salvinorin A in Schedule III to the CDSA will reduce the potential health and safety risks associated with the ready availability, increased use and unknown effects of these substances. Further to the regulation of these substances under the CDSA, the following activities would be prohibited unless authorized by regulation: possession, trafficking, possession for the purposes of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation).		
<b>Page 1: [2] Deleted</b>	<b>STCHANDL</b>	<b>2011-01-14 10:30:00 AM</b>
Health Canada will inform stakeholders of its proposal by publishing a <i>Notice to Interested Parties</i> (NOI) in <i>Canada Gazette</i> , Part I. The NOI will provide stakeholders and other interested parties with the opportunity to provide comments on the proposal to regulate <i>Salvia divinorum</i> and salvinorin A as controlled substances.		
<b>Page 1: [3] Deleted</b>	<b>STCHANDL</b>	<b>2011-01-14 10:31:00 AM</b>
, and their impact on physical and mental functions		
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Nevertheless, when specifically marketed for its hallucinogenic properties, <i>Salvia divinorum</i> meets the definition of a natural health product under the <i>Natural Health Products Regulations</i> .		
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**Publication of Salvia NOI on Jan 29 - Items for review**  
Stephanie Chandler to: Stephanie Chandler

2011-01-18 04:34 PM

Hi Denis,

Jocelyn has received confirmation from DGO that we are to publish the Salvia NOI in CG1 on Jan 29th. Therefore, we need to submit our package to Canada Gazette on Friday, Jan 21. Jocelyn would like you to revise the three month report to indicate this accordingly.

There are a number of documents which I need you to review:

**For approval before Jan 21:**

Letter to Canada Gazette requesting insertion:



Salvia NOI Transmittal Letter.wpd

Request for Insertion form:

-Currently missing some administrative info, but I will provide to you once I have completed it.

I am awaiting approval of the NOI so that it can be sent for translation. Lisa Marie will also make a diskette with both versions on it.

**For approval before Jan 29:**

The list of stakeholders which I propose we send the NOI notification to:



List of Salvia Stakeholders v.1.doc

English notification to stakeholders:



Stakeholder notification of NOI Dec 23 2010 EN.wpd

This notification also needs to be translated to French. HPFB will also need to approve as NHPD will be sending the notification to their stakeholders as well. My original thinking was that we would use this document to notify our stakeholders once the NOI was published, however a recent email from Christine suggests that we should be giving some groups (such as the RCMP?) a heads-up prior to publication. If you agree, we should discuss who should be contacted.

Also, we have not yet discussed any web postings (on the Health Canada site). Is one necessary? Would this consist of the news release? Is there anything I should be preparing?

(You also have not yet approved the Jan 6th version of the Salvia IAS, but I don't believe that is a priority at this point.)

I am at the conference tomorrow in the AM, but happy to discuss in the afternoon.

Thanks,

Stephanie

Stephanie Chandler

Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: [stephanie.chandler@hc-sc.gc.ca](mailto:stephanie.chandler@hc-sc.gc.ca)

## **Salvia divinorum NOI Stakeholders**

### **Groups**

CSTD - RCMP  
CSTD - Police  
~~CSTD - Class A Precursor Licensed Dealers~~  
~~CSTD - Class B Precursor Licensed Dealers - SPIC~~  
~~CSTD - Controlled Substances Licensed Dealers - OPIC~~  
CSTD - RPD - Deans of Canadian Universities  
CSTD - RPD - P/T Licensing Authorities - Registrars of Pharmacy  
CSTD - RPD - P/T Licensing Authorities - Registrars of Physicians and Surgeons  
CSTD - RPD - P/T Licensing Authorities - Registrars of Dental Surgeons  
CSTD - RPD - P/T Licensing Authorities - Registrars of Veterinary Medicine  
CSTD - RPD - P/T Licensing Authorities - Registrars of Naturopathy  
CSTD - RPD - Professional Associations - Pharmacy Associations  
CSTD - RPD - Professional Associations - Medical Associations  
CSTD - RPD - Professional Associations - Dental Associations  
CSTD - RPD - Professional Associations - Veterinary Associations  
CSTD - RPD - P/T Deputy Ministers of Health

### **Individual Associations/ Agencies**

Canadian Psychiatric Association  
Canadian Association of Naturopathic Doctors  
Canadian Public Health Association

Natural Health Products Manufacturers of Canada

CSTD - RPD - Other Government Departments - Canada Border Services Agency (3  
Contacts)

CSTD - RPD - Other Government Departments - Public Safety (5 Contacts)

Canada Border Services Agency - OGD Programs Unit (3 Contacts)

Canadian Mental Health Association  
Canadian Centre on Substance Abuse  
Canadian Homeopathic Pharmaceutical Association  
Centre for Addiction and Mental Health (6 Contacts)  
Public Health Agency of Canada (Johnson, Mary - Manager)  
Public Health Agency of Canada (Vieira, Gaby - Policy Analyst)  
Public Health Agency of Canada (Director General's Office, Palak, Monica)  
Public Health Agency of Canada (Mental Health Promotions Unit)  
Public Health Agency of Canada (Strategic Policy and Research)

[Martin.Burt@cbasa-sfc.gc.ca](mailto:Martin.Burt@cbasa-sfc.gc.ca)

[George.Mezher@cbasa-sfc.gc.ca](mailto:George.Mezher@cbasa-sfc.gc.ca)

[Nicole.Rougier@cbasa-sfc.gc.ca](mailto:Nicole.Rougier@cbasa-sfc.gc.ca)

**DRAFT V.9**

DEPARTMENT OF HEALTH

CONTROLLED DRUGS AND SUBSTANCES ACT

*Notice to interested parties - Proposal regarding the addition of Salvia divinorum and salvinorin A to Schedule III to the Controlled Drugs and Substances Act*

This notice provides interested stakeholders with the opportunity to provide comments on Health Canada's proposal to add the plant *Salvia divinorum* (*S. divinorum*) and its main active ingredient salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA). Stakeholders may also identify themselves for inclusion in any future consultation.

*S. divinorum* is a species of sage belonging to the mint family. Its leaves are generally chewed or smoked to obtain psychotropic effects. While uncertainty remains surrounding the health risks of *S. divinorum*, known effects are reported to be short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant. Neither *S. divinorum* nor salvinorin A are currently included in any of the Schedules to the CDSA.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. *S. divinorum* is widely touted as a "legal" hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs.<sup>1</sup> Results from the *Canadian Alcohol and Drug Use Monitoring Survey* (CADUMS) reveal that, in 2009, 1.6% of Canadians aged 15 years and older reported having used *S. divinorum* at least once in their lifetime, and that youth aged 15-24 were much more likely to have used it than adults aged 25 years and older. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *S. divinorum* in the past year. Moreover, the *2009 Ontario Student Drug Use and Health Survey* (OSDUHS) indicated that 5.4% of Ontario students in grades 7-12 reported ever using *S. divinorum* and 4.4% of these students reported using this substance in the past year. Given its unknown effects and pharmacological similarity to other substances included in Schedule III to the CDSA such as lysergic acid diethylamide (LSD) and psilocybin, Health Canada is concerned that the ready availability and use of *S. divinorum* poses a risk to the health and safety of Canadians, particularly youth.

While *S. divinorum* and salvinorin A are not currently included in any of the United Nations Drug Control Conventions, a number of countries have chosen to regulate one or both as controlled substances. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden have all placed controls on the import and/or sale of *S. divinorum*

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<sup>1</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.

and/or salvinorin A. Some American states have also implemented laws restricting their use, sale and/or distribution.

Including these substances within Schedule III to the CDSA would prohibit: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation). The regulation of *S. divinorum* and salvinorin A under the CDSA will also enable law enforcement agencies to take action against suspected illegal activities involving these substances.

As this action is not intended to interfere with the use and availability of *S. divinorum* and/or salvinorin A for legitimate medical, scientific or industrial purposes, Health Canada is seeking information from stakeholders on whether there are any such uses in Canada. Information received in response to this notice will be instrumental in determining appropriate regulation under the CDSA.

The publication of this notice begins a 30-day comment period. There will be additional opportunities to provide comments as the federal regulatory process progresses.

If you are interested in this process or have comments on this proposal, please contact Stephanie Chandler, Regulatory Policy Division, Office of Controlled Substances, Address Locator: 3503D, 123 Slater St., Ottawa, Ontario, Canada, K1A 1B9, by fax at (613) 946-4224 or by email at [OCS\\_Policy\\_and\\_Regulatory\\_Affairs@hc-sc.gc.ca](mailto:OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca).

Cathy A. Sabiston  
Director General  
Controlled Substances and Tobacco Directorate

Date \_\_\_\_\_



**Re: Salvia Media Lines**  
Christine Roush to: Stephanie Chandler  
Cc: Denis Arsenault, Jocelyn Kula, Nicole Prentice

2011-01-18 05:07 PM

History: This message has been replied to.

HPFB will need to approve the lines and we can get the names for you. Please advise if you will be notifying your partners - RCMP, Justice.

Christine Roush  
Senior Communications Advisor/

Stephanie Chandler Hi Christine, We will work on that question, ho... 2011-01-18 04:58:22 PM

From: Stephanie Chandler/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Nicole Prentice/HC-SC/GC/CA@HWC  
Date: 2011-01-18 04:58 PM  
Subject: Re: Salvia Media Lines

Hi Christine,

We will work on that question, however, I'm not sure if we will be able to have it back to you by 10:00am tomorrow.

In regards to the approvals, how would you advise we proceed? We are not sure if HPFB needs to review. There seems to be only one line which refers to the NHP issue, so perhaps just Robin Marles in NHPD needs to see it? There also may be some changes as to who in PACCB needs to approve (e.g. Dave Stephens is not currently included in the list).

Thanks for your help with this.

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

Christine Roush Hi Stephanie, I have reviewed the MLs and mad... 2011-01-18 03:36:37 PM

From: Christine Roush/HC-SC/GC/CA  
To: Stephanie Chandler/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Nicole Prentice/HC-SC/GC/CA@HWC  
Date: 2011-01-18 03:36 PM  
Subject: Re: Salvia NOI

Hi Stephanie,



I have reviewed the MLs and made some changes in blue. Could you please provide a better answer to the question below -as it currently doesn't answer the question, which is about the process involved in listing - (i.e., we have finished our assessment, and are posting to CG1 for comment - but what comes after this, and how much time is involved and when are we likely to have it listed. Also, could you please update the approval totem at the end of the document listing who needs to approve these lines from HECS and HPFB. Please return them to me by 10:00 am tomorrow for one final review. Thanks.

[attachment "Salvia Media Lines\_Jan 18 2011 (1).doc" deleted by Stephanie Chandler/HC-SC/GC/CA]

**Q1 – What is involved in regulating *Salvia divinorum* as a controlled substance and what stage is it at?**

A1 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada recently concluded its assessment of *Salvia divinorum* and salvinorin A against the aforementioned factors and proposes to include both substances in Schedule III to the CDSA. The regulation of these products will reduce the potential risks to the health and safety of Canadians associated with their ready availability, with their increased use and their unknown effects. The scheduling of *Salvia divinorum* and salvinorin A will also eliminate the current perception that these substances are a safe alternative to other illegal drugs.

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
Health Canada/Santé Canada  
Tel/Tél : (613) 954-0712/Cell: (613) 219-7194  
Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca

Stephanie Chandler Hi Christine, With regards to our earlier conver...

2011-01-18 02:53:10 PM

DRAFT 154

December 22/January 14, 2011

Canadian Media Lines  
Salvia divinorum  
surveillance data

#### Issue

There is ongoing media interest regarding the availability of *Salvia divinorum* in Canada and as well as reports from scientific and media sources suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has concluded that *Salvia divinorum* and its main active ingredient salvinorin A should be regulated under the *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth.

#### Key Messages:

- Health Canada has concluded its assessment of *Salvia divinorum* and its main active ingredient salvinorin A and is proposing to regulate both *Salvia divinorum* and its main active ingredient salvinorin A substances under Schedule III to the *CDSA in order to protect the health and safety of Canadians, particularly youth* *Controlled Drugs and Substances Act* (CDSA). Formatted: Font: Italic
- As a first step, in February 2011, Health Canada has published a *Notice to Interested Parties* (NOI) in *Canada Gazette*, Part I on January 29, 2011. The NOI is intended to give Canadians the opportunity to provide comments on the proposal to regulate *Salvia divinorum* and salvinorin A as controlled substances. The inclusion of *Salvia divinorum* and salvinorin A in Schedule III to the CDSA will reduce the potential health and safety risks associated with the ready availability, increased use and unknown effects of these substances. Further to the regulation of these substances under the CDSA, the following activities would be prohibited unless authorized by regulation: possession, trafficking, possession for the purposes of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation).
- Health Canada will inform stakeholders of its proposal by publishing a *Notice to Interested Parties* (NOI) in *Canada Gazette*, Part I. The NOI will provide stakeholders and other interested parties with the opportunity to provide comments on the proposal to regulate *Salvia divinorum* and salvinorin A as controlled substances. The inclusion of *Salvia divinorum* and salvinorin A in Schedule III to the CDSA will make possession, trafficking, importation, exportation, and production (or cultivation) illegal unless authorized by regulation.

#### Supplementary Messages:

- Canadians should not use products containing *Salvia divinorum* and/or salvinorin A because very little is known about these substances and their potential effects on the brain and/or body, and their impact on physical and mental functions.

- The plant *Salvia divinorum* is not regulated under the CDSA and therefore the plant is not considered to be "banned", nor are activities with it considered to be illegal in Canada. H
- However, as *Salvia divinorum* is a plant with hallucinogenic properties when consumed by humans, it meets the definition of a natural health product (NHP) under the *Natural Health Products Regulations* when marketed as a hallucinogen.
- Nevertheless, when specifically marketed for its hallucinogenic properties, *Salvia divinorum* meets the definition of a natural health product under the *Natural Health Products Regulations*. To date, however, Health Canada has not authorized for sale any natural health products which contain *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products containing *Salvia divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

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### Questions and Answers:

**Q1 – Are *Salvia divinorum* and/or salvinorin A controlled internationally? How are these substances regulated in other countries?**

A1 – Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions; as a result, they do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

The move to include *Salvia divinorum* and salvinorin A in Schedule III to the CDSA is consistent with actions taken by several countries (e.g. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Some individual U.S. states have implemented laws restricting their use, sale and/or distribution.

**Q21 – Past media reports have indicated that Health Canada is assessing the possibility of regulating *Salvia divinorum* as a controlled substance. What is involved in does regulating *Salvia divinorum* as a controlled substance that involve and what stage is it at?**

A21 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada recently concluded its assessment of *Salvia divinorum* and salvinorin A against the aforementioned factors and proposes to include both substances in Schedule III to the CDSA. The first step in the process of regulating a substance under the CDSA is the publication of a Notice to Interested Parties (NOI) in Canada Gazette, Part I. The publication of the *Salvia divinorum* NOI on January 29, 2011 is followed by a 30-day comment period. Any comments received will be considered during the preparation of a regulatory proposal. There will be additional opportunities for comment as the federal regulatory process progresses.

–The regulation of these products will reduce the potential risks to the health and safety of Canadians associated with their ready availability, with their increased use and their unknown effects. The scheduling of *Salvia divinorum* and salvinorin A will also eliminate the current perception that these substances are a safe alternative to other illegal drugs.

**Q2 – Are *Salvia divinorum* and/or salvinorin A controlled internationally? How are these substances regulated in other countries?**

A2 - Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions; as a result, they do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

The move to include *Salvia divinorum* and salvinorin A in Schedule III to the CDSA is consistent with actions taken by several countries (e.g., Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Some individual U.S. states have implemented laws restricting their use, sale and/or distribution.

**Q3 – Is there any research on the use of *Salvia divinorum* in Canada?**

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A3 - Results from the Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *Salvia divinorum* at least once in their lifetime, and that youth aged 15-24 were much more likely to have used it than adults aged 25 years and older. The results from the Canadian 2008-2009 Youth Smoking Survey also show that 5% of 15 year olds have used *Salvia divinorum* in the past year. The 2009 Ontario Student Drug Use and Health Survey (OSDUHS) indicated that 5.4% of Ontario students in grades 7-12 reported ever using *Salvia divinorum* and 4.4% of these students reported using this substance in the past year.

**Q34 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why isn't it illegal?**

Health Canada recently concluded its assessment of *Salvia divinorum* and salvinorin A against the aforementioned factors and proposes to include both substances in Schedule III to the CDSA. The regulation of these products will reduce the potential risks to the health and safety of Canadians associated with their ready availability, with their increased use and their unknown effects. The scheduling of *Salvia divinorum* and salvinorin A will also eliminate the current perception that these substances are a safe alternative to other illegal drugs.

**Q2 – Are *Salvia divinorum* and/or salvinorin A controlled internationally? How are these substances regulated in other countries?**

A2 - Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions; as a result, they do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

The move to include *Salvia divinorum* and salvinorin A in Schedule III to the CDSA is consistent with actions taken by several countries (e.g., Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Some individual U.S. states have implemented laws restricting their use, sale and/or distribution.

**Q3 – Is there any research on the use of *Salvia divinorum* in Canada?**

A3 - Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *Salvia divinorum* at least once in their lifetime, and that youth aged 15-24 were much more likely to have used it than adults aged 25 years and older. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *Salvia divinorum* in the past year. The 2009 *Ontario Student Drug Use and Health Survey (OSDUHS)* indicated that 5.4% of Ontario students in grades 7-12 reported ever using *Salvia divinorum* and 4.4% of these students reported using this substance in the past year.

**Q34 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why isn't it illegal?**

A34 – Health Canada proposes to include *Salvia divinorum* and salvinorin A under Schedule III to the CDSA. Further to the regulation of these substances under the CDSA, the following activities ~~may~~ be ~~prohibited~~ unless authorized by regulation: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation). Law enforcement agencies will ~~then~~ be able to take action against suspected illegal activities involving these substances.

~~In the interim, as *Salvia divinorum* is a plant with hallucinogenic properties, it meets the definition of a natural health product under the *Natural Health Products Regulations (NHPR)*~~

Handwritten notes: "illegal", "also however", "Salvia D..."

Handwritten note: "sll"

natural health

Needs line about none approved to date

when marketed as a hallucinogen. The ~~unauthorized sale of such~~ <sup>natural health</sup> ~~unauthorized~~ products containing *Salvia divinorum* and/or salvinorin A may be subject to compliance and enforcement action under the *Food and Drugs Act*.

**Q45 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A45 – Once *Salvia divinorum* and salvinorin A are included in Schedule III to the CDSA, law enforcement will be able to take appropriate action in response to suspected illegal activities with these substances.

Currently however,

~~In the interim,~~ *S. divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. Complaints about the illegal sale of drugs containing *Salvia divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

**Q6 - Has Health Canada issued any kind of warning to Canadians about *Salvia divinorum*?**

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A6 - Health Canada is developing an *It's Your Health* article about *Salvia divinorum* to help inform the general public about the risks associated with the use of this plant.

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Formatted: English (Canada)

~~If pressed on whether Health Canada has issued any kind of warning to Canadians about *Salvia divinorum*~~

~~A – Health Canada is developing an *It's Your Health* article on about *Salvia divinorum* to help inform the general public about the risks associated with the use of this plant.~~

**Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

Data from the 2008-2009 Youth Smoking Survey indicates that:

- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;

Denis/Stephanie

# QUESTION PERIOD NOTE

## NOTE POUR LA PÉRIODE DE QUESTIONS

Date:	January 18, 2011
Classification:	HECS PROTECTED - SESC PROTÉGÉ

### SUBJECT - SUJET

English:  
**DRUGS - SALVIA DIVINORUM**

Français:  
**DROGUES - SALVIA DIVINORUM**

*with changes*

### SYNOPSIS - SOMMAIRE

*analysis*  
*data*

English:  
Media interest in Salvia divinorum is recurrent. Questions around this substance generally focus on its legality. Recently, a number of media reports have commented on a YouTube video which reportedly shows the young celebrity Miley Cyrus smoking Salvia divinorum. ~~Health Canada~~ surveillance indicates that this substance is being used by adolescents and young adults for its hallucinogenic properties, ~~and~~ there have also been several reports from scientific ~~and media~~ sources indicating that Salvia divinorum has the potential for abuse.

*↑ whole point was to*

### ANTICIPATED QUESTION - QUESTION PRÉVUE

English:  
What is Health Canada doing to protect young Canadians from the potential adverse effects associated with the use of Salvia divinorum?

Français:  
Quelles mesures Santé Canada prend-il pour protéger les jeunes Canadiens contre les effets indésirables possibles liés à l'utilisation de la Salvia divinorum?

*refer implication that we rely on media to act!*

English:

- Health Canada is proposing to regulate Salvia under the *Controlled Drugs and Substances Act* in order to protect the health and safety of Canadians, particularly youth.
- Health Canada has published a *Notice to Interested Parties* in *Canada Gazette*, Part I, to give Canadians the opportunity to provide comments on ~~the~~ proposal to regulate Salvia. 13
- The regulation of Salvia will make possession, trafficking, importation, exportation, and production illegal unless authorized by regulation.

Français:

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## **BACKGROUND - CONTEXTE**

English:

### **BACKGROUND / CONTEXTE**

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, diviner's sage, magic mint, and puff. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs.

Both the plant *S. divinorum* and its main active ingredient salvinorin A are known to have physical and mental effects which are often described as unpleasant, including:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination



- slurred speech and awkward sentence patterns

Recent surveys indicate that Canadian youth are trying this substance which could be dangerous to their health. Results from the *Canadian Alcohol and Drug Use Monitoring Survey* (CADUMS) reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *Salvia divinorum* at least once in their lifetime, and that youth aged 15-24 were much more likely to have used it than adults aged 25 years and older. The results from the Canadian 2008-2009 *Youth Smoking Survey* also show that 5% of 15 year olds have used *Salvia divinorum* in the past year. The 2009 *Ontario Student Drug Use and Health Survey* (OSDUHS) indicated that 5.4% of Ontario students in grades 7-12 reported ever using *Salvia divinorum* and 4.4% of these students reported using this substance in the past year.

#### International Control of *S. divinorum*

Neither *Salvia divinorum* nor its main active ingredient salvinorin A are listed under the United Nations Drug Control Conventions; as a result, they do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions. The move to include *Salvia divinorum* and salvinorin A in Schedule III to the CDSA is consistent with actions taken by several countries (e.g. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Some individual U.S. states have also implemented laws restricting their use, sale and/or distribution.

#### Current Situation in Canada

Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted, namely:

- International requirements and trends in control and/or scheduling;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e. therapeutic, scientific, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada recently concluded its assessment of *S. divinorum* and its main active ingredient salvinorin A against the aforementioned factors and now proposes to include both substances in Schedule III to the CDSA.

The regulation of *Salvia divinorum* will allow law enforcement to take action against illegal activities involving this substance. The possession, trafficking, importation, exportation and production of *Salvia divinorum* and salvinorin A will be illegal unless authorized by regulation.

The plant *Salvia divinorum* is not currently regulated under the *Controlled Drugs and Substances Act* (CDSA) and therefore the plant is not considered to be "banned" nor are activities with it considered to be illegal in Canada. However, as *Salvia divinorum* is a plant with hallucinogenic properties when consumed by humans, it meets the definition of a natural health product (NHP) under the *Natural Health Products Regulations* when marketed as a hallucinogen. To date, Health Canada has not licensed for sale any natural health product which contains *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products containing *Salvia divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

ATTACHMENTS / PIÈCE(S)-JOINTE(S)

Contact/Personne ressource : Denis Arsenault/HC-SC/GC/CA	Tel. no./No de tél. 613-957-6828	Approved by/ Approuvé par Paul Glover, ADM (HECS/SESC)	Tel. no./No. de tél. 946-6701
	Mobile/ Cellulaire: 613-296-4239	Title/ Titre:	Mobile/ Cellulaire:
Alternate/ Secondaire: Jocelyn Kula	Telephone/ Téléphone: 613-952-2177		
	Mobile/ Cellulaire: 613-797-2103		

**Date Prepared/Préparé le :** 2010-09-07

**Prepared by/Préparé par :** Stephanie Chandler **Phone/ No de tél. :** 613-946-0124

**Office/Bureau :** CSTD - Office of Controlled Substances

**Date Contact Signed/  
Signature de la personne  
ressource :**

**Contact Signed - Signé**

**D.G. Verification/  
Vérification par le D.E. :**

Cathy Sabiston

**D.G. Approved / Approuvé D.E.**

**Date D.G. Verified/  
Date vérifié par le D.E. :**

**Programme :** Controlled Substances and Tobacco Directorate

**ADM Approved/ Approbation  
par le SMA :** Paul Glover  
(946-6701)

**Branch/ Direction générale :** HECS/SESC

**Department/ Ministère :** Health Canada / Santé Canada

1 minor  
chg,

DRAFT V.9

DEPARTMENT OF HEALTH

## CONTROLLED DRUGS AND SUBSTANCES ACT

### *Notice to interested parties - Proposal regarding the addition of Salvia divinorum and salvinorin A to Schedule III to the Controlled Drugs and Substances Act*

This notice provides interested stakeholders with the opportunity to provide comments on Health Canada's proposal to add the plant *Salvia divinorum* (*S. divinorum*) and its main active ingredient salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA). Stakeholders may also identify themselves for inclusion in any future consultation.

*S. divinorum* is a species of sage belonging to the mint family. Its leaves are generally chewed or smoked to obtain psychotropic effects. While uncertainty remains surrounding the health risks of *S. divinorum*, known effects are reported to be short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant. Neither *S. divinorum* nor salvinorin A are currently included in any of the Schedules to the CDSA.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. *S. divinorum* is widely touted as a "legal" hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs.<sup>1</sup> Results from the *Canadian Alcohol and Drug Use Monitoring Survey* (CADUMS) reveal that, in 2009, 1.6% of Canadians aged 15 years and older reported having used *S. divinorum* at least once in their lifetime, and that youth aged 15-24 were much more likely to have used it than adults aged 25 years and older. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *S. divinorum* in the past year. Moreover, the 2009 *Ontario Student Drug Use and Health Survey* (OSDUHS) indicated that 5.4% of Ontario students in grades 7-12 reported ever using *S. divinorum* and 4.4% of these students reported using this substance in the past year. Given its unknown effects and pharmacological similarity to other substances included in Schedule III to

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concerned that the ready availability and use of *S. divinorum* poses a risk to the health and safety of Canadians, particularly youth.

While *S. divinorum* and salvinorin A are not currently included in any of the United Nations Drug Control Conventions, a number of countries have chosen to regulate one or both as controlled substances. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden have all placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. Some American states have also implemented laws restricting their use, sale and/or distribution.

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<sup>1</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.

Including these substances within Schedule III to the CDSA would prohibit: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation). The regulation of *S. divinorum* and salvinorin A under the CDSA will enable law enforcement agencies to take action against suspected illegal activities involving these substances.

As this action is not intended to interfere with the use and availability of *S. divinorum* and/or salvinorin A for legitimate medical, scientific or industrial purposes, Health Canada is seeking information from stakeholders on whether there are any such uses in Canada. Information received in response to this notice will be instrumental in determining appropriate regulation under the CDSA.

The publication of this notice begins a 30-day comment period. There will be additional opportunities to provide comments as the federal regulatory process progresses.

If you are interested in this process or have comments on this proposal, please contact Stephanie Chandler, Regulatory Policy Division, Office of Controlled Substances, Address Locator: 3503D, 123 Slater St., Ottawa, Ontario, Canada, K1A 1B9, by fax at (613) 946-4224 or by email at [OCS\\_Policy\\_and\\_Regulatory\\_Affairs@hc-sc.gc.ca](mailto:OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca).

Cathy A. Sabiston  
Director General  
Controlled Substances and Tobacco Directorate

Date \_\_\_\_\_

## DEPARTMENT OF HEALTH

### CONTROLLED DRUGS AND SUBSTANCES ACT

#### *Notice to interested parties - Proposal regarding the addition of Salvia divinorum and salvinorin A to Schedule III to the Controlled Drugs and Substances Act*

This notice provides interested stakeholders with the opportunity to provide comments on Health Canada's proposal to add the plant *Salvia divinorum* (*S. divinorum*) and its main active ingredient salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA). Stakeholders may also identify themselves for inclusion in any future consultation.

*S. divinorum* is a species of sage belonging to the mint family. Its leaves are generally chewed or smoked to obtain psychotropic effects. While uncertainty remains surrounding the health risks of *S. divinorum*, known effects are reported to be short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant. Neither *S. divinorum* nor salvinorin A are currently included in any of the Schedules to the CDSA.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. *S. divinorum* is widely touted as a "legal" hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs.<sup>1</sup> Results from the *Canadian Alcohol and Drug Use Monitoring Survey* (CADUMS) reveal that, in 2009, 1.6% of Canadians aged 15 years and older reported having used *S. divinorum* at least once in their lifetime, and that youth aged 15-24 were much more likely to have used it than adults aged 25 years and older. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *S. divinorum* in the past year. Moreover, the 2009 *Ontario Student Drug Use and Health Survey* (OSDUHS) indicated that 5.4% of Ontario students in grades 7-12 reported ever using *S. divinorum* and 4.4% of these students reported using this substance in the past year. Given its unknown effects and pharmacological similarity to other substances included in Schedule III to

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Canadians, particularly youth.

While *S. divinorum* and salvinorin A are not currently included in any of the United Nations Drug Control Conventions, a number of countries have chosen to regulate one or both as controlled substances. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden have all placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. Some American states have also implemented laws restricting their use, sale and/or distribution.

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<sup>1</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.

Including these substances within Schedule III to the CDSA would prohibit: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation). The regulation of *S. divinorum* and salvinorin A under the CDSA will also enable law enforcement agencies to take action against suspected illegal activities involving these substances.

As this action is not intended to interfere with the use and availability of *S. divinorum* and/or salvinorin A for legitimate medical, scientific or industrial purposes, Health Canada is seeking information from stakeholders on whether there are any such uses in Canada. Information received in response to this notice will be instrumental in determining appropriate regulation under the CDSA.

The publication of this notice begins a 30-day comment period. There will be additional opportunities to provide comments as the federal regulatory process progresses.

If you are interested in this process or have comments on this proposal, please contact Stephanie Chandler, Regulatory Policy Division, Office of Controlled Substances, Address Locator: 3503D, 123 Slater St., Ottawa, Ontario, Canada, K1A 1B9, by fax at (613) 946-4224 or by email at [OCS\\_Policy\\_and\\_Regulatory\\_Affairs@hc-sc.gc.ca](mailto:OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca).

Cathy A. Sabiston  
Director General  
Controlled Substances and Tobacco Directorate

Date \_\_\_\_\_

Alors que la *S. divinorum* et la salvinorine A ne sont actuellement comprises dans aucune des Conventions de l'ONU sur le contrôle des drogues, de nombreux pays ont choisi de réglementer une de ces substances, ou les deux, comme substance désignée. L'Australie, la Belgique, le Danemark, la Finlande, l'Allemagne, l'Italie, le Japon, la Corée du Sud, l'Espagne et la Suède ont tous établi des contrôles sur les importations ou la vente, ou les deux, de *S. divinorum* et/ou de salvinorine A. Certains États américains ont aussi mis en oeuvre des lois restreignant son utilisation, sa vente et/ou sa distribution.

Le fait d'ajouter ces substances à l'annexe III de la LRCDas en interdirait la possession, le commerce, la possession aux fins de commerce, l'importation, l'exportation, la possession aux fins d'exportation et la production (ou la culture). La réglementation de la *S. divinorum* et de la salvinorine A conformément à la LRCDas permettrait également aux organismes d'application de la loi de prendre des mesures contre les activités illicites présumées liées à ces substances.

Étant donné que cette mesure ne vise pas à interférer avec l'utilisation et la disponibilité de la *S. divinorum* et/ou de la salvinorine A à des fins médicales, scientifiques ou industrielles légitimes, Santé Canada sollicite de l'information aux parties intéressées sur les possibilités de ces types d'utilisation au Canada. L'information reçue en réponse à cet avis sera déterminante dans la rédaction d'un règlement approprié conformément à la LRCDas.

La publication de cet avis entame une période de commentaires de 30 jours. Il y aura des occasions supplémentaires de fournir des commentaires au fur et à mesure que progresse le processus de réglementation fédéral.

Si vous êtes intéressé par ce processus ou que vous avez des commentaires sur cette proposition, veuillez communiquer avec Stephanie Chandler de la Division de la politique réglementaire, du Bureau des substances contrôlées, situé au : 3503D, 123, rue Slater, Ottawa (Ontario), Canada, K1A 1B9, par télécopieur au (613) 946-4224 ou par courriel au [OCS\\_Policy\\_and\\_Regulatory\\_Affairs@hc-sc.gc.ca](mailto:OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca).

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Cathy A. Sabiston  
Directrice générale  
Direction des substances contrôlées et de la lutte au  
tabagisme

Date \_\_\_\_\_

## MINISTÈRE DE LA SANTÉ

### LOI RÉGLEMENTANT CERTAINES DROGUES ET AUTRES SUBSTANCES

*Avis aux parties intéressées - Proposition concernant l'ajout de Salvia divinorum et de salvinorine A à l'annexe III de la Loi réglementant certaines drogues et autres substances*

Cet avis informe les parties intéressées de la possibilité de commenter la proposition de Santé Canada d'ajouter la plante *Salvia divinorum* (*S. divinorum*) et son principal ingrédient actif, la salvinorine A, à l'annexe III de la *Loi réglementant certaines drogues et autres substances* (LRCDas). Les parties intéressées ont aussi l'occasion d'ajouter leur nom pour toute consultation future.

*S. divinorum* est une espèce de sauge appartenant à la famille des menthes. Généralement, ses feuilles sont mâchées ou fumées pour obtenir des effets psychotropes. Alors qu'une incertitude subsiste quant aux risques pour la santé découlant de la consommation de *S. divinorum*, les effets de cette consommation sont connus pour être brefs et comprennent des hallucinations, une dysphorie, des expériences extra-corporel, l'inconscience et une perte de mémoire à court terme. Les effets, qui varient d'une personne à l'autre, sont également souvent décrits comme déplaisants. Ni la *S. divinorum* ni la salvinorine A ne sont actuellement incluses dans les annexes de la LRCDas.

Des rapports ont récemment été publiés, indiquant que des adolescents et des jeunes adultes canadiens consomment de la *S. divinorum* pour sa capacité à produire des hallucinations. *S. divinorum* est largement vantée comme un hallucinogène "légal" sur Internet et a aussi été signalée comme l'un des produits à base d'herbes médicinales les plus courants utilisés comme option alternative aux drogues illicites.<sup>1</sup> Les conclusions tirées de l'*Enquête de surveillance canadienne de la consommation d'alcool et de drogues* (ESCCAD) révèlent que, en 2009, 1,6 % des Canadiens âgés de 15 ans ou plus ont déclaré avoir consommé de la *S. divinorum* au moins une fois dans leur vie, et que les jeunes âgés de 15 à 24 ans étaient beaucoup plus nombreux à en avoir consommé que les adultes âgés de 25 ans ou plus. Les résultats de l'*Enquête sur le*

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*la consommation de drogues et la santé des élèves de l'Ontario* (SCDSEO) de 2009 indique que 5,4 % des élèves de l'Ontario des classes scolaires 7 à 12 ont déclaré avoir déjà consommé de la *S. divinorum* et que 4,4 % de ces élèves ont indiqué avoir consommé cette substance au cours de la dernière année. Étant donné ses effets inconnus, ainsi que sa similarité pharmacologique avec d'autres substances comprises dans l'annexe III de la LRCDas, comme l'acide lysergique diéthylamide (LSD) et la psilocybine, Santé Canada craint que la disponibilité immédiate et la consommation de *S. divinorum* ne posent un risque pour la santé et la sécurité des Canadiens, en particulier pour celles des jeunes.

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<sup>1</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. Oct 2005, vol. 39, no°10, pp. 1634-1639.



Alors que la *S. divinorum* et la salvinorine A ne sont actuellement comprises dans aucune des Conventions de l'ONU sur le contrôle des drogues, de nombreux pays ont choisi de réglementer une de ces substances, ou les deux, comme substance désignée. L'Australie, la Belgique, le Danemark, la Finlande, l'Allemagne, l'Italie, le Japon, la Corée du Sud, l'Espagne et la Suède ont tous établi des contrôles sur les importations ou la vente, ou les deux, de *S. divinorum* et/ou de salvinorine A. Certains États américains ont aussi mis en oeuvre des lois restreignant son utilisation, sa vente et/ou sa distribution.

Le fait d'ajouter ces substances à l'annexe III de la LRCDas en interdirait la possession, le commerce, la possession aux fins de commerce, l'importation, l'exportation, la possession aux fins d'exportation et la production (ou la culture). La réglementation de la *S. divinorum* et de la salvinorine A conformément à la LRCDas permettrait également aux organismes d'application de la loi de prendre des mesures contre les activités illicites présumées liées à ces substances.

Étant donné que cette mesure ne vise pas à interférer avec l'utilisation et la disponibilité de la *S. divinorum* et/ou de la salvinorine A à des fins médicales, scientifiques ou industrielles légitimes, Santé Canada sollicite de l'information aux parties intéressées sur les possibilités de ces types d'utilisation au Canada. L'information reçue en réponse à cet avis sera déterminante dans la rédaction d'un règlement approprié conformément à la LRCDas.

La publication de cet avis entame une période de commentaires de 30 jours. Il y aura des occasions supplémentaires de fournir des commentaires au fur et à mesure que progresse le processus de réglementation fédéral.

Si vous êtes intéressé par ce processus ou que vous avez des commentaires sur cette proposition, veuillez communiquer avec Stephanie Chandler de la Division de la politique réglementaire, du Bureau des substances contrôlées, situé au : 3503D, 123, rue Slater, Ottawa (Ontario), Canada, K1A 1B9, par télécopieur au (613) 946-4224 ou par courriel au [OCS\\_Policy\\_and\\_Regulatory\\_Affairs@hc-sc.gc.ca](mailto:OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca).

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Cathy A. Sabiston  
Directrice générale  
Direction des substances contrôlées et de la lutte au  
tabagisme

Date \_\_\_\_\_



*"Clients come first"*

**Branch Correspondence**  
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Comments

Records Office



**Fw: Revised salvia products**

Jocelyn Kula to: stephanie.szick, CSTD-DGO

2011-01-19 03:28 PM

Cc: Stephanie Chandler, Denis Arsenault

Approved for OCS.....

JK

Stephanie C- pls send updated docs to Christine for her use in preparing NR. Note that Cathy has not approved of course.....

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Jocelyn Kula

Acting Director/ Directrice par intérim

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs


Health Canada/ Santé Canada

Tel: (613) 952-2177 Fax: (613) 946-4224

---- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2011-01-19 03:26 PM ----

From: Stephanie Chandler/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: CSTD-OCS-DO, Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2011-01-19 03:06 PM  
Subject: Revised salvia products

Hi Jocelyn,

Please see the revised media lines, NOI and QP Note (available here: )



Salvia Media Lines\_Jan 19 2011.doc DRAFT Salvia NOI\_Jan 19.wpd

Thanks,

Stephanie

Stephanie Chandler

Junior Regulatory Project Officer

Regulatory Policy Division/ Division de la politique réglementaire

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs

Health Canada/ Santé Canada

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DRAFT 15  
January 18, 2011

**Media Lines**  
*Salvia divinorum*

**Issue**

There is ongoing media interest regarding the availability of *Salvia divinorum* in Canada as well as Canadian surveillance data suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has concluded that *Salvia divinorum* and its main active ingredient salvinorin A should be regulated under the *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth.

**Key Messages:**

- Health Canada is proposing to regulate both *Salvia divinorum* and its main active ingredient salvinorin A under Schedule III to the *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth.
- As a first step, Health Canada published a *Notice to Interested Parties* (NOI) in *Canada Gazette*, Part I on January 29, 2011. The NOI is intended to give Canadians the opportunity to provide comments on its proposal to regulate *Salvia divinorum* and salvinorin A as controlled substances.
- The inclusion of *Salvia divinorum* and salvinorin A in Schedule III to the CDSA will make possession, trafficking, importation, exportation, and production (or cultivation) illegal unless authorized by regulation.

**Supplementary Messages:**

- Canadians should not use products containing *Salvia divinorum* and/or salvinorin A because very little is known about these substances and their potential effects on the brain and body.
- The plant *Salvia divinorum* is not regulated under the CDSA and therefore it is not considered to be "banned", nor are activities with it considered to be illegal in Canada.
- However, as *Salvia divinorum* is a plant with hallucinogenic properties when consumed by humans, it meets the definition of a natural health product (NHP) under the *Natural Health Products Regulations* when marketed as a hallucinogen.
- To date, Health Canada has not authorized for sale any natural health products which contain *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products containing *Salvia divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

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Questions and Answers:

**Q1 – What is involved in regulating *Salvia divinorum* as a controlled substance and what stage is it at?**

**A1 -** Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act (CDSA)* is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada recently concluded its assessment of *Salvia divinorum* and salvinorin A against the aforementioned factors and proposes to include both substances in Schedule III to the CDSA. The first step in the process of regulating a substance under the CDSA is the publication of a *Notice to Interested Parties (NOI)* in *Canada Gazette*, Part I. Any comments received will be considered during the preparation of a regulatory proposal. There will be additional opportunities for comment as the federal regulatory process progresses.

The regulation of these products will reduce the potential risks to the health and safety of Canadians associated with their ready availability, with their increased use and their unknown effects. The scheduling of *Salvia divinorum* and salvinorin A will also eliminate the current perception that these substances are a safe alternative to other illegal drugs.

**Q2 – Are *Salvia divinorum* and/or salvinorin A controlled internationally? How are these substances regulated in other countries?**

**A2 -** Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions; as a result, they do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

The move to include *Salvia divinorum* and salvinorin A in Schedule III to the CDSA is consistent with actions taken by several countries (e.g., Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Some individual U.S. states have implemented laws restricting their use, sale and/or distribution.

**Q3 – Is there any research on the use of *Salvia divinorum* in Canada?**

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¶ A1 - Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions; as a result, they do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.¶

¶ The move to include *Salvia divinorum* and salvinorin A in Schedule III to the CDSA is consistent with actions taken by several countries (e.g. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Some individual U.S. states have implemented laws restricting their use, sale and/or distribution.¶

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A3 - Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *Salvia divinorum* at least once in their lifetime, and that youth aged 15-24 were much more likely to have used it than adults aged 25 years and older. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *Salvia divinorum* in the past year. The 2009 *Ontario Student Drug Use and Health Survey (OSDUHS)* indicated that 5.4% of Ontario students in grades 7-12 reported ever using *Salvia divinorum* and 4.4% of these students reported using this substance in the past year.

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**Q4 - If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why isn't it illegal?**

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A4 - Health Canada proposes to include *Salvia divinorum* and salvinorin A under Schedule III to the CDSA. Further to the regulation of these substances under the CDSA, the following activities will be illegal unless authorized by regulation: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation). Law enforcement agencies will also be able to take action against suspected illegal activities involving these substances.

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As a plant with hallucinogenic properties, however, *Salvia divinorum* meets the definition of a natural health product under the *Natural Health Products Regulations (NHPR)* when marketed as a hallucinogen. To date, Health Canada has not authorized for sale any natural health products which contain *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products may be subject to compliance and enforcement action under the *Food and Drugs Act*.

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**Q5 - What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

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A5 - Once *Salvia divinorum* and salvinorin A are included in Schedule III to the CDSA, law enforcement will be able to take appropriate action in response to suspected illegal activities with these substances.

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Currently however, *Salvia divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. Complaints about the unauthorized sale of drugs containing *Salvia divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

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**Q6 - Has Health Canada issued any kind of warning to Canadians about *Salvia divinorum*?**

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A6 - Health Canada is developing an *It's Your Health* article about *Salvia divinorum* to help inform the general public about the risks associated with the use of this plant.

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**Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

Data from the 2008-2009 Youth Smoking Survey indicates that:

- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;
- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year; and.
- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using Salvia in their lifetime (0.2% in the past year); and
- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that:

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;
- 5.4% of students (grades 7-12) ever used *Salvia divinorum*; and
- the use of *Salvia divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

**Prepared by:** Stephanie Chandler and Denis Arsenault, OCS, CSTD

**Input by:** Lisa Mackay IYH/PACCB, Suzanne Desjardins HECSB/ODARS, Hanan Abramovici HECSB/ODARS, Bruna Brands HECSB/ODARS, Jocelyn Kula, HECSB/OCS, Robin Marles HPFB/NHPD, Maggie Graham HPFB/NHPD, Stephanie Collins HPFB/NHPD, Mano Murty HPFB/MHPD, Robert Leitch HPFB/MHPD, Shahid Perwaiz HPFB/MHPD, Collin Pinto, HPFB/HPFBI

**Approved by:**

Robin Marles, Director, Bureau of Clinical Trials, NHPD (pending)  
Lindsay Blaney, Director, Policy and Regulatory Affairs, NHPD (pending)  
Duc Vu, Director, Marketed Biologics, Biotechnology and Natural Health Products  
Bureau, MHPD (pending)  
Kim Dayman-Rutkas, Director, HPFBI (pending)

Jocelyn Kula, A/Director, OCS, CSTD, HECS (pending)  
Suzanne Desjardins, Director, ODARS, CSTD, HECS (approved, Sept 30, 2010)  
Cathy Sabiston, DG, CSTD, HECS (pending)  
Chris Turner, DG, MHPD (pending)  
Nancy Richards, DG, NHPD (pending)  
Diana Dowthwaite, DG, HPFBI (pending)  
Ken Polk, Communications Executive, HPFB (pending)  
Jean Tessier, Senior Media Relations, PACCB (pending)  
Warren Braun, Director, Strategic Communications, PACCB (pending)  
Peter Yendall, Director, Public Affairs, PACCB (pending)  
HECS Legal (pending)  
HPFB Legal (pending)  
Paul Glover, ADM, HECSB (pending)  
Meena Ballantyne, ADM, HPFB (pending)  
Anne Lamar, ADM, PACCB (pending)  
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2010



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The inclusion of <i>Salvia divinorum</i> and salvinorin A in Schedule III to the CDSA will reduce the potential health and safety risks associated with the ready availability, increased use and unknown effects of these substances. Further to the regulation of these substances under the CDSA, the following activities would be prohibited unless authorized by regulation: possession, trafficking, possession for the purposes of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation).		
<b>Page 1: [2] Deleted</b>	<b>STCHANDL</b>	<b>2011-01-14 10:30:00 AM</b>
Health Canada will inform stakeholders of its proposal by publishing a <i>Notice to Interested Parties</i> (NOI) in <i>Canada Gazette</i> , Part I. The NOI will provide stakeholders and other interested parties with the opportunity to provide comments on the proposal to regulate <i>Salvia divinorum</i> and salvinorin A as controlled substances.		
<b>Page 1: [3] Deleted</b>	<b>STCHANDL</b>	<b>2011-01-14 10:31:00 AM</b>
, and their impact on physical and mental functions		
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<b>Page 1: [11] Formatted</b>	<b>CROUSH</b>	<b>2011-01-18 3:25:00 PM</b>
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Nevertheless, when specifically marketed for its hallucinogenic properties, <i>Salvia divinorum</i> meets the definition of a natural health product under the <i>Natural Health Products Regulations</i> .		
<b>Page 1: [13] Change</b>	<b>CROUSH</b>	<b>2011-01-18 3:25:00 PM</b>
Formatted Bullets and Numbering		



**Re: Fw: Revised salvia products**   
Stephanie Szick to: Jocelyn Kula  
Cc: CSTD-DGO, Denis Arsenault, Stephanie Chandler

2011-01-19 04:26 PM

Ok, so will pull the media lines.  
I have some v. minor comments on the lines - can I leave the hard copy in your inbox here for pick-up??

Stephanie Szick  
Director General's Office / Bureau du directeur général  
Controlled Substances & Tobacco Directorate (CSTD) /  
Direction des substances contrôlées et de la lutte au tabagisme (DSCLT)  
Health Canada / Santé Canada  
Tel / Tél: (613) 948-8651

Jocelyn Kula      Stephanie C has shared with her and advised th...      2011-01-19 04:22:57 PM

From: Jocelyn Kula/HC-SC/GC/CA  
To: Stephanie Szick/HC-SC/GC/CA@HWC  
Cc: CSTD-DGO, Denis Arsenault/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2011-01-19 04:22 PM  
Subject: Re: Fw: Revised salvia products

Stephanie C has shared with her and advised that not approved by Cathy.....so that she can do her own thing.....  
no word back from Martina yet

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

Stephanie Szick      Have these media lines come through Christine...      2011-01-19 03:39:31 PM

From: Stephanie Szick/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: CSTD-DGO, Denis Arsenault/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2011-01-19 03:39 PM  
Subject: Re: Fw: Revised salvia products

Have these media lines come through Christine R -- i.e. she is aware we are providing to Cathy? Or would she prefer to do so per usual comms process?

Jocelyn Kula      Approved for OCS..... JK      2011-01-19 03:28:56 PM

From: Jocelyn Kula/HC-SC/GC/CA  
To: stephanie.szick@hc-sc.gc.ca, CSTD-DGO  
Cc: Stephanie Chandler/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2011-01-19 03:28 PM  
Subject: Fw: Revised salvia products

002363

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Approved for OCS.....

JK

Stephanie C- pls send updated docs to Christine for her use in preparing NR. Note that Cathy has not approved of course.....

---

Jocelyn Kula

Acting Director/ Directrice par intérim

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs

Health Canada/ Santé Canada


Tel: (613) 952-2177 Fax: (613) 946-4224

----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2011-01-19 03:26 PM -----

From: Stephanie Chandler/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: CSTD-OCS-DO, Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2011-01-19 03:06 PM  
Subject: Revised salvia products

---

Hi Jocelyn,

Please see the revised media lines, NOI and QP Note (available here: )

[attachment "Salvia Media Lines\_Jan 19 2011.doc" deleted by Stephanie Szick/HC-SC/GC/CA]

[attachment "DRAFT Salvia NOI\_Jan 19.wpd" deleted by Stephanie Szick/HC-SC/GC/CA]

Thanks,

Stephanie

Stephanie Chandler

Junior Regulatory Project Officer

Regulatory Policy Division/ Division de la politique réglementaire

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs

Health Canada/ Santé Canada

Tel: (613) 946-0124, Fax: (613) 946-4224

E-Mail: stephanie.chandler@hc-sc.gc.ca



**Re: Salvia Media Lines**  
Christine Roush to: Stephanie Chandler  
Cc: Denis Arsenault, Jocelyn Kula, Nicole Prentice

2011-01-19 04:49 PM

History: This message has been replied to.

Thanks Stephanie - we have communication contacts in both RCMP, Justice and Public Safety and I will give them all a head's up about this announcement. I will send the MLs to Suzanne Desjardins now for her approval, and also start the approvals in HPFB too. The clean version is below.



Salvia MLs\_Jan 19(3)\_ENG.doc

Christine Roush  
Senior Communications Advisor/

Stephanie Chandler Hi Christine, Here are the revised media lines... 2011-01-19 03:39:45 PM

From: Stephanie Chandler/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Nicole Prentice/HC-SC/GC/CA@HWC  
Date: 2011-01-19 03:39 PM  
Subject: Re: Salvia Media Lines

Hi Christine,

Here are the revised media lines approved by Jocelyn.  
[attachment "Salvia Media Lines\_Jan 19 2011.doc" deleted by Christine Roush/HC-SC/GC/CA]

In addition, here is the most recent draft of the NOI. Please note neither the MLs or the NOI have been approved by DGO.

[attachment "DRAFT Salvia NOI\_Jan 19.wpd" deleted by Christine Roush/HC-SC/GC/CA]

OCS has a list of stakeholders who will be notified that the NOI has been posted. However, contacts from the RCMP or Justice who would benefit from having a heads up prior to the posting would most likely be from their respective communication departments, in which I do not have any contacts. Do you or your group have any contacts in these areas?

Thanks,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

Christine Roush	HPFB will need to approve the lines and we can...	2011-01-18 05:07:42 PM
Stephanie Chandler	Hi Christine, We will work on that question, ho...	2011-01-18 04:58:22 PM
Christine Roush	Hi Stephanie, I have reviewed the MLs and mad...	2011-01-18 03:36:37 PM
Stephanie Chandler	Hi Christine, With regards to our earlier conver...	2011-01-18 02:53:10 PM

**DRAFT**  
19/01/2011

## **Media Lines** ***Salvia divinorum***

### **Issue**

There is ongoing media interest regarding the availability of *Salvia divinorum* in Canada as well as Canadian surveillance data suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has concluded that *Salvia divinorum* and its main active ingredient salvinorin A should be regulated under the *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth.

### **Key Messages:**

- Health Canada is proposing to regulate both *Salvia divinorum* and its main active ingredient salvinorin A under Schedule III to the *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth.
- As a first step, Health Canada published a *Notice to Interested Parties* (NOI) in *Canada Gazette*, Part I on January 29, 2011. The NOI is intended to give Canadians the opportunity to provide comments on its proposal to regulate *Salvia divinorum* and salvinorin A as controlled substances.
- The inclusion of *Salvia divinorum* and salvinorin A in Schedule III to the CDSA will make possession, trafficking, importation, exportation, and production (or cultivation) illegal unless authorized by regulation.

### **Supplementary Messages:**

- Canadians should not use products containing *Salvia divinorum* and/or salvinorin A because very little is known about these substances and their potential effects on the brain and body.
- The plant *Salvia divinorum* is not regulated under the CDSA and therefore it is not considered to be "banned", nor are activities with it considered to be illegal in Canada.
- However, as *Salvia divinorum* is a plant with hallucinogenic properties when consumed by humans, it meets the definition of a natural health product (NHP) under the *Natural Health Products Regulations* when marketed as a hallucinogen.
- To date, Health Canada has not authorized for sale any natural health products which contain *Salvia divinorum* as an ingredient. The sale of unauthorized

**DRAFT**  
19/01/2011

natural health products containing *Salvia divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

### Questions and Answers:

#### **Q1 – What is involved in regulating *Salvia divinorum* as a controlled substance and what stage is it at?**

A1 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada recently concluded its assessment of *Salvia divinorum* and salvinorin A against the aforementioned factors and proposes to include both substances in Schedule III to the CDSA. The first step in the process of regulating a substance under the CDSA is the publication of a *Notice to Interested Parties* (NOI) in *Canada Gazette*, Part I. Any comments received will be considered during the preparation of a regulatory proposal. There will be additional opportunities for comment as the federal regulatory process progresses.

The regulation of these products will reduce the potential risks to the health and safety of Canadians associated with their ready availability, with their increased use and their unknown effects. The scheduling of *Salvia divinorum* and salvinorin A will also eliminate the current perception that these substances are a safe alternative to other illegal drugs.

#### **Q2 – Are *Salvia divinorum* and/or salvinorin A controlled internationally? How are these substances regulated in other countries?**

A2 - Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions; as a result, they do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

The move to include *Salvia divinorum* and salvinorin A in Schedule III to the CDSA is consistent with actions taken by several countries (e.g., Australia, Belgium, Denmark,

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19/01/2011

Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Some individual U.S. states have implemented laws restricting their use, sale and/or distribution.

**Q3 – Is there any research on the use of *Salvia divinorum* in Canada?**

A3 - Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *Salvia divinorum* at least once in their lifetime, and that youth aged 15-24 were much more likely to have used it than adults aged 25 years and older. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *Salvia divinorum* in the past year. The *2009 Ontario Student Drug Use and Health Survey (OSDUHS)* indicated that 5.4% of Ontario students in grades 7-12 reported ever using *Salvia divinorum* and 4.4% of these students reported using this substance in the past year.

**Q4 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why isn't it illegal?**

A4 – Health Canada proposes to include *Salvia divinorum* and salvinorin A under Schedule III to the CDSA. Further to the regulation of these substances under the CDSA, the following activities will be illegal unless authorized by regulation: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation). Law enforcement agencies will also be able to take action against suspected illegal activities involving these substances.

As a plant with hallucinogenic properties, however, *Salvia divinorum* meets the definition of a natural health product under the *Natural Health Products Regulations (NHPR)* when marketed as a hallucinogen. To date, Health Canada has not authorized for sale any natural health products which contain *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products may be subject to compliance and enforcement action under the *Food and Drugs Act*.

**Q5 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A5 – Once *Salvia divinorum* and salvinorin A are included in Schedule III to the CDSA, law enforcement will be able to take appropriate action in response to suspected illegal activities with these substances.

Currently however, *Salvia divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement



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action by Health Canada. Complaints about the unauthorized sale of drugs containing *Salvia divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

**Q6 - Has Health Canada issued any kind of warning to Canadians about *Salvia divinorum*?**

A6 - Health Canada has developed an *It's Your Health* article about *Salvia divinorum* to help inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at:

**Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

Data from the 2008-2009 Youth Smoking Survey indicates that:

- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;
- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year; and
- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using *Salvia* in their lifetime (0.2% in the past year); and
- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that:

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;

**DRAFT**  
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- 5.4% of students (grades 7-12) ever used *Salvia divinorum*; and
- the use of *Salvia divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

**Prepared by:** Stephanie Chandler and Denis Arsenault, OCS, CSTD  
Reviewed and revised by: Christine Roush, Senior Communications  
Advisor, HECS, Communications

**Input by:** Lisa Mackay IYH/PACCB,  
Suzanne Desjardins HECSB/ODARS,  
Hanan Abramovici HECSB/ODARS,  
Bruna Brands HECSB/ODARS,  
Jocelyn Kula, HECSB/OCS,  
Robin Marles HPFB/NHPD,  
Maggie Graham HPFB/NHPD,  
Stephanie Collins HPFB/NHPD,  
Mano Murty HPFB/MHPD,  
Robert Leitch HPFB/MHPD,  
Shahid Perwaiz HPFB/MHPD,  
Collin Pinto, HPFB/HPFBI

**Approved by:**

Robin Marles, Director, Bureau of Clinical Trials, NHPD (pending)  
Lindsay Blaney, Director, Policy and Regulatory Affairs, NHPD (pending)  
Duc Vu, Director, Marketed Biologics, Biotechnology and Natural Health  
Products Bureau, MHPD (pending)  
Kim Dayman-Rutkas, Director, HPFBI (pending)  
Jocelyn Kula, A/Director, OCS, CSTD, HECS (Approved Jan 19, 2011)  
Suzanne Desjardins, Director, ODARS, CSTD, HECS (Pending)  
Cathy Sabiston, DG, CSTD, HECS (pending)  
Chris Turner, DG, MHPD (pending)  
Nancy Richards, DG, NHPD (pending)  
Diana Dowthwaite, DG, HPFBI (pending)  
Ken Polk, Communications Executive, HPFB (pending)  
Jean Tessier, Senior Media Relations, PACCB (pending)  
Warren Braun, Director, Strategic Communications, PACCB (pending)  
Peter Yendall, Director, Public Affairs, PACCB (pending)  
HECS Legal (pending)  
HPFB Legal (pending)  
Paul Glover, ADM, HECSB (pending)  
Meena Ballantyne, ADM, HPFB (pending)  
Anne Lamar, ADM, PACCB (pending)  
DMO (pending)  
MO (pending)  
PCO (pending)

**DRAFT**  
19/01/2011

**Re: Salvia Announcement** 

Cathy A Sabiston to: Dave Stephens

2011-01-19 03:07 PM

Cc: Christine Roush, Denis Arsenault, Jocelyn Kula, Nicole Prentice, Stephanie  
Chandler, Stephanie Szick, Jesse Arnup-Blondin

Sounds good  
Dave Stephens

----- Original Message -----

**From:** Dave Stephens  
**Sent:** 2011-01-19 03:06 PM EST  
**To:** Cathy A Sabiston  
**Cc:** Christine Roush; Denis Arsenault; Jocelyn Kula; Nicole Prentice;  
Stephanie Chandler; Stephanie Szick; Jesse Arnup-Blondin  
**Subject:** Re: Salvia Announcement

FYI: I have sent a note to DGO Comms, asking them to remind MO that this is just the first step in a very long process..... We'll need lots of Q's and A's to explain timelines going forward, if this event does take place.

Dave Stephens  
Senior Communications Executive-Gestionnaire Principal des Communications HECSB/DGSCSE  
6th Floor, Room 6-033, 269 Laurier Ave. W., Ottawa, ON  
Tel: (613) 946-8107  
Cell: (613) 859-3581

Cathy A Sabiston We shld also get the it's your health finalized an...

2011-01-19 03:03:17 PM

**From:** Cathy A Sabiston/HC-SC/GC/CA  
**To:** Christine Roush/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC  
**Cc:** Denis Arsenault/HC-SC/GC/CA@HWC, Nicole Prentice/HC-SC/GC/CA@HWC, Stephanie  
Chandler/HC-SC/GC/CA@HWC, Stephanie Szick/HC-SC/GC/CA@HWC, Dave  
Stephens/HC-SC/GC/CA@HWC  
**Date:** 2011-01-19 03:03 PM  
**Subject:** Re: Salvia Announcement

We shld also get the it's your health finalized and posted on launch day. Cas

Christine Roush

----- Original Message -----

**From:** Christine Roush  
**Sent:** 2011-01-19 02:59 PM EST  
**To:** Jocelyn Kula  
**Cc:** Denis Arsenault; Nicole Prentice; Stephanie Chandler; Stephanie Szick;  
Cathy A Sabiston; Dave Stephens  
**Subject:** Re: Salvia Announcement

Hi Jocelyn

We've been told that the Minister's office wants to do an event for the posting of the NOI for Salvia. We told MO the posting was going to happen on Friday, January 28th. I sent you yesterday the revised MLs, and am waiting on Stephanie C to get back with a complete answer to Q1. We have started drafting the News Release, and I can send you the first draft tomorrow am. I imagine there will be an MBU request for a teleconf at some point to discuss venue, partners, etc.

Christine Roush  
Senior Communications Advisor/

Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
Health Canada/Santé Canada  
Tel/Tél : (613) 954-0712/Cell: (613) 219-7194  
Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca

Stephanie Chandler	Hi Christine, We will work on that question, ho...	2011-01-18 04:58:22 PM
Christine Roush	Hi Stephanie, I have reviewed the MLs and mad...	2011-01-18 03:36:37 PM
Stephanie Chandler	Hi Christine, With regards to our earlier conver...	2011-01-18 02:53:10 PM

**Re: Salvia Announcement** 

Cathy A Sabiston to: Christine Roush, Jocelyn Kula

2011-01-19 03:02 PM

Cc: Denis Arsenault, Nicole Prentice, Stephanie Chandler, Stephanie Szick, Dave Stephens, Suzanne Desjardins

Thx Christine.

I think rapb and suzanne's group shld be involved in thinking thru "event"  
Christine Roush

----- Original Message -----

**From:** Christine Roush  
**Sent:** 2011-01-19 02:59 PM EST  
**To:** Jocelyn Kula  
**Cc:** Denis Arsenault; Nicole Prentice; Stephanie Chandler; Stephanie Szick; Cathy A Sabiston; Dave Stephens  
**Subject:** Re: Salvia Announcement

Hi Jocelyn

We've been told that the Minister's office wants to do an event for the posting of the NOI for Salvia. We told MO the posting was going to happen on Friday, January 28th. I sent you yesterday the revised MLs, and am waiting on Stephanie C to get back with a complete answer to Q1. We have started drafting the News Release, and I can send you the first draft tomorrow am. I imagine there will be an MBU request for a teleconf at some point to discuss venue, partners, etc.

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
Health Canada/Santé Canada  
Tel/Tél : (613) 954-0712/Cell: (613) 219-7194  
Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca

Stephanie Chandler	Hi Christine, We will work on that question, ho...	2011-01-18 04:58:22 PM
Christine Roush	Hi Stephanie, I have reviewed the MLs and mad...	2011-01-18 03:36:37 PM
Stephanie Chandler	Hi Christine, With regards to our earlier conver...	2011-01-18 02:53:10 PM

## Salvia divinorum

### Issue

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff, incense special, and salvia.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs. As of [REDACTED] 2011, Health Canada has not authorized for sale any products containing *S. divinorum*.

Deleted:

Deleted: 0

Health Canada recommends that you avoid using this plant because very little is known about the effects it may have on your body and/or brain functions. There is also no way to predict how it will affect you with each use.

Health Canada is proposing to regulate both *S. divinorum* and its main active ingredient salvinorin A under Schedule III to the *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth.

Deleted: 1

### Risks Associated with the Use of *Salvia divinorum*

*S. divinorum* is known to have both physical and mental effects. The effects of *S. divinorum*, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product
- how much is used
- the purity of the product (products that contain *S. divinorum* may be mixed with other substances)
- how it is taken, for example, whether the product is chewed, swallowed or smoked
- the user's mood and expectations

As a result of these concerns

While scientists know which brain receptors are targeted by the active ingredient, salvinorin A, very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or if it can cause permanent damage
- how it interacts with other substances, including other drugs, natural health products and alcohol
- the potential of *S. divinorum* to produce physical dependence and/or addiction.)

### Minimizing Your Risk

(Hallucinogens like *S. divinorum* work by modifying functions in the brain. Health Canada recommends that you avoid using *S. divinorum* because very little is known about the effects it may have on your body and/or brain functions. There is also no way to predict how it will affect you with each use.) Just because a drug is plant-based or "natural", does not mean that it is safe.

Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs, such as marijuana, cocaine, ecstasy, LSD and other substances that distort reality. See the "Need More Info?" section below for links to resources that can help you with this.

### Legal Status of *Salvia divinorum*

#### In Canada

Neither *S. divinorum* nor salvinorin A are currently regulated under the *Controlled Drugs and Substances Act* (CDSA). However, after reviewing the available information regarding these substances, Health Canada is proposing to add *S. divinorum* and its main active ingredient, salvinorin A, to Schedule III to the CDSA.

As *S. divinorum* is a plant with hallucinogenic properties when consumed by humans, it meets the definition of a natural health product (NHP) under the *Natural Health Products Regulations* when marketed as a hallucinogen. As of [redacted] 2011, Health Canada has not authorized for sale any natural health products which contain *S. divinorum* as an ingredient. The sale of unauthorized natural health products containing *S. divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

#### In Other Countries

Several countries including but not limited to Australia, Belgium, Germany, Italy, Japan, etc. have placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on their sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various

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Deleted: hallucinogenic properties, products containing <i>S. divinorum</i> or salvinorin A meet the definition of a Natural Health Product (NHP) in accordance with the <i>Natural Health Products Regulations</i> and the definition of a drug under the <i>Food and Drugs Act</i> . It is illegal to sell drugs or NHPs in Canada, unless they have been reviewed and authorized for sale by Health Canada. In the case of NHPs, they need to be labelled with one of the following:¶ a Natural Product Number (NPN); or¶ an Exemption Number (EN); or¶ a Drug Identification Number - Homeopathic Medicine Number (DIN-HM). ¶
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Deleted: As of [redacted] 2010 no products containing <i>S. divinorum</i> or salvinorin A have been authorized by Health Canada for sale. The sale of unauthorized drugs and NHPs is illegal, and may be subject to compliance and enforcement actions by the Department. ¶ Neither <i>S. divinorum</i> nor salvinorin A are currently regulated under the <i>Controlled Drugs and Substances Act</i> (CDSA). Health Canada is currently considering the available information to determine whether regulation as a controlled substance is warranted.¶



degrees, while others have placed restrictions on distribution. For example, In some states, for example, it is illegal for *S. divinorum* to be sold to anyone under the age of 18.

### Background

The leaves of this plant have been used traditionally by the Mazatec people for medicinal and mystical purposes.

Products that claim to contain *S. divinorum* or its main active ingredient, salvinorin A are widely available on the Internet and are sold in various "head shops" and natural food stores. The products are sold in a number of forms, including fresh or dried leaves, liquids or seeds and plant cuttings for growing purposes.

Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *S. divinorum* at least once in their lifetime, and that youth aged 15-24 were much more likely to have used it than adults aged 25 years and older. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *S. divinorum* in the past year. The *2009 Ontario Student Drug Use and Health Survey (OSDUHS)* indicated that 5.4% of Ontario students in grades 7-12 reported ever using *S. divinorum* and 4.4% of these students reported using this substance in the past year. For more information on these surveys, see the *Need More Info* section below.

### Health Canada's Role

Health Canada will continue to collect and consider safety information regarding *S. divinorum* and will continue to consult with key stakeholders including health officials in other countries and law enforcement officials here at home. Health Canada will also continue to move forward with its proposal to include *S. divinorum* and salvinorin A under Schedule III of the CDSA according to the Canadian regulatory process. The first step of this process was the issuance of the *Notice to Interested Parties (NOI)* to schedule these substances under the CDSA. In the interim, Health Canada will continue to monitor the sale of unauthorized health products, including those that contain *S. divinorum* or its main active ingredient salvinorin A, and will take appropriate action when the department becomes aware of any unauthorized health products that may pose a risk to Canadians.

### Need More Info?

- Complaints about the <sup>unauthorized</sup> illegal sale of drugs containing *S. divinorum* can be made to the **Health Products and Food Branch Inspectorate** at: [http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_44\\_consumer\\_consommateur\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_44_consumer_consommateur_cp-pc-eng.php)  
Tel: 1-800-267-9675.
- You can report any adverse reactions to the Canada Vigilance Program by one of the following three ways:

**Deleted:** Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, less than 2% of Canadians age 15 and older reported having used *S. divinorum* at least once in their lifetime. Youth, ages 15-24 were much more likely to have used it than adults. The results from the *Canadian 2008-2009 Youth Smoking Survey* show that 5% of 15yr olds have used *S. divinorum* in the past year.

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Report online at the MedEffect™ Canada website at: <http://www.hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>

Call toll-free at 1-866-234-2345

Complete a Canada Vigilance Reporting Form and either:

Fax toll-free to 1-866-678-6789

Mail to: Canada Vigilance Program

Health Canada

AL 0701C

Ottawa, ON K1A 0K9

To have postage pre-paid, download the postage paid label from the MedEffect™ Canada website. The Canada Vigilance Reporting Form and the adverse reaction reporting guidelines may also be obtained via this website at : [http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei\\_form-eng.php](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei_form-eng.php)

- For information about the Government of Canada's Anti-Drug Strategy, go to: [www.nationalantidrugstrategy.gc.ca/](http://www.nationalantidrugstrategy.gc.ca/)  
The Prevention section on this site has a number of helpful resources for parents, including:
  - **Tips on Talking to Your Teenager**, at: [www.hc-sc.gc.ca/hc-ps/pubs/adp-adp/talk-aborder/index-eng.php](http://www.hc-sc.gc.ca/hc-ps/pubs/adp-adp/talk-aborder/index-eng.php)
  - **What to Do if Your Teen is Using Drugs**, at: [www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html](http://www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html)
  - Health Canada's **Not4Me** youth drug prevention section at: <http://www.hc-sc.gc.ca/hc-ps/drugs-drogues/youth-jeunes/facts-faits/index-eng.php>
- Information on natural health products and the Natural Health Products Regulations can be found at: [www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php)

For more on the surveys that have collected information about *Salvia divinorum* use in Canada, see:

- **The 2008-2009 Youth Smoking Survey**, at: <http://www.yss.uwaterloo.ca/index.cfm?section=5&page=288>
- **The 2009 Canadian Alcohol and Drug Use Monitoring Survey**, at: <http://www.hc-sc.gc.ca/hc-ps/drugs-drogues/stat/index-eng.php>
- **The 2009 Ontario Student Drug Use and Health Survey**, at: [http://www.camh.net/News\\_events/News\\_releases\\_and\\_media\\_advisories\\_and\\_b\\_ackgrounders/osduhs2009\\_advisory.html](http://www.camh.net/News_events/News_releases_and_media_advisories_and_b_ackgrounders/osduhs2009_advisory.html)

Additional Resources:

- U.S. Drug Enforcement Administration: **Drugs and Chemicals of Concern: *Salvia divinorum* and Salvinorin A** at: [www.dea.gov/diversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.dea.gov/diversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)

- U.S. Department of Health & Human Services, **National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006** at:  
[www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf](http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf)
- For additional articles on health and safety issues go to the **It's Your Health** web section at: [www.healthcanada.gc.ca/iyh](http://www.healthcanada.gc.ca/iyh)

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

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PACCB IYH - Lisa Mackay: 613-954-0105 – [Lisa.Mackay@hc-sc.gc.ca](mailto:Lisa.Mackay@hc-sc.gc.ca)

Comments from: HECSB - CSTD (OCS&ODARS) & HPFB – NHPD, MHPD & HPFBI

Contacts: HECSB: Jocelyn Kula, Stephanie Chandler, Suzanne Desjardin, Denis Arsenault, Hanan Abramovici, Bruna Brands  
HECSB comms: Christine Roush, Bronwyn Cline  
HPFB-NHPD: Valerie Hurry, Robin Marles, Maggie Graham, Stephanie Collins  
HPFB-MHPD: Scott Jordan, Robert Leitch, Mano Murty, Shahid Perwaiz  
HPFBI : Collin Pinto  
HPFB comms: Elizabeth Keeping, Blossom Leung

## Salvia divinorum

### Issue

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff, incense special, and salvia.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs. As of [REDACTED] 2011, Health Canada has not authorized for sale any products containing *S. divinorum*.

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Health Canada recommends that you avoid using this plant because very little is known about the effects it may have on your body and/or brain functions. There is also no way to predict how it will affect you with each use.

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Canadian surveillance data and scientific reports have indicated that *S. divinorum* has the potential for abuse. As a result, Health Canada is proposing to regulate both *S. divinorum* and its main active ingredient salvinorin A under Schedule III to the *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth.

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### Risks Associated with the Use of *Salvia divinorum*

*S. divinorum* is known to have both physical and mental effects. The effects of *S. divinorum*, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product
- how much is used
- the purity of the product (products that contain *S. divinorum* may be mixed with other substances)

- how it is taken, for example, whether the product is chewed, swallowed or smoked
- the user's mood and expectations

While scientists know which brain receptors are targeted by the active ingredient, salvinorin A, very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or if it can cause permanent damage
- how it interacts with other substances, including other drugs, natural health products and alcohol
- the potential of *S. divinorum* to produce physical dependence and/or addiction

### Minimizing Your Risk

Hallucinogens like *S. divinorum* work by modifying functions in the brain. Health Canada recommends that you avoid using *S. divinorum* because very little is known about the effects it may have on your body and/or brain functions. There is also no way to predict how it will affect you with each use. Just because a drug is plant-based or "natural", does not mean that it is safe.

Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs, such as marijuana, cocaine, ecstasy, LSD and other substances that distort reality. See the "Need More Info?" section below for links to resources that can help you with this.

### Legal Status of *Salvia divinorum*

#### In Canada

Neither *S. divinorum* nor salvinorin A are currently regulated under the *Controlled Drugs and Substances Act (CDSA)*. However, after reviewing the available information regarding these substances, Health Canada is proposing to add *S. divinorum* and its main active ingredient, salvinorin A, to Schedule III to the CDSA.

Nevertheless, as *S. divinorum* is a plant with hallucinogenic properties when consumed by humans, it meets the definition of a natural health product (NHP) under the *Natural Health Products Regulations* when marketed as a hallucinogen. As of [redacted] 2011, Health Canada has not authorized for sale any natural health products which contain *S. divinorum* as an ingredient. The sale of unauthorized natural health products containing *S. divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

#### In Other Countries

Several countries including but not limited to Australia, Belgium, Germany, Italy and Japan, have placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A.

*More Comment to ISSUP section*

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**Deleted:** As of [redacted] 2010 no products containing *S. divinorum* or *salvinorin A* have been authorized by Health Canada for sale. The sale of unauthorized drugs and NHPs is illegal, and may be subject to compliance and enforcement actions by the Department. ¶

¶ Neither *S. divinorum* nor salvinorin A are currently regulated under the *Controlled Drugs and Substances Act (CDSA)*. Health Canada is currently considering the available information to determine whether regulation as a controlled substance is warranted. ¶

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In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on their sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution. ~~For example,~~ <sup>for example,</sup> in some states, it is illegal for *S. divinorum* to be sold to anyone under the age of 18.

### Background

The leaves of this plant have been used traditionally by the Mazatec people for medicinal and mystical purposes.

Products that claim to contain *S. divinorum* or its main active ingredient, salvinorin A are widely available on the Internet and are sold in various "head shops" and natural food stores. The products are sold in a number of forms, including fresh or dried leaves, liquids or seeds and plant cuttings for growing purposes.

Results from the Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *S. divinorum* at least once in their lifetime, and that youth aged 15-24 were much more likely to have used it than adults aged 25 years and older. The results from the Canadian 2008-2009 Youth Smoking Survey also show that 5% of 15 year olds have used *S. divinorum* in the past year. The 2009 Ontario Student Drug Use and Health Survey (OSDUHS) indicated that 5.4% of Ontario students in grades 7-12 reported ever using *S. divinorum* and 4.4% of these students reported using this substance in the past year. For more information on these surveys, see the *Need More Info* section below.

### Health Canada's Role

<sup>potential</sup>  
In light of the health and safety risks associated with the use of *S. divinorum*, Health Canada proposes to include *S. divinorum* and salvinorin A under Schedule III of the CDSA. As a first step in the process of regulating these substances, Health Canada issued a *Notice to Interested Parties (NOI)* outlining its proposal to schedule these substances under the CDSA. In the interim, Health Canada will continue to monitor the sale of unauthorized health products, including those that contain *S. divinorum* or its main active ingredient salvinorin A, and will take appropriate action when the department becomes aware of any unauthorized health products that may pose a risk to Canadians.

### Need More Info?

- Complaints about the unauthorized sale of drugs containing *S. divinorum* can be made to the **Health Products and Food Branch Inspectorate** at: [http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_44\\_consumer\\_consommateur\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_44_consumer_consommateur_cp-pc-eng.php)  
Tel: 1-800-267-9675.

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- You can report any adverse reactions to the Canada Vigilance Program by one of the following three ways:  
Report online at the MedEffect™ Canada website at: <http://www.hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>  
Call toll-free at 1-866-234-2345  
Complete a Canada Vigilance Reporting Form and either:  
Fax toll-free to 1-866-678-6789  
Mail to: Canada Vigilance Program  
Health Canada  
AL 0701C  
Ottawa, ON K1A 0K9  
To have postage pre-paid, download the postage paid label from the MedEffect™ Canada website. The Canada Vigilance Reporting Form and the adverse reaction reporting guidelines may also be obtained via this website at : [http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei\\_form-eng.php](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei_form-eng.php)
- For information about the Government of Canada's Anti-Drug Strategy, go to: [www.nationalantidrugstrategy.gc.ca/](http://www.nationalantidrugstrategy.gc.ca/)  
The Prevention section on this site has a number of helpful resources for parents, including:
  - **Tips on Talking to Your Teenager**, at: [www.hc-sc.gc.ca/hc-ps/pubs/adp-adp/talk-aborder/index-eng.php](http://www.hc-sc.gc.ca/hc-ps/pubs/adp-adp/talk-aborder/index-eng.php)
  - **What to Do if Your Teen is Using Drugs**, at: [www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html](http://www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html)
  - Health Canada's **Not4Me** youth drug prevention section at: <http://www.hc-sc.gc.ca/hc-ps/drugs-drogues/youth-jeunes/facts-faits/index-eng.php>
- Information on natural health products and the Natural Health Products Regulations can be found at: [www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php)

For more on the surveys that have collected information about *Salvia divinorum* use in Canada, see:

- **The 2008-2009 Youth Smoking Survey**, at: <http://www.yss.uwaterloo.ca/index.cfm?section=5&page=288>
- **The 2009 Canadian Alcohol and Drug Use Monitoring Survey**, at: <http://www.hc-sc.gc.ca/hc-ps/drugs-drogues/stat/index-eng.php>
- **The 2009 Ontario Student Drug Use and Health Survey**, at: [http://www.camh.net/News\\_events/News\\_releases\\_and\\_media\\_advisories\\_and\\_b\\_ackgrounders/osduhs2009\\_advisory.html](http://www.camh.net/News_events/News_releases_and_media_advisories_and_b_ackgrounders/osduhs2009_advisory.html)

**Additional Resources:**

- U.S. Drug Enforcement Administration: **Drugs and Chemicals of Concern: *Salvia divinorum* and Salvinorin A** at: [www.dea.gov/diversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.dea.gov/diversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)

- U.S. Department of Health & Human Services, **National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006** at:  
[www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf](http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf)
- For additional articles on health and safety issues go to the ***It's Your Health*** web section at: [www.healthcanada.gc.ca/iyh](http://www.healthcanada.gc.ca/iyh)

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

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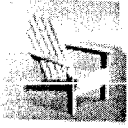
Version/date: Draft 17. September 8, 2010.

PACCB IYH - Lisa Mackay: 613-954-0105 – [Lisa.Mackay@hc-sc.gc.ca](mailto:Lisa.Mackay@hc-sc.gc.ca)

Comments from: HECSB - CSTD (OCS&ODARS) & HPFB – NHPD, MHPD & HPFBI

Contacts: HECSB: Jocelyn Kula, Stephanie Chandler, Suzanne Desjardin, Denis  
Arsenault, Hanan Abramovici, Bruna Brands  
HECSB comms: Christine Roush, Bronwyn Cline  
HPFB-NHPD: Valerie Hurry, Robin Marles, Maggie Graham, Stephanie  
Collins  
HPFB-MHPD: Scott Jordan, Robert Leitch, Mano Murty, Shahid Perwaiz  
HPFBI : Collin Pinto  
HPFB comms: Elizabeth Keeping, Blossom Leung





**Salvia IYH**

Nicole Prentice to: Jocelyn Kula, Denis Arsenault, Stephanie  
Chandler

2011-01-19 04:29 PM

Cc: Christine Roush, CSTD-OCS-DO

Hi all,

Since the Minister's office now wants to have an event on Jan 28 for the publication of the NOI for Salvia, Cathy has asked that we push along the IYH. It will need to be posted to the website with the news release on Jan 28, probably early morning depending on the time of the event. This leaves us a week to update, share with HPFB, get all approvals and get translated , so we will need your input asap.

This is the latest version I have on hand of the IYH. Can you and your team please take a look at the content and provide input asap (Jan 20 COB or by noon Jan 21 at the latest).

Thanks in advance and sorry for the short time line.

Nicole



IYH Salvia divinatorum\_v18 clean Oct 1.doc

**Nicole Prentice**

Junior Communications Officer | Agente junior des Communications  
Regulatory Communications and Media Relations Division | Division des communications  
réglementaires et des relations avec les médias  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires  
publiques, de la consultation et des communications  
Health Canada | Santé Canada  
Tel: 613.941.3107  
Fax: 613.948.8085



**QUESTION PERIOD NOTE**  
**NOTE POUR LA PÉRIODE DE**  
**QUESTIONS**

Date:	January 19, 2011
Classification:	HECS PROTECTED - SESC PROTÉGÉ

**SUBJECT - SUJET**

English:

**DRUGS - SALVIA DIVINORUM**

Français:

**DROGUES - SALVIA DIVINORUM**

**SYNOPSIS - SOMMAIRE**

English:

Media interest in Salvia divinorum is recurrent. Questions around this substance generally focus on its legality. Recently, a number of media reports have commented on a YouTube video which reportedly shows the young celebrity Miley Cyrus smoking Salvia divinorum. Canadian surveillance data indicates that this substance is being used by adolescents and young adults for its hallucinogenic properties, and there have also been several reports from scientific sources indicating that Salvia divinorum has the potential for abuse.

**ANTICIPATED QUESTION - QUESTION PRÉVUE**

English:

What is Health Canada doing to protect young Canadians from the potential adverse effects associated with the use of Salvia divinorum?

Français:

Quelles mesures Santé Canada prend-il pour protéger les jeunes Canadiens contre les effets indésirables possibles liés à l'utilisation de la Salvia divinorum?

---

English:

- Health Canada is proposing to regulate Salvia under the ~~Controlled Drugs and Substances Act~~ in order to protect the health and safety of Canadians, particularly youth.
- Health Canada has published a *Notice to Interested Parties* in *Canada Gazette*, Part I, to give Canadians the opportunity to provide comments on its proposal to regulate Salvia.
- The regulation of Salvia will make possession, trafficking, importation, exportation, and production illegal unless authorized by regulation.

Français:

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## BACKGROUND - CONTEXTE

English:

### BACKGROUND / CONTEXTE

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, diviner's sage, magic mint, and puff. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs.

Both the plant *S. divinorum* and its main active ingredient salvinorin A are known to have physical and mental effects which are often described as unpleasant, including:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination

- slurred speech and awkward sentence patterns

Recent surveys indicate that Canadian youth are trying this substance which could be dangerous to their health. Results from the *Canadian Alcohol and Drug Use Monitoring Survey* (CADUMS) reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *Salvia divinorum* at least once in their lifetime, and that youth aged 15-24 were much more likely to have used it than adults aged 25 years and older. The results from the Canadian 2008-2009 *Youth Smoking Survey* also show that 5% of 15 year olds have used *Salvia divinorum* in the past year. The 2009 *Ontario Student Drug Use and Health Survey* (OSDUHS) indicated that 5.4% of Ontario students in grades 7-12 reported ever using *Salvia divinorum* and 4.4% of these students reported using this substance in the past year.

#### International Control of *S. divinorum*

Neither *Salvia divinorum* nor its main active ingredient salvinorin A are listed under the United Nations Drug Control Conventions; as a result, they do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions. The move to include *Salvia divinorum* and salvinorin A in Schedule III to the CDSA is consistent with actions taken by several countries (e.g. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Some individual U.S. states have also implemented laws restricting their use, sale and/or distribution.

#### Current Situation in Canada

Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted, namely:

- International requirements and trends in control and/or scheduling;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e. therapeutic, scientific, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada recently concluded its assessment of *S. divinorum* and its main active ingredient salvinorin A against the aforementioned factors and now proposes to include both substances in Schedule III to the CDSA.

The regulation of *Salvia divinorum* will allow law enforcement to take action against illegal activities involving this substance. The possession, trafficking, importation, exportation and production of *Salvia divinorum* and salvinorin A will be illegal unless authorized by regulation.

The plant *Salvia divinorum* is not currently regulated under the *Controlled Drugs and Substances Act* (CDSA) and therefore the plant is not considered to be "banned" nor are activities with it considered to be illegal in Canada. However, as *Salvia divinorum* is a plant with hallucinogenic properties when consumed by humans, it meets the definition of a natural health product (NHP) under the *Natural Health Products Regulations* when marketed as a hallucinogen. To date, Health Canada has not licensed for sale any natural health product which contains *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products containing *Salvia divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

ATTACHMENTS / PIÈCE(S)-JOINTE(S)

Contact/Personne ressource : Denis Arsenault/HC-SC/GC/CA	Tel. no./No de tél. 613-957-6828	Approved by/ Approuvé par Paul Glover, ADM (HECS/SESC)	Tel. no./No. de tél. 946-6701
	Mobile/ Cellulaire: 613-296-4239	Title/ Titre:	Mobile/ Cellulaire:
Alternate/ Secondaire: Jocelyn Kula	Telephone/ Téléphone: 613-952-2177		
	Mobile/ Cellulaire: 613-797-2103		

**Date Prepared/Préparé le :** 2010-09-07

**Prepared by/Préparé par :** Stephanie Chandler **Phone/ No de tél. :** 613-946-0124

**Office/Bureau :** CSTD - Office of Controlled Substances

**Date Contact Signed/  
Signature de la personne  
ressource :**

Contact Signed - Signé

**D.G. Verification/  
Vérification par le D.E. :**

Cathy Sabiston

D.G. Approved / Approuvé D.E.

**Date D.G. Verified/  
Date vérifié par le D.E. :**

**Programme :** Controlled Substances and Tobacco Directorate

**ADM Approved/ Approbation  
par le SMA :** Paul Glover  
(946-6701)

**Branch/ Direction générale :** HECS/SESC

**Department/ Ministère :** Health Canada / Santé Canada

letter to stakeholders  
for review  
prior to translation  
The  
Stephanie

Dear Sir/Madam:

The purpose of this email is to advise you that a *Notice of Intent* regarding the following substances was published in the *Canada Gazette*, Part I (CGI) on January 29, 2011:

- *Salvia divinorum*
- Salvinorin A

The electronic version of the NOI is available at the following website:  
<http://canadagazette.gc.ca/> pages xx-xx in PDF format (pages xxxx-xxxx in *Canada Gazette*, Part I).

This NOI <sup>indicates</sup> Health Canada's <sup>proposal</sup> intent to include *Salvia divinorum* and salvinorin A in Schedule III to the *Controlled Drugs and Substances Act* (CDSA). In particular, Health Canada is seeking further information from stakeholders as to whether these substances have any legitimate industrial, scientific or medical uses in Canada. Information received in response to this notice will be instrumental in determining ~~appropriate scheduling under the CDSA~~ <sup>regulatory controls.</sup>

If you are interested in this process or wish to provide us with information for our consideration please do so by February 28, 2011. You may send your comments to Stephanie Chandler, Regulatory Policy Division, Office of Controlled Substances, Address Locator: 3503D, 123 Slater St., Ottawa, Ontario, Canada K1A 1B9, by fax at (613) 946-4224 or by email to [OCS\\_Policy\\_and\\_Regulatory\\_Affairs@hc-sc.gc.ca](mailto:OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca).

PLEASE FORWARD THIS EMAIL TO OTHERS WHO MAY BE INTERESTED.

Should this notification have reached you in error, it would be appreciated if you could please forward it to the appropriate person in your organization and ask that person to inform us of this by sending an e-mail to: [OCS\\_Policy\\_and\\_Regulatory\\_Affairs@hc-sc.gc.ca](mailto:OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca).

Thank you,

Regulatory Policy Division  
Office of Controlled Substances  
Drug Strategy and Controlled Substances Directorate  
Healthy Environments and Consumer Safety Branch

Address Locator: 3503D  
Ottawa ON K1A 0K9

11-xxxxxx-xxx

Josée Boisvert  
A/Manager, Editing Services  
Canada Gazette Directorate  
Government of Canada  
350 Albert Street, 5th Floor  
Ottawa, Ontario  
K1A 0S5

Dear Ms. Boisvert:

Re: **Notice to Interested Parties - Proposal regarding the addition of *Salvia divinorum* and salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA).**

Please find enclosed, in both official languages, the following documents:

- two hard copies of a Notice to Interested Parties regarding these substances;
- electronic copies of the notice, English and French versions in two separate files; and
- a signed and completed "Request for Insertion" form.

We ask that the notice be published in *Canada Gazette*, Part I, on January 29, 2011. The departmental contact for this notice is Stephanie Chandler, who can be reached at 613-946-0124.

Yours sincerely,

Jocelyn Kula  
A/Director  
Office of Controlled Substances  
Controlled Substances and Tobacco Directorate

Attachments



**Re: Salvia Media Lines**  
Christine Roush to: Stephanie Chandler  
Cc: Nicole Prentice

2011-01-20 09:58 AM

Thanks Stephanie.

Christine Roush  
Senior Communications Advisor/

Stephanie Chandler Thanks! FYI The revised IYH is currently with... 2011-01-20 09:24:41 AM

From: Stephanie Chandler/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Cc: Nicole Prentice/HC-SC/GC/CA@HWC  
Date: 2011-01-20 09:24 AM  
Subject: Re: Salvia Media Lines

Thanks!

FYI The revised IYH is currently with Denis for review. Will forward once Jocelyn has approved.

Stephanie

Christine Roush	Thanks Stephanie - we have communication co...	2011-01-19 04:49:12 PM
Stephanie Chandler	Hi Christine, Here are the revised media lines...	2011-01-19 03:39:45 PM
Christine Roush	HPFB will need to approve the lines and we can...	2011-01-18 05:07:42 PM
Stephanie Chandler	Hi Christine, We will work on that question, ho...	2011-01-18 04:58:22 PM
Christine Roush	Hi Stephanie, I have reviewed the MLs and mad...	2011-01-18 03:36:37 PM
Stephanie Chandler	Hi Christine, With regards to our earlier conver...	2011-01-18 02:53:10 PM





**Re: Draft email to stakeholders re: Salvia NOI** 

Jocelyn Kula to: Stephanie Chandler  
Cc: CSTD-OCS-DO, Denis Arsenault

2011-01-20 10:17 AM

---

History: This message has been forwarded.

looks good to me; assume is very like what we have done in the past....will forward on to Christine Roush and Stephanie Szick as an FYI

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

---

Stephanie Chandler Hi Jocelyn, I have drafted the following email t... 2011-01-20 09:28:14 AM

From: Stephanie Chandler/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC, CSTD-OCS-DO  
Date: 2011-01-20 09:28 AM  
Subject: Draft email to stakeholders re: Salvia NOI

---

Hi Jocelyn,

I have drafted the following email to send to our stakeholders through SIMS once the NOI is posted. Denis has approved.

For your review.



Stakeholder notification of NOI Jan 19 2011 EN.wpd

Thanks,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

Dear Sir/Madam:

The purpose of this email is to advise you that a *Notice of Intent to Interested Parties* (NOI) regarding the following substances was published in the *Canada Gazette*, Part I (CGI) on January 29, 2011:

- *Salvia divinorum*
- Salvinorin A

The electronic version of the NOI is available at the following website:

<http://canadagazette.gc.ca/> pages xx-xx in PDF format (pages xxxx-xxxx in *Canada Gazette*, Part I).

This NOI outlines Health Canada's proposal to include *Salvia divinorum* and salvinorin A in Schedule III to the *Controlled Drugs and Substances Act* (CDSA). In particular, Health Canada is seeking further information from stakeholders as to whether these substances have any legitimate industrial, scientific or medical uses in Canada. Information received in response to this notice will be instrumental in determining appropriate regulatory controls.

If you are interested in this process or wish to provide us with information for our consideration please do so by February 28, 2011. You may send your comments to Stephanie Chandler, Regulatory Policy Division, Office of Controlled Substances, Address Locator: 3503D, 123 Slater St., Ottawa, Ontario, Canada K1A 1B9, by fax at (613) 946-4224 or by email to [OCS\\_Policy\\_and\\_Regulatory\\_Affairs@hc-sc.gc.ca](mailto:OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca).

PLEASE FORWARD THIS EMAIL TO OTHERS WHO MAY BE INTERESTED.

Should this notification have reached you in error, it would be appreciated if you could please forward it to the appropriate person in your organization and ask that person to inform us of this by sending an e-mail to: [OCS\\_Policy\\_and\\_Regulatory\\_Affairs@hc-sc.gc.ca](mailto:OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca).

Thank you,

Regulatory Policy Division  
Office of Controlled Substances  
Drug Strategy and Controlled Substances Directorate  
Healthy Environments and Consumer Safety Branch



**Fw: Issues Mgmt Table - Salvia**  
Jocelyn Kula to: Stephanie Chandler

2011-01-20 10:26 AM

for the file

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224  
----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2011-01-20 10:26 AM -----

---

From: Stephanie Szick/HC-SC/GC/CA  
To: Cathy A Sabiston/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC  
Date: 2011-01-12 03:34 PM  
Subject: Fw: Issues Mgmt Table - Salvia

---

hi both,  
Per below -- Ruth can proceed to send her memo to PMO.

Jocelyn - will you let Ruth know....and, any luck yet on getting a copy?

Thanks,  
Stephanie

----- Forwarded by Stephanie Szick/HC-SC/GC/CA on 2011-01-12 03:32 PM -----

---

From: Jesse Arnup-Blondin/HC-SC/GC/CA  
To: Stephanie Szick/HC-SC/GC/CA@HWC  
Date: 2011-01-12 03:23 PM  
Subject: Re: Issues Mgmt Table - Salvia

---

Paul mentioned this when Cathy was here, but he is fine with PCO sending to PMO - he says that is their call, and we don't need to check with MO.

---

Stephanie Szick Well, that's good news. Thanks for checking Jes... 2011-01-12 12:16:51 PM

---

From: Stephanie Szick/HC-SC/GC/CA  
To: Jesse Arnup-Blondin/HC-SC/GC/CA@HWC  
Date: 2011-01-12 12:16 PM  
Subject: Re: Issues Mgmt Table - Salvia

---

Well, that's good news. Thanks for checking Jesse.

That approach makes sense. Let us know how it goes.

I'll flag to Cathy and Jocelyn.

---

Jesse Arnup-Blondin Turns out - it has gone to MO. It just wasn't ro... 2011-01-12 11:58:14 AM



**Fw: Note for PCO re salvia**  
Jocelyn Kula to: Stephanie Chandler

2011-01-20 10:27 AM

for the file

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224  
----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2011-01-20 10:27 AM -----

From: Stephanie Szick/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Cathy A Sabiston/HC-SC/GC/CA@HWC, CSTD-DGO  
Date: 2011-01-05 03:00 PM  
Subject: Note for PCO re salvia

---

hi Jocelyn,

Following up on the trail below --- Paul approved the Salvia note with v. minor edits, and this morning DMO gave nod for us to share that version of the note with Ruth in PCO. For quick grab, I've attached here the Paul approved version of the note from MECS.

Further to Ruth's emails last week and your conversation with her, please send this briefing note to Ruth, with a cc to Cathy.

Thanks very much!



10-127340-194REVINMBUJAN5.wpd  
Stephanie Szick

Director General's Office / Bureau du directeur général  
Controlled Substances & Tobacco Directorate (CSTD) /  
Direction des substances contrôlées et de la lutte au tabagisme (DSCLT)  
Health Canada / Santé Canada  
Tel / Tél: (613) 948-8651

----- Forwarded by Stephanie Szick/HC-SC/GC/CA on 2011-01-05 02:31 PM -----

From: Jesse Arnup-Blondin/HC-SC/GC/CA  
To: stephanie.szick@hc-sc.gc.ca  
Date: 2011-01-05 11:18 AM  
Subject: Fw: Note for PCO re salvia

---

Just spoke to DMO - okay to share with PCO.

Thanks!

----- Forwarded by Jesse Arnup-Blondin/HC-SC/GC/CA on 2011-01-05 11:18 AM -----

From: Jesse Arnup-Blondin/HC-SC/GC/CA  
To: Stephanie Szick/HC-SC/GC/CA@HWC  
Date: 2011-01-05 11:00 AM  
Subject: Re: Note for PCO re salvia

The revised document would be in MECS. DMO is looking at it right now - it would be preferable to wait until they have had a chance to review before we send to PCO just in case there are any show-stoppers. Will advise later this afternoon.

From: Stephanie Szick/HC-SC/GC/CA  
To: Jesse Arnup-Blondin/HC-SC/GC/CA@HWC  
Date: 2011-01-05 10:16 AM  
Subject: Re: Note for PCO re salvia

hi Jesse

Hope you had a relaxing holiday!

Back at it today.

What were the changes...can you send that version?

Also, Cathy wondering if we could send to Ruth now....with caveat it's in approvals. We provided her with the IAS last week. I will send you an email now re: summary of Jocelyn's conversation with Ruth...

From: Jesse Arnup-Blondin/HC-SC/GC/CA  
To: stephanie.szick@hc-sc.gc.ca  
Date: 2011-01-04 01:09 PM  
Subject: Note for PCO re salvia

Paul signed off on the note today with a few minor edits. Once it arrives in MO (that is, once it has been DM approved), CSTD can send that version to PCO.

Let me know if there are any questions - I know there was a bit of confusion last week about the best process for this.

Jesse

10-127340-194

## BRIEFING NOTE TO THE MINISTER'S OFFICE

### Regulatory Status of *Salvia divinorum* in Canada

#### ISSUE:

To provide information regarding the regulatory status of *Salvia divinorum* in Canada.

#### BACKGROUND:

*Salvia divinorum* is a species of sage belonging to the mint family. While uncertainty remains surrounding the health risks of the plant *Salvia divinorum* and its main active ingredient salvinorin A, physical and mental effects are reported to include hallucinations, out-of-body experiences, uncontrollable laughter, short-term memory loss, and loss of consciousness.

Media interest surrounding *Salvia divinorum* is recurrent. Questions regarding this substance generally focus on its legality. Recently, a number of media reports have commented on a YouTube video which reportedly shows a young Hollywood celebrity smoking *Salvia divinorum*. There have also been several reports from scientific and media sources indicating that *Salvia divinorum* has the potential for abuse, and is being used by adolescents and young adults for its hallucinogenic properties.

#### CURRENT STATUS:

Results from the 2009 *Canadian Alcohol and Drug Use Monitoring Survey* (CADUMS) reveal that 1.6% of Canadians aged 15 years and older reported having used *Salvia divinorum* at least once in their lifetime, and that youth aged 15 to 24 were much more likely to have used it than adults aged 25 years and older. Among respondents aged 15 years and older, 0.2% reported having used *Salvia divinorum* in the past year, compared to 0.7% having reported using other illicit hallucinogens such as lysergic acid diethylamide (LSD) and phencyclidine (PCP). In addition, the results from the 2008-2009 *Youth Smoking Survey* also show that 5% of 15-year-olds have used *Salvia divinorum* in the past 12 months, compared to 6.9% who indicated that they had used other hallucinogens in the last 12 months. Moreover, the 2009 *Ontario Student Drug Use and Health Survey* (OSDUHS)

- 2 -

indicated that 5.4% of Ontario students in grades 7-12 reported ever using *Salvia divinorum* and 4.4% of those students reported using this substance in the past year. By way of comparison, only 2.4% of students reported using LSD in their lifetime while 6.3% of students reported using other hallucinogens (not including LSD or phencyclidine).

Neither *Salvia divinorum* nor its active ingredient salvinorin A are listed under the United Nations Drug Control Conventions. As a result, they do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these conventions. Several countries, e.g. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden, as well as some individual American States, have however placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A.

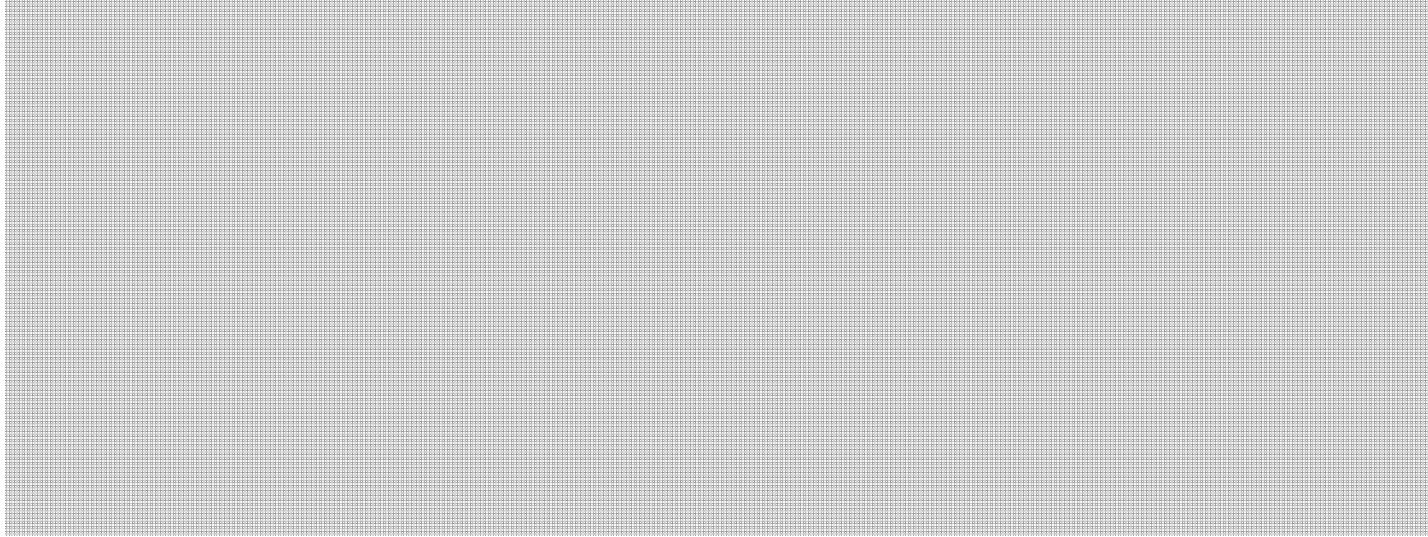
At present, the plant *Salvia divinorum* is not regulated under the *Controlled Drugs and Substances Act* (CDSA) and therefore the plant is not considered to be “banned,” nor are activities with it considered to be illegal in Canada. Nevertheless, when specifically marketed for its hallucinogenic properties, *Salvia divinorum* meets the definition of a natural health product under the *Natural Health Products Regulations*. Health Canada has not authorized for sale any natural health products containing *Salvia divinorum* or salvinorin A as an ingredient. However, to date most *Salvia divinorum* products consumed for recreational purposes appear to be sold as “incense.”

While the sale of unauthorized natural health products containing *Salvia divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act* (FDA), the penalties applicable to incidences of unauthorized sale under the FDA are very low and would likely not deter a retailer from continuing to market unauthorized products.

It is because of this and the surveillance data indicating that there is an interest in *Salvia divinorum* among youth that the Department is now proposing to add *Salvia divinorum* and salvinorin A to Schedule III to the CDSA. This action will reduce the potential health and safety risks associated with the ready availability, increased use and unknown effects of these substances and will thus protect the health and safety of Canadians, particularly youth. The Issue Analysis Summary included in Appendix A summarizes the scheduling assessment on *Salvia divinorum*.



**CONCLUSION:**



---


Deputy Minister's Office

MECS #10-127340-194

Branch Head: Paul Glover, ADM, HECSB  
Telephone: 613-946-6701

Attachment  
Appendix A - Draft Issue Analysis Summary



**Re: Salvia Media Lines**   
Christine Roush to: Stephanie Chandler  
Cc: Denis Arsenault, Jocelyn Kula, Nicole Prentice

2011-01-20 02:34 PM

Stephanie,  
Here is the first draft of the news release for your review and comments. Please let me know at your soonest if you have any changes.

thx.



Salvia NR\_Jan 20\_V3\_2h30(revcr).doc

Christine Roush  
Senior Communications Advisor/

Stephanie Chandler Hi Christine, Here are the revised media lines... 2011-01-19 03:39:45 PM

From: Stephanie Chandler/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Nicole Prentice/HC-SC/GC/CA@HWC  
Date: 2011-01-19 03:39 PM  
Subject: Re: Salvia Media Lines

---

Hi Christine,

Here are the revised media lines approved by Jocelyn.



Salvia Media Lines\_Jan 19 2011.doc

In addition, here is the most recent draft of the NOI. Please note neither the MLs or the NOI have been approved by DGO.



DRAFT Salvia NOI\_Jan 19.wpd

OCS has a list of stakeholders who will be notified that the NOI has been posted. However, contacts from the RCMP or Justice who would benefit from having a heads up prior to the posting would most likely be from their respective communication departments, in which I do not have any contacts. Do you or your group have any contacts in these areas?

Thanks,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées

Health Canada

2010-XX

# News Release

## The Government of Canada Proposes to Regulate *Salvia Divinorum* and Salvinorin A as Controlled Substances

January 28, 2011  
For immediate release

OTTAWA – Today, the Honourable Leona Aglukkaq, Minister of Health released a Notice to Interested Parties, also known as a Notice of Intent, in the *Canada Gazette*, Part I, on the proposal to regulate *Salvia divinorum* and salvinorin A, known as *Salvia*, as controlled substances.

This notice will provide interested stakeholders with the opportunity to comment on Health Canada's proposal to add the plant *Salvia divinorum* (*S. divinorum*) and its main active ingredient salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA).

"After reviewing available information and reports that suggest this substance has the potential for abuse, especially among young people, we are taking these steps to protect the health and safety of Canadians, particularly youth, from the potentially harmful effects of this substance," said Minister Aglukkaq. "The use of this substance is a serious concern for all Canadians because not enough is known about the long-term effects of *Salvia divinorum*," added Aglukkaq.

Including these substances within the *Controlled Drugs and Substances Act* will make possession, trafficking, importation, exportation, and production (or cultivation) illegal unless authorized by regulation. Also, the regulation of *S. divinorum* and salvinorin A under the CDSA will enable law enforcement agencies to take action against suspected illegal activities involving these substances.

The Notice to Interested Parties will be published in *Canada Gazette*, Part I, on January 29, 2011. Interested parties are encouraged to submit comments before February 27, 2011.

For more information on *Salvia divinorum*, please visit: *It's Your Health - Salvia divinorum*: [XXXX](#)

**Comment [h1]:** Standard text from previous enquiries.

**Comment [h2]:** For confirmation from program that this is the end of public comment.

**Comment [h3]:** Weblink – OCS - Please advise whether this will be posted next week.

-30-

**Media Enquiries:**

Health Canada  
(613) 957-2983

*Également disponible en français*

Jenny Van Alstyne  
Office of the Honourable Leona Aglukkaq  
Federal Minister of Health  
(613) 957-0200

**Public Enquiries:**

(613) 957-2991  
1-866 225-0709

Health Canada news releases are available on the Internet at  
[www.healthcanada.gc.ca/media](http://www.healthcanada.gc.ca/media)



Government  
of Canada

Gouvernement  
du Canada

Canada

DRAFT 15  
January 18, 2011

**Media Lines**  
***Salvia divinorum***

**Issue**

There is ongoing media interest regarding the availability of *Salvia divinorum* in Canada as well as Canadian surveillance data suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has concluded that *Salvia divinorum* and its main active ingredient salvinorin A should be regulated under the *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth.

**Key Messages:**

- Health Canada is proposing to regulate both *Salvia divinorum* and its main active ingredient salvinorin A under Schedule III to the *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth.
- As a first step, Health Canada published a *Notice to Interested Parties* (NOI) in *Canada Gazette*, Part I on January 29, 2011. The NOI is intended to give Canadians the opportunity to provide comments on its proposal to regulate *Salvia divinorum* and salvinorin A as controlled substances.
- The inclusion of *Salvia divinorum* and salvinorin A in Schedule III to the CDSA will make possession, trafficking, importation, exportation, and production (or cultivation) illegal unless authorized by regulation.

**Supplementary Messages:**

- Canadians should not use products containing *Salvia divinorum* and/or salvinorin A because very little is known about these substances and their potential effects on the brain and body.
- The plant *Salvia divinorum* is not regulated under the CDSA and therefore it is not considered to be "banned", nor are activities with it considered to be illegal in Canada.
- However, as *Salvia divinorum* is a plant with hallucinogenic properties when consumed by humans, it meets the definition of a natural health product (NHP) under the *Natural Health Products Regulations* when marketed as a hallucinogen.
- To date, Health Canada has not authorized for sale any natural health products which contain *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products containing *Salvia divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

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- Deleted: December 22
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- Deleted: reports from scientific and media sources
- Deleted: has concluded its assessment of *Salvia divinorum* and its main active ingredient salvinorin A and
- Deleted: substances
- Deleted: CDSA
- Formatted: Font: Italic
- Deleted: In February 2011,
- Deleted: has
- Deleted: 31
- Deleted: The inclusion of *Salvia divinorum* and salvinorin A in Schedule III to the CDSA will reduce the potential health and safety risks associated with the ready availability, increased use and unknown effects of these substances. Further to the regulation of these substances under the CDSA, the following activities would be prohibited unless authorized by regulation: possession, trafficking, possession for the purposes of trafficki ... [1]
- Deleted: Health Canada v ... [2]
- Deleted: /or
- Deleted: , and their impac ... [3]
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- Formatted ... [4]
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- Formatted ... [11]
- Deleted: Nevertheless, v ... [12]
- Formatted: Bullets and Numbering ... [13]
- Deleted: however,

Questions and Answers:

**Q1 - What is involved in regulating *Salvia divinorum* as a controlled substance and what stage is it at?**

A1 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada recently concluded its assessment of *Salvia divinorum* and salvinorin A against the aforementioned factors and proposes to include both substances in Schedule III to the CDSA. The first step in the process of regulating a substance under the CDSA is the publication of a *Notice to Interested Parties* (NOI) in *Canada Gazette*, Part I. Any comments received will be considered during the preparation of a regulatory proposal. There will be additional opportunities for comment as the federal regulatory process progresses.

The regulation of these products will reduce the potential risks to the health and safety of Canadians associated with their ready availability, with their increased use and their unknown effects. The scheduling of *Salvia divinorum* and salvinorin A will also eliminate the current perception that these substances are a safe alternative to other illegal drugs.

**Q2 - Are *Salvia divinorum* and/or salvinorin A controlled internationally? How are these substances regulated in other countries?**

A2 - Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions; as a result, they do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

The move to include *Salvia divinorum* and salvinorin A in Schedule III to the CDSA is consistent with actions taken by several countries (e.g., Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Some individual U.S. states have implemented laws restricting their use, sale and/or distribution.

**Q3 - Is there any research on the use of *Salvia divinorum* in Canada?**

Deleted: Q1 - Are *Salvia divinorum* and/or salvinorin A controlled internationally? How are these substances regulated in other countries?¶

¶ A1 - Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions; as a result, they do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.¶

¶ The move to include *Salvia divinorum* and salvinorin A in Schedule III to the CDSA is consistent with actions taken by several countries (e.g. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Some individual U.S. states have implemented laws restricting their use, sale and/or distribution.¶

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A3 - Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *Salvia divinorum* at least once in their lifetime, and that youth aged 15-24 were much more likely to have used it than adults aged 25 years and older. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *Salvia divinorum* in the past year. The 2009 *Ontario Student Drug Use and Health Survey (OSDUHS)* indicated that 5.4% of Ontario students in grades 7-12 reported ever using *Salvia divinorum* and 4.4% of these students reported using this substance in the past year.

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**Q4 - If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why isn't it illegal?**

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A4 - Health Canada proposes to include *Salvia divinorum* and salvinorin A under Schedule III to the CDSA. Further to the regulation of these substances under the CDSA, the following activities will be illegal unless authorized by regulation: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation). Law enforcement agencies will also be able to take action against suspected illegal activities involving these substances.

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As a plant with hallucinogenic properties, however, *Salvia divinorum* meets the definition of a natural health product under the *Natural Health Products Regulations (NHPR)* when marketed as a hallucinogen. To date, Health Canada has not authorized for sale any natural health products which contain *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products may be subject to compliance and enforcement action under the *Food and Drugs Act*.

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Deleted: containing *Salvia divinorum* and/or salvinorin A

**Q5 - What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

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A5 - Once *Salvia divinorum* and salvinorin A are included in Schedule III to the CDSA, law enforcement will be able to take appropriate action in response to suspected illegal activities with these substances.

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Currently however, *Salvia divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. Complaints about the unauthorized sale of drugs containing *Salvia divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

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If pressed on whether Health Canada has issued any kind of warning to Canadians about *Salvia divinorum*¶

¶ A - Health Canada is developing an It's Your Health article

**Q6 - Has Health Canada issued any kind of warning to Canadians about *Salvia divinorum*?**

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A6 - Health Canada is developing an *It's Your Health* article about *Salvia divinorum* to help inform the general public about the risks associated with the use of this plant.

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**Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

Data from the 2008-2009 Youth Smoking Survey indicates that:

- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;
- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year; and
- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using Salvia in their lifetime (0.2% in the past year); and
- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that:

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;
- 5.4% of students (grades 7-12) ever used *Salvia divinorum*; and
- the use of *Salvia divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

**Prepared by:** Stephanie Chandler and Denis Arsenault, OCS, CSTD

**Input by:** Lisa Mackay IYH/PACCB, Suzanne Desjardins HECSB/ODARS, Hanan Abramovici HECSB/ODARS, Bruna Brands HECSB/ODARS, Jocelyn Kula, HECSB/OCS, Robin Marles HPFB/NHPD, Maggie Graham HPFB/NHPD, Stephanie Collins HPFB/NHPD, Mano Murty HPFB/MHPD, Robert Leitch HPFB/MHPD, Shahid Perwaiz HPFB/MHPD, Collin Pinto, HPFB/HPFBI

**Approved by:**

Robin Marles, Director, Bureau of Clinical Trials, NHPD (pending)  
Lindsay Blaney, Director, Policy and Regulatory Affairs, NHPD (pending)  
Duc Vu, Director, Marketed Biologics, Biotechnology and Natural Health Products  
Bureau, MHPD (pending)  
Kim Dayman-Rutkas, Director, HPFBI (pending)



Jocelyn Kula, A/Director, OCS, CSTD, HECS (pending)

Suzanne Desjardins, Director, ODARS, CSTD, HECS (approved, Sept 30, 2010)

Cathy Sabiston, DG, CSTD, HECS (pending)

Chris Turner, DG, MHPD (pending)

Nancy Richards, DG, NHPD (pending)

Diana Dowthwaite, DG, HPFBI (pending)

Ken Polk, Communications Executive, HPFB (pending)

Jean Tessier, Senior Media Relations, PACCB (pending)

Warren Braun, Director, Strategic Communications, PACCB (pending)

Peter Yendall, Director, Public Affairs, PACCB (pending)

HECS Legal (pending)

HPFB Legal (pending)

Paul Glover, ADM, HECSB (pending)

Meena Ballantyne, ADM, HPFB (pending)

Anne Lamar, ADM, PACCB (pending)

DMO (pending)

MO (pending)

PCO (pending)

**Deleted:** Diane Allan

**Deleted:** approved, Sept 29,  
2010

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The inclusion of *Salvia divinorum* and salvinorin A in Schedule III to the CDSA will reduce the potential health and safety risks associated with the ready availability, increased use and unknown effects of these substances. Further to the regulation of these substances under the CDSA, the following activities would be prohibited unless authorized by regulation: possession, trafficking, possession for the purposes of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation).

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Health Canada will inform stakeholders of its proposal by publishing a *Notice to Interested Parties* (NOI) in *Canada Gazette*, Part I. The NOI will provide stakeholders and other interested parties with the opportunity to provide comments on the proposal to regulate *Salvia divinorum* and salvinorin A as controlled substances.

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, and their impact on physical and mental functions

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**Page 1: [5] Change** CROUSH 2011-01-18 2:51:00 PM

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**Page 1: [9] Formatted** STCHANDL 2011-01-14 10:33:00 AM

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**Page 1: [11] Formatted** CROUSH 2011-01-18 3:25:00 PM

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Nevertheless, when specifically marketed for its hallucinogenic properties, *Salvia divinorum* meets the definition of a natural health product under the *Natural Health Products Regulations*.

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**DRAFT V.9**

DEPARTMENT OF HEALTH

CONTROLLED DRUGS AND SUBSTANCES ACT

*Notice to interested parties - Proposal regarding the addition of Salvia divinorum and salvinorin A to Schedule III to the Controlled Drugs and Substances Act*

This notice provides interested stakeholders with the opportunity to provide comments on Health Canada's proposal to add the plant *Salvia divinorum* (*S. divinorum*) and its main active ingredient salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA). Stakeholders may also identify themselves for inclusion in any future consultation.

*S. divinorum* is a species of sage belonging to the mint family. Its leaves are generally chewed or smoked to obtain psychotropic effects. While uncertainty remains surrounding the health risks of *S. divinorum*, known effects are reported to be short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant. Neither *S. divinorum* nor salvinorin A are currently included in any of the Schedules to the CDSA.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. *S. divinorum* is widely touted as a "legal" hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs.<sup>1</sup> Results from the *Canadian Alcohol and Drug Use Monitoring Survey* (CADUMS) reveal that, in 2009, 1.6% of Canadians aged 15 years and older reported having used *S. divinorum* at least once in their lifetime, and that youth aged 15-24 were much more likely to have used it than adults aged 25 years and older. The results from the Canadian 2008-2009 *Youth Smoking Survey* also show that 5% of 15 year olds have used *S. divinorum* in the past year. Moreover, the 2009 *Ontario Student Drug Use and Health Survey* (OSDUHS) indicated that 5.4% of Ontario students in grades 7-12 reported ever using *S. divinorum* and 4.4% of these students reported using this substance in the past year. Given its unknown effects and pharmacological similarity to other substances included in Schedule III to the CDSA such as lysergic acid diethylamide (LSD) and psilocybin, Health Canada is concerned that the ready availability and use of *S. divinorum* poses a risk to the health and safety of Canadians, particularly youth.

While *S. divinorum* and salvinorin A are not currently included in any of the United Nations Drug Control Conventions, a number of countries have chosen to regulate one or both as controlled substances. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden have all placed controls on the import and/or sale of *S. divinorum*

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<sup>1</sup>Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.

and/or salvinorin A. Some American states have also implemented laws restricting their use, sale and/or distribution.

Including these substances within Schedule III to the CDSA would prohibit: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation). The regulation of *S. divinorum* and salvinorin A under the CDSA will also enable law enforcement agencies to take action against suspected illegal activities involving these substances.

As this action is not intended to interfere with the use and availability of *S. divinorum* and/or salvinorin A for legitimate medical, scientific or industrial purposes, Health Canada is seeking information from stakeholders on whether there are any such uses in Canada. Information received in response to this notice will be instrumental in determining appropriate regulation under the CDSA.

The publication of this notice begins a 30-day comment period. There will be additional opportunities to provide comments as the federal regulatory process progresses.

If you are interested in this process or have comments on this proposal, please contact Stephanie Chandler, Regulatory Policy Division, Office of Controlled Substances, Address Locator: 3503D, 123 Slater St., Ottawa, Ontario, Canada, K1A 1B9, by fax at (613) 946-4224 or by email at [OCS\\_Policy\\_and\\_Regulatory\\_Affairs@hc-sc.gc.ca](mailto:OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca).

Cathy A. Sabiston  
Director General  
Controlled Substances and Tobacco Directorate

Date \_\_\_\_\_

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

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Christine Roush	HPFB will need to approve the lines and we can...	2011-01-18 05:07:42 PM
-----------------	---	------------------------

From: Christine Roush/HC-SC/GC/CA  
To: Stephanie Chandler/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Nicole  
Prentice/HC-SC/GC/CA@HWC  
Date: 2011-01-18 05:07 PM  
Subject: Re: Salvia Media Lines

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HPFB will need to approve the lines and we can get the names for you. Please advise if you will be  
notifying your partners - RCMP, Justice.

Christine Roush  
Senior Communications Advisor/

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Stephanie Chandler	Hi Christine, We will work on that question, ho...	2011-01-18 04:58:22 PM
Christine Roush	Hi Stephanie, I have reviewed the MLs and mad...	2011-01-18 03:36:37 PM
Stephanie Chandler	Hi Christine, With regards to our earlier conver...	2011-01-18 02:53:10 PM

Health Canada

2010-XX

# News Release

## The Government of Canada Proposes to Regulate *Salvia Divinorum* and Salvinorin A as Controlled Substances

January 28, 2011  
For immediate release

OTTAWA – Today, the Honourable Leona Aglukkaq, Minister of Health released a Notice to Interested Parties, also known as a Notice of Intent, in the *Canada Gazette*, Part I, on the proposal to regulate Salvia divinorum and salvinorin A, known as Salvia, as controlled substances.

This notice will provide interested stakeholders with the opportunity to comment on Health Canada's proposal to add the plant *Salvia divinorum* (*S. divinorum*) and its main active ingredient salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA).

"After reviewing available information and reports that suggest this substance has the potential for abuse, especially among young people, we are taking these steps to protect the health and safety of Canadians, particularly youth, from the potentially harmful effects of this substance," said Minister Aglukkaq. "The use of this substance is a serious concern for all Canadians because not enough is known about the long-term effects of Salvia divinorum," added Aglukkaq. *font*

Including these substances within the *Controlled Drugs and Substances Act* will make possession, trafficking, importation, exportation, and production (or cultivation) illegal unless authorized by regulation. Also, the regulation of *S. divinorum* and salvinorin A under the CDSA will enable law enforcement agencies to take action against suspected illegal activities involving these substances.

The Notice to Interested Parties will be published in *Canada Gazette*, Part I, on January 29, 2011. Interested parties are encouraged to submit comments before February 27, 2011. *28*

For more information on *Salvia divinorum*, please visit: *It's Your Health - Salvia divinorum*: XXX

*Link to NOI?*

**Comment [h1]:** Standard text from previous enquiries.

**Comment [h2]:** For confirmation from program that this is the end of public comment.

**Comment [h3]:** Weblink - OCS - Please advise whether this will be posted next week.

-30-

**Media Enquiries:**

Health Canada  
(613) 957-2983

*Également disponible en français*

Jenny Van Alstyne  
Office of the Honourable Leona Aglukkaq  
Federal Minister of Health  
(613) 957-0200

**Public Enquiries:**

(613) 957-2991  
1-866 225-0709

Health Canada news releases are available on the Internet at  
[www.healthcanada.gc.ca/media](http://www.healthcanada.gc.ca/media)



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of Canada

Gouvernement  
du Canada

Canada

Health Canada

2011-XX

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# News Release

## The Government of Canada Proposes to Regulate *Salvia Divinorum* and *Salvinorin A* as Controlled Substances

January 28, 2011  
For immediate release

OTTAWA – Today, the Honourable Leona Aglukkaq, Minister of Health released a Notice to Interested Parties, also known as a Notice of Intent, in the *Canada Gazette*, Part I, on the proposal to regulate *Salvia divinorum* and salvinorin A, known as *Salvia*, as controlled substances.

This notice will provide interested stakeholders with the opportunity to comment on Health Canada's proposal to add the plant *Salvia divinorum* (*S. divinorum*) and its main active ingredient salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA).

"After reviewing Canadian surveillance data and scientific reports that suggest this substance has the potential for abuse, especially among young people, we are taking these steps to protect the health and safety of Canadians from the potentially harmful effects of this substance," said Minister Aglukkaq. "The use of this substance is a serious concern for all Canadians because very little is known about the long-term effects of *Salvia divinorum*," added Aglukkaq.

Including these substances within the *Controlled Drugs and Substances Act* will make possession, trafficking, importation, exportation, and production (or cultivation) illegal unless authorized by regulation. The regulation of *S. divinorum* and salvinorin A under the CDSA will also enable law enforcement agencies to take action against suspected illegal activities involving these substances.

The Notice to Interested Parties will be published in *Canada Gazette*, Part I, on January 29, 2011. Interested parties are encouraged to submit comments before February 28, 2011.

For more information on *Salvia divinorum*, please visit: *It's Your Health - Salvia divinorum*: XXX

"announced that a Notice to Interested Parties would be published in CG, Part I over the weekend. Can we actually say this?"

to HC (?)

Comment [S1]: Seems awkward...

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Comment [S2]: Too strong wording?

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Comment [h3]: Standard text from previous enquiries.

Comment [S4]: Should we also include a link to the NOI once it is published online?

Comment [h5]: Weblink - OCS - Please advise whether this will be posted next week.



-30-

**Media Enquiries:**

Health Canada  
(613) 957-2983

*Également disponible en français*

Jenny Van Alstyne  
Office of the Honourable Leona Aglukkaq  
Federal Minister of Health  
(613) 957-0200

**Public Enquiries:**

(613) 957-2991  
1-866 225-0709

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of Canada

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Canada



**Fw: For HPFB Approvals: Salvia MLs**

Jocelyn Kula to: Stephanie Chandler, Denis Arsenault

2011-01-20 12:49 PM

FYI, and I am going to confirm with Cathy that we definitely still need to do the IYH at the same time.....don't stop working on revisions though....just in case  
:)

---

Jocelyn Kula

Acting Director/ Directrice par intérim

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs

Health Canada/ Santé Canada

Tel: (613) 952-2177 Fax: (613) 946-4224

----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2011-01-20 12:48 PM -----

From: Christine Roush/HC-SC/GC/CA

To: Lisa MacKay/HC-SC/GC/CA@HWC, Elizabeth Keeping/HC-SC/GC/CA@HWC

Cc: Nicole Prentice/HC-SC/GC/CA@HWC, David Gottlieb/HC-SC/GC/CA@HWC, Jaimie Banks/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC

Date: 2011-01-20 12:47 PM

Subject: Re: For HPFB Approvals: Salvia MLs

---

Lisa/Elizabeth,

Could you please **hold off** on circulating versions of the It's Your Health article for review and approvals **until further notice**. My client is reassessing the need to publish the article at this time - and if the decision is taken to publish it, then the Office of Controlled Substances will need to revise the article to ensure it is in line with the Notice of Intent.

Thank you all for your continued patience with this issue.

Christine Roush

Senior Communications Advisor/

Conseillère principale en communications

Public Affairs, Consultation and Communications Branch/

Direction générale des affaires publiques,  
de la consultation et des communications

Health Canada/Santé Canada

Tel/Tél : (613) 954-0712/Cell: (613) 219-7194

Fax/Facsimile : 948-8085

E-mail / courriel : christine\_roush@hc-sc.gc.ca

---

Lisa MacKay

Hi Beth, I'm sure there will be changes from OC...

2011-01-20 12:00:59 PM

From: Lisa MacKay/HC-SC/GC/CA

To: Elizabeth Keeping/HC-SC/GC/CA@HWC

Cc: Nicole Prentice/HC-SC/GC/CA@HWC, Christine Roush/HC-SC/GC/CA@HWC, David Gottlieb/HC-SC/GC/CA@HWC, Jaimie Banks/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC

Date: 2011-01-20 12:00 PM

Subject: Re: For HPFB Approvals: Salvia MLs

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Hi Beth,

I'm sure there will be changes from OCS so you may want to wait to hear from Nicole before getting formal approval.

Thanks

Lisa

---

Elizabeth Keeping I just sent along the version to NHPD that Lisa s... 2011-01-20 11:36:02 AM

From: Elizabeth Keeping/HC-SC/GC/CA  
To: Nicole Prentice/HC-SC/GC/CA@HWC  
Cc: Lisa MacKay/HC-SC/GC/CA@HWC, Christine Roush/HC-SC/GC/CA@HWC, David  
Gotlieb/HC-SC/GC/CA@HWC, Jaimie Banks/HC-SC/GC/CA@HWC, Jocelyn  
Kula/HC-SC/GC/CA@HWC  
Date: 2011-01-20 11:36 AM  
Subject: Re: For HPFB Approvals: Salvia MLs

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I just sent along the version to NHPD that Lisa shared a few minutes ago.

Is there a different version that we should be working on?

B

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Nicole Prentice Thanks Lisa. FYI - I have a version with my pro... 2011-01-20 11:35:42 AM

From: Nicole Prentice/HC-SC/GC/CA  
To: Lisa MacKay/HC-SC/GC/CA@HWC  
Cc: Christine Roush/HC-SC/GC/CA@HWC, Elizabeth Keeping/HC-SC/GC/CA@HWC, David  
Gotlieb/HC-SC/GC/CA@HWC, Jaimie Banks/HC-SC/GC/CA@HWC, Jocelyn  
Kula/HC-SC/GC/CA@HWC  
Date: 2011-01-20 11:35 AM  
Subject: Re: For HPFB Approvals: Salvia MLs

---

Thanks Lisa.

FYI - I have a version with my program right now, so I will share it with HPFB once it comes out of the Director's office so we can get concurrent approvals.

**Nicole Prentice**

Junior Communications Officer | Agente junior des Communications  
Regulatory Communications and Media Relations Division | Division des communications  
réglementaires et des relations avec les médias  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires  
publiques, de la consultation et des communications  
Health Canada | Santé Canada  
Tel: 613.941.3107  
Fax: 613.948.8085

---

Lisa MacKay Hello all, I need full approvals of the IYH article... 2011-01-20 11:27:20 AM

From: Lisa MacKay/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Cc: Elizabeth Keeping/HC-SC/GC/CA@HWC, David Gotlieb/HC-SC/GC/CA@HWC, Nicole

Prentice/HC-SC/GC/CA@HWC, Jaimie Banks/HC-SC/GC/CA@HWC, Jocelyn  
Kula/HC-SC/GC/CA@HWC  
Date: 2011-01-20 11:27 AM  
Subject: Re: For HPFB Approvals: Salvia MLs

---

Hello all,

I need full approvals of the IYH article by end of day Friday at the latest. All the same people need to approve the IYH at HECSB and HPFB and I also need time for translation, revision and formatting. I will need all approvals (HECSB and HPFB) completed by Wednesday morning at the very latest in order to complete this and even at that this will be a huge push to get it done. It's too bad that it wasn't ready to go earlier in case something like this came up.

Here is the latest version I have, I assume there have been additional changes made...  
[attachment "IYH Salvia divinorum\_v20 Oct2010.doc" deleted by Nicole Prentice/HC-SC/GC/CA]

Thanks

Lisa Mackay  
It's Your Health Project Manager/Gestionnaire du projet Votre santé et vous  
Consumer Information Bureau / Bureau d'information aux consommateurs  
Marketing and Communications Services Directorate/Direction des services de marketing et de communications  
Public Affairs, Consultation and Communications Branch/ Direction générale des affaires publiques, de la consultation et des communications  
Health Canada | Santé Canada  
Tel 613.954.0105  
Lisa\_Mackay@hc-sc.gc.caa

Christine Roush      Since there is a long list of people who need to s...      2011-01-19 05:16:37 PM

From: Christine Roush/HC-SC/GC/CA  
To: Elizabeth Keeping/HC-SC/GC/CA@HWC  
Cc: David Gotlieb/HC-SC/GC/CA@HWC, Lisa MacKay/HC-SC/GC/CA@HWC, Nicole Prentice/HC-SC/GC/CA@HWC  
Date: 2011-01-19 05:16 PM  
Subject: For HPFB Approvals: Salvia MLs

---

Since there is a long list of people who need to see and approve the Salvia MLs from HPFB, could you please start the review and approval process. Jocelyn Kula, A/Director of the Office of Controlled Substances has signed off on these lines. I am continuing to move them through CSTD approvals. Ideally, we would need full approvals of the lines by **Monday, Jan 24**, the latest.

Thanks,

[attachment "Salvia MLs\_Jan 19(3)\_ENG.doc" deleted by Nicole Prentice/HC-SC/GC/CA]

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
Health Canada/Santé Canada  
Tel/Tél : (613) 954-0712/Cell: (613) 219-7194  
Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca



**Fw: Shooting Suspect Had Been Known to Use Potent, and Legal,  
Hallucinogen**

Suzanne Desjardins to: Hanan Abramovici, Denis Arsenault,  
Jocelyn Kula, Stephanie Chandler

2011-01-20 04:34 PM

FYI

----- Forwarded by Suzanne Desjardins/HC-SC/GC/CA on 2011-01-20 04:33 PM -----

From: Mark Latendresse/HC-SC/GC/CA  
To: Suzanne Desjardins/HC-SC/GC/CA@HWC  
Date: 2011-01-18 11:09 AM  
Subject: Shooting Suspect Had Been Known to Use Potent, and Legal, Hallucinogen

---

Hi Suzanne,

I read this story in the NY times this morning on the bus regarding salvia. Not sure if it is of interest to your group, but considering the high profile of the Arizona shooting it may raise more awareness around salvia.

Thanks,  
Mark

[http://www.nytimes.com/2011/01/18/us/18salvia.html?\\_r=1&ref=us](http://www.nytimes.com/2011/01/18/us/18salvia.html?_r=1&ref=us)

---

Mark Latendresse, M.A.  
Senior Epidemiologist Bio-Statistician  
Controlled Substances and Tobacco Directorate  
Healthy Environments and Consumer Safety Branch  
Health Canada

6th Floor, Room B642, AL 3506D  
MacDonald Building, 123 Slater, Ottawa, ON K1A 0K9  
PH: 613-948-8965  
FX: 613-952-4622  
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January 17, 2011

## Shooting Suspect Had Been Known to Use Potent, and Legal, Hallucinogen

By A. G. SULZBERGER and JENNIFER MEDINA

TUCSON — No one has suggested that his use of a hallucinogenic herb or any other drugs contributed to Jared L. Loughner's apparent mental unraveling that culminated with his being charged in a devastating outburst of violence here.

Yet it is striking how closely the typical effects of smoking the herb, *Salvia divinorum* — which federal drug officials warn can closely mimic psychosis — matched Mr. Loughner's own comments about how he saw the world, like his often-repeated assertion that he spent most of his waking hours in a dream world that he had learned to control.

Salvia is a potent but legal drug marketed with promises of producing a transcendental spiritual journey: out-of-body experiences, existence in multiple realities, the revelation of secret knowledge and, according to one online seller, "permanent mind-altering change in perception."

Mr. Loughner, 22, was at one point a frequent user of the plant, also known as diviner's sage, which he began smoking while in high school during a time in which he was also experimenting with marijuana, hallucinogenic mushrooms and other drugs, according to friends. Mental health professionals warn that drug use can both aggravate and mask the onset of mental illness.

"He always had it on him," said George Osler IV, whose son, Zach, was good friends with Mr. Loughner in high school. It is unclear when Mr. Loughner last used the drug.

It remains unclear what, if any, role salvia played in shaping Mr. Loughner's views. But the shootings have once again drawn attention to a drug that — for little more than the cost of a pack of cigarettes and without the hassle of showing a driver's license — a growing number of young people here and throughout much of the country are legally buying and using.

"It's a draw for adventure seekers — the people who are attracted to the sort of bungee-jumping attempt in psychopharmacology," said Matthew W. Johnson, a professor of behavioral pharmacology at Johns Hopkins University medical school, who has studied the effect of the drug on humans. "They are looking for that sort of thing as a part of their belief system. Sometimes they are extremely compelled by what they are experiencing."

A perennial in the mint family related to the ornamental plant popular with gardeners, *Salvia divinorum* is native to Mexico and has historically been used by Mazatec shamans in religious rituals, where the large green leaves are chewed or made into a tea. (Some researchers have said the herb holds promise for developing new medicine to control pain and treat drug addiction.)

Smoked, the effect is shorter and more intense, typically lasting just a few minutes.

People who have smoked the herb say the experience is often unpleasant, and many never use it again. The powerful effects have been documented in thousands of online videos documenting experiences on the drug — including a recent video of the teenage music and television star Miley Cyrus laughing hysterically and babbling nonsensically after smoking the drug. Nearly 6 percent of high school seniors and college students reported using the drug in the previous year, a higher percentage than used Ecstasy or cocaine and more than twice as much as LSD, according to a federal survey released in 2009.

“It pretty much puts you in a different world,” said Casey Hazelton, 19, describing his own experience with the drug while visiting a local smoke shop that sells packets of the herb. “It’s like you’re dreaming if you’re awake.”

Nationwide, poison centers treated 117 *Salvia divinorum* exposures in 2010, up from 81 the year before.

*Salvia*’s growing popularity has led nearly half the states to ban or restrict the sale of the herb, which is often treated with concentrated extract of the active chemical to make it more powerful. The push coincides with recent efforts by states around the country to outlaw a number of other legal drugs that often sit alongside *salvia* on the shelves that use chemical additives to mimic the effects of illegal drugs like marijuana.

“It’s an issue that the states are increasingly paying attention to,” said Alison Lawrence, policy specialist for the National Conference of State Legislatures.

In Arizona, however, *salvia* and other synthetic drugs like Spice and K2 can legally be sold to anyone, including minors, and are available at smoke shops, liquor stores and even grocery stores. The drug is also widely sold on the Internet with more potent versions accompanied by warnings like “reality is ripped to shreds.”

Eric Meyer, a doctor and member of the Arizona Legislature, has introduced bills each of the past two years to restrict the sale of *salvia* to those 21 and older (three states, including California, have age restrictions). Both years the bill died without coming to a final vote. Mr. Meyer said he planned to introduce the legislation again next week, with the hope that the increased attention would allow the bill to go forward.

“It’s a first step to get some control over the drug,” he said.

The Drug Enforcement Agency has listed salvia as a drug of concern and is considering classifying it as a Schedule I drug, like LSD or marijuana, according to the National Institutes of Health.

*Michael Luo contributed reporting.*





**Re: Fw: Draft email to stakeholders re: Salvia NOI**   
Lisa Marie NG to: Stephanie Chandler  
Cc: Denis Arsenault, Isabel.Shanahan

2011-01-20 04:01 PM

Please find the translated document attached.



8035235\_FR\_Stakeholder\_notification\_of\_NOI\_Jan\_19\_2011\_EN.wpd

Lisa Marie Ng  
Clerk  
Regulatory Policy Division  
Office of Controlled Substances  
Controlled Substances and Tobacco Directorate  
Healthy Environments and Consumer Safety Branch  
Health Canada  
Tel: 613-960-6069  
lisa.marie.ng@hc-sc.gc.ca

Stephanie Chandler      Hi Lisa Marie, Could you please get this transl...      2011-01-20 10:21:46 AM

From: Stephanie Chandler/HC-SC/GC/CA  
To: Lisa Marie NG/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2011-01-20 10:21 AM  
Subject: Fw: Draft email to stakeholders re: Salvia NOI

Hi Lisa Marie,

Could you please get this translated for us? Document is attached at the bottom of email thread. Won't need it until next week (Thurs Jan 27th) so we can go through the translation bureau.

Thanks!

Steph

Stephanie Chandler

---

Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca  
----- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2011-01-20 10:19 AM -----

From: Jocelyn Kula/HC-SC/GC/CA  
To: Stephanie Chandler/HC-SC/GC/CA@HWC  
Cc: CSTD-OCS-DO, Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2011-01-20 10:17 AM  
Subject: Re: Draft email to stakeholders re: Salvia NOI

Madame, Monsieur,

Le présent courriel a pour but de vous informer qu'un *Avis d'intention aux parties intéressées* concernant les substances ci-dessous a été publié dans la Partie I de la *Gazette du Canada*, le 29 janvier 2011:

- *Salvia divinorum* (sauge des devins)
- Salvinorine A

La version électronique de l'Avis d'intention est disponible à l'adresse Internet [www.gazette.gc.ca](http://www.gazette.gc.ca), pages xx-xx, en format PDF (pages xxxx-xxxx dans la partie I de la *Gazette du Canada*).

Cet avis d'intention décrit la proposition de Santé Canada qui consiste à inclure la *Salvia divinorum* (sauge des devins) et la salvinorine A dans l'annexe III de la *Loi réglementant certaines drogues et autres substances*. Santé Canada cherche précisément à obtenir plus d'information de la part des intervenants afin de déterminer si ces substances ont une utilité légitime sur les plans industriel, scientifique ou médical au Canada. Les renseignements qui seront obtenus permettront de prendre des mesures réglementaires appropriées.

Si vous désirez participer à ce processus ou tout simplement nous fournir de l'information, veuillez communiquer avec nous d'ici le 28 février 2011. Vous pouvez envoyer vos commentaires par la poste à Stephanie Chandler, Division de la politique réglementaire, Bureau des substances contrôlées, indice de l'adresse : 3503D, 123 rue Slater, Ottawa, Ontario, Canada K1A 1B9, par télécopieur, au 613-946-4224, ou par courriel à [OCS\\_Policy\\_and\\_Regulatory\\_Affairs@hc-sc.gc.ca](mailto:OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca).

**VEUILLEZ TRANSFÉRER LE PRÉSENT COURRIEL AUX PERSONNES QUI POURRAIENT ÊTRE INTÉRESSÉES.**

Si vous avez reçu cet avis par erreur, nous vous saurions gré de le transférer à la personne concernée de votre organisation et de lui demander de nous en informer par courriel à : [OCS\\_Policy\\_and\\_Regulatory\\_Affairs@hc-sc.gc.ca](mailto:OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca).

Merci.

Division de la politique réglementaire  
Bureau des substances contrôlées  
Direction de la stratégie antidrogue et des substances contrôlées  
Direction générale de la santé environnementale et de la sécurité des consommateurs

looks good to me; assume is very like what we have done in the past....will forward on to Christine Roush and Stephanie Szick as an FYI

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

Stephanie Chandler Hi Jocelyn, I have drafted the following email t...

2011-01-20 09:28:14 AM

Re: Salvia Event is on 

Jocelyn Kula to: Christine Roush

2011-01-20 05:43 PM

Cc: Dave Stephens, Cathy A Sabiston, Stephanie Szick, Denis Arsenault, Stephanie Chandler

Hi Christine,

Thanks for the intel and well, I guess we wait to hear exactly what kind of event they have in mind.

Re publication of the NOI, it is certainly no trouble to wait. CGI is published every Saturday and the cut off for submission of items is 6 business days before publication. Ergo, if we were to look at Feb 5, we would have to submit content by COB on January 29.

In the meantime, I will review the NR tonight (Stephanie and Denis have suggested some changes) and we will keep working on the IYH just in case.

Cathy- we have been consulting Suzanne on docs as you know but I will now make sure she is in the loop about an event as depending on what MO wants, she may be able to help with content from the surveillance community.

Jocelyn

Sent by blackberry

Jocelyn Kula

A/ Director/ Directrice par interim

Office of Controlled Substances/ Bureau des substances contrôllées

Christine Roush

----- Original Message -----

From: Christine Roush

Sent: 2011-01-20 05:21 PM EST

To: Jocelyn Kula

Cc: Dave Stephens; Cathy A Sabiston; Stephanie Szick; Denis Arsenault; Stephanie Chandler; Dave Stephens

Subject: Salvia Event is on

Hi Jocelyn,

We have heard that it has been confirmed by MO that they would like an event the first week of February regarding the proposal to schedule Salvia. They also said that they do not want the NOI to be published next week. Could you please let us know when the next earliest date would be for publishing the NOI to Canada Gazette I? MO would prefer the publishing to happen after the event. Our DG, Comms has asked MO to schedule a planning meeting as soon as possible. I hope this helps to clarify things a bit.

Christine Roush

Senior Communications Advisor/

Dave Stephens

and MO is now calling PMO for confirmation Da...

2011-01-20 04:11:28 PM

From: Dave Stephens/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Christine Roush/HC-SC/GC/CA@HWC  
Date: 2011-01-20 04:11 PM  
Subject: Re: Fw: Salvia Announcement

and MO is now calling PMO for confirmation

Dave Stephens  
Senior Communications Executive-Gestionnaire Principal des Communications HECSB/DGSCSE  
6th Floor, Room 6-033, 269 Laurier Ave. W., Ottawa, ON  
Tel: (613) 946-8107  
Cell: (613) 859-3581

Jocelyn Kula great thanks \_\_\_\_\_ Jo... 2011-01-20 04:02:07 PM

From: Jocelyn Kula/HC-SC/GC/CA  
To: Dave Stephens/HC-SC/GC/CA@HWC  
Cc: Christine Roush/HC-SC/GC/CA@HWC  
Date: 2011-01-20 04:02 PM  
Subject: Re: Fw: Salvia Announcement

great thanks

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

Dave Stephens DGO Comms is calling Tim right now to explain... 2011-01-20 03:47:30 PM

From: Dave Stephens/HC-SC/GC/CA  
To: Dave Stephens/HC-SC/GC/CA@HWC  
Cc: Christine Roush/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC  
Date: 2011-01-20 03:47 PM  
Subject: Re: Fw: Salvia Announcement

DGO Comms is calling Tim right now to explain that they need to decide right away. Instructing us to hold off on submitting the NOI for publication is an option, but we will try to explain once again the issues around an event.

Dave Stephens  
Senior Communications Executive-Gestionnaire Principal des Communications HECSB/DGSCSE  
6th Floor, Room 6-033, 269 Laurier Ave. W., Ottawa, ON  
Tel: (613) 946-8107  
Cell: (613) 859-3581

Dave Stephens Christine, Jocelyn: Though I wouldn't bet any m... 2011-01-20 03:01:29 PM

From: Dave Stephens/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC  
Date: 2011-01-20 03:01 PM  
Subject: Re: Fw: Salvia Announcement

Christine, Jocelyn:

Though I wouldn't bet any money on this, what I think has happened is that MO has received instructions from the Centre in the past 24 hours or so telling them there should be an event. Everyone in MO may not be aware of this.

002430

We have passed on the various considerations, first and foremost the likelihood that the NOI will attract media attention if it's posted on Jan 28-29....so if there's going to be an event, it'll have to be on the 28th or sooner....or publication would have to be delayed.

Dave

Dave Stephens  
Senior Communications Executive-Gestionnaire Principal des Communications HECSB/DGSCSE  
6th Floor, Room 6-033, 269 Laurier Ave. W., Ottawa, ON  
Tel: (613) 946-8107  
Cell: (613) 859-3581

Christine Roush FYI - see Jocelyn's note below. I guess we wait... 2011-01-20 02:51:14 PM

From: Christine Roush/HC-SC/GC/CA  
To: Dave Stephens/HC-SC/GC/CA@HWC  
Date: 2011-01-20 02:51 PM  
Subject: Fw: Salvia Announcement

---

FYI - see Jocelyn's note below. I guess we wait until Tim gets back to DG,Comms about this?

Christine Roush  
Senior Communications Advisor/

From: Jocelyn Kula/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Date: 2011-01-20 02:47 PM  
Subject: Re: Salvia Announcement

---

I talked to Martina in MO (only because she used to work for me so I know her- I will get in trouble if you share this info)....I was actually trying to clarify something on the med mari side, and she raised salvia (cause she was on the file at one point when she was here), and shared that her view was that Scott T had only talked about an NR, not an event.....she was going to clarify with Tim and make sure word got down (hence my reference to hopefully you have heard.....).

At the end of the day, it just seems to be extraordinary that we would organize an event regarding what, as Dave pointed out, is the beginning of a long long process.....

Please don't make a fuss about this....if your instructions are to start plans for an event, so be it, just let us know what you need from us. That said, wasn't Dave going to ask about whether an event made sense yesterday anyways??

JK

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

Christine Roush Could you please tell me who you heard this fro... 2011-01-20 02:37:19 PM

From: Christine Roush/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Dave Stephens/HC-SC/GC/CA@HWC  
Date: 2011-01-20 02:37 PM  
Subject: Re: Salvia Announcement

---

Could you please tell me who you heard this from - the "no event" for Salvia. We have not heard this through the Comms channel.

Christine Roush  
Senior Communications Advisor/

---

Jocelyn Kula      Hopefully you have heard through channels that...      2011-01-20 10:37:04 AM

From: Jocelyn Kula/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Date: 2011-01-20 10:37 AM  
Subject: Re: Salvia Announcement

---

Hopefully you have heard through channels that there is no event, just the NR.  
Any chance we will see a draft today?

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

---

Christine Roush      Hi Jocelyn We've been told that the Minister's of...      2011-01-19 02:59:21 PM

From: Christine Roush/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Denis Arseneault/HC-SC/GC/CA@HWC, Nicole Prentice/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC, Stephanie Szick/HC-SC/GC/CA@HWC, Cathy A Sabiston/HC-SC/GC/CA@HWC, Dave Stephens/HC-SC/GC/CA@HWC  
Date: 2011-01-19 02:59 PM  
Subject: Re: Salvia Announcement

---

Hi Jocelyn  
We've been told that the Minister's office wants to do an event for the posting of the NOI for Salvia. We told MO the posting was going to happen on Friday, January 28th. I sent you yesterday the revised MLs, and am waiting on Stephanie C to get back with a complete answer to Q1. We have started drafting the News Release, and I can send you the first draft tomorrow am. I imagine there will be an MBU request for a teleconf at some point to discuss venue, partners, etc.

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
Health Canada/Santé Canada  
Tel/Tél : (613) 954-0712/Cell: (613) 219-7194

Fax/Facsimile : 948-8085

E-mail / courriel : christine\_roush@hc-sc.gc.ca

Stephanie Chandler	Hi Christine, We will work on that question, ho...	2011-01-18 04:58:22 PM
Christine Roush	Hi Stephanie, I have reviewed the MLs and mad...	2011-01-18 03:36:37 PM
Stephanie Chandler	Hi Christine, With regards to our earlier conver...	2011-01-18 02:53:10 PM



Suzanne's  
revisions

DEPARTMENT OF HEALTH

CONTROLLED DRUGS AND SUBSTANCES ACT

*Notice to interested parties - Proposal regarding the addition of Salvia divinorum and salvinorin A to Schedule III to the Controlled Drugs and Substances Act*

This notice provides interested stakeholders with the opportunity to provide comments on Health Canada's proposal to add the plant *Salvia divinorum* (*S. divinorum*) and its main active ingredient salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA). Stakeholders may also identify themselves for inclusion in any future consultation.

*S. divinorum* is a species of sage belonging to the mint family. Its leaves are generally chewed or smoked to obtain psychotropic effects. While uncertainty remains surrounding the health risks of *S. divinorum*, known effects are reported to be short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant. Neither *S. divinorum* nor salvinorin A are currently included in any of the Schedules to the CDSA.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. *S. divinorum* is widely touted as a "legal" hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs.<sup>1</sup> Results from the *Canadian Alcohol and Drug Use Monitoring Survey* (CADUMS) reveal that, in 2009, 1.6% of Canadians aged 15 years and older reported having used *S. divinorum* at least once in their lifetime, and that youth aged 15-24 were much more likely to have used it than adults aged 25 years and older. The results from the Canadian 2008-2009 *Youth Smoking Survey* also show that 5% of 15 year olds have used *S. divinorum* in the past year. Moreover, the 2009 *Ontario Student Drug Use and Health Survey* (OSDUHS) indicated that 5.4% of Ontario students in grades 7-12 reported ever using *S. divinorum* and 4.4% of these students reported using this substance in the past year. Given its unknown effects and pharmacological similarity to other substances included in Schedule III to the CDSA such as lysergic acid diethylamide (LSD) and psilocybin, Health Canada is concerned that the ready availability and use of *S. divinorum* poses a risk to the health and safety of Canadians, particularly youth.

with a much higher rate (7.3%) in  
↓  
as per approved  
HL

Because its effects resemble those of

While *S. divinorum* and salvinorin A are not currently included in any of the United Nations Drug Control Conventions, a number of countries have chosen to regulate one or both as controlled substances. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden have all placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. Some American states have also implemented laws restricting their use, sale and/or distribution.

<sup>1</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.

Including these substances within Schedule III to the CDSA would prohibit: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation). The regulation of *S. divinorum* and salvinorin A under the CDSA will also enable law enforcement agencies to take action against suspected illegal activities involving these substances.

As this action is not intended to interfere with the use and availability of *S. divinorum* and/or salvinorin A for legitimate medical, scientific or industrial purposes, Health Canada is seeking information from stakeholders on whether there are any such uses in Canada. Information received in response to this notice will be instrumental in determining appropriate regulation under the CDSA.

The publication of this notice begins a 30-day comment period. There will be additional opportunities to provide comments as the federal regulatory process progresses.

If you are interested in this process or have comments on this proposal, please contact Stephanie Chandler, Regulatory Policy Division, Office of Controlled Substances, Address Locator: 3503D, 123 Slater St., Ottawa, Ontario, Canada, K1A 1B9, by fax at (613) 946-4224 or by email at [OCS\\_Policy\\_and\\_Regulatory\\_Affairs@hc-sc.gc.ca](mailto:OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca).

Cathy A. Sabiston  
Director General  
Controlled Substances and Tobacco Directorate

Date \_\_\_\_\_

# QUESTION PERIOD NOTE

## NOTE POUR LA PÉRIODE DE QUESTIONS

Date:	January 20, 2011
Classification :	HECS PROTECTED - SESC PROTÉGÉ

### SUBJECT - SUJET

English:

**DRUGS - SALVIA DIVINORUM**

Français:

**DROGUES - SALVIA DIVINORUM**

### SYNOPSIS - SOMMAIRE

English:

Media interest in Salvia divinorum is recurrent. Questions around this substance generally focus on its legality. Recently, a number of media reports have commented on a YouTube video which reportedly shows the young celebrity Miley Cyrus smoking Salvia divinorum. Canadian surveillance data indicates that this substance is being used by adolescents and young adults for its hallucinogenic properties, and there have also been several reports from scientific sources indicating that Salvia divinorum has the potential for abuse.

### ANTICIPATED QUESTION - QUESTION PRÉVUE

English:

What is Health Canada doing to protect young Canadians from the potential adverse effects associated with the use of Salvia divinorum?

Français:

Quelles mesures Santé Canada prend-il pour protéger les jeunes Canadiens contre les effets indésirables possibles liés à l'utilisation de la Salvia divinorum?

Jocelyn,  
Do you want to also include the recent shooting in Arizona where the accused was reported as a regular Salvia user? (I sent you the link)  
Suzanne

Suzanne's Comments  
-not sure if we want to reference Arizona shooter article as its the only one I've seen so far. Not aware of any Canadian coverage yet.

*Salvia divinorum*

English:

- Health Canada is proposing to regulate *Salvia* in order to protect the health and safety of Canadians, particularly youth.
- Health Canada has published a *Notice to Interested Parties* in *Canada Gazette*, Part I, to give Canadians the opportunity to provide comments on its proposal to regulate *Salvia*. *divinorum* / *divinorum*
- The regulation of *Salvia* will make possession, trafficking, importation, exportation, and production illegal unless authorized by regulation.

Français:

leaving as  
'Salvia' as  
per DGo  
comments

---

## BACKGROUND - CONTEXTE

English:

### BACKGROUND / CONTEXTE

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, diviner's sage, magic mint, and puff. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs.

Both the plant *S. divinorum* and its main active ingredient salvinorin A are known to have physical and mental effects which are often described as unpleasant, including:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination

with a much higher rate (7.3%) in

- slurred speech and awkward sentence patterns

Recent surveys indicate that Canadian youth are trying this substance which could be dangerous to their health. Results from the *Canadian Alcohol and Drug Use Monitoring Survey* (CADUMS) reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *Salvia divinorum* at least once in their lifetime, ~~and that youth aged 15-24 were much more likely to have used it than adults aged 25 years and older.~~ The results from the Canadian 2008-2009 *Youth Smoking Survey* also show that 5% of 15 year olds have used *Salvia divinorum* in the past year. The 2009 *Ontario Student Drug Use and Health Survey* (OSDUHS) indicated that 5.4% of Ontario students in grades 7-12 reported ever using *Salvia divinorum* and 4.4% of these students reported using this substance in the past year.

#### International Control of *S. divinorum*

Neither *Salvia divinorum* nor its main active ingredient salvinorin A are listed under the United Nations Drug Control Conventions; as a result, they do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions. The move to include *Salvia divinorum* and salvinorin A in Schedule III to the CDSA is consistent with actions taken by several countries (e.g. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Some individual U.S. states have also implemented laws restricting their use, sale and/or distribution.

#### Current Situation in Canada

Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted, namely:

- International requirements and trends in control and/or scheduling;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e. therapeutic, scientific, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada recently concluded its assessment of *S. divinorum* and its main active ingredient salvinorin A against the aforementioned factors and now proposes to include both substances in Schedule III to the CDSA.

The regulation of *Salvia divinorum* will allow law enforcement to take action against illegal activities involving this substance. The possession, trafficking, importation, exportation and production of *Salvia divinorum* and salvinorin A will be illegal unless authorized by regulation.

The plant *Salvia divinorum* is not currently regulated under the *Controlled Drugs and Substances Act* (CDSA) and therefore the plant is not considered to be "banned" nor are activities with it considered to be illegal in Canada. However, as *Salvia divinorum* is a plant with hallucinogenic properties when consumed by humans, it meets the definition of a natural health product (NHP) under the *Natural Health Products Regulations* when marketed as a hallucinogen. To date, Health Canada has not licensed for sale any natural health product which contains *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products containing *Salvia divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

ATTACHMENTS / PIÈCE(S)-JOINTE(S)

Contact/Personne ressource : Denis Arsenault/HC-SC/GC/CA	Tel. no./No de tél. 613-957-6828	Approved by/ Approuvé par Paul Glover, ADM (HECS/SESC)	Tel. no./No. de tél. 946-6701
	Mobile/ Cellulaire: 613-296-4239	Title/ Titre:	Mobile/ Cellulaire:
Alternate/ Secondaire: Jocelyn Kula	Telephone/ Téléphone: 613-952-2177		
	Mobile/ Cellulaire: 613-797-2103		

**Date Prepared/Préparé le :** 2010-09-07

**Prepared by/Préparé par :** Stephanie Chandler **Phone/ No de tél. :** 613-946-0124

**Office/Bureau :** CSTD - Office of Controlled Substances

**Date Contact Signed/  
Signature de la personne  
ressource :**

Contact Signed - Signé

**D.G. Verification/  
Vérification par le D.E. :**

Cathy Sabiston

D.G. Approved / Approuvé D.E.

**Date D.G. Verified/  
Date vérifié par le D.E. :**

**Programme :** Controlled Substances and Tobacco Directorate

**ADM Approved/ Approbation  
par le SMA :** Paul Glover  
(946-6701)

**Branch/ Direction générale :** HECS/SESC

**Department/ Ministère :** Health Canada / Santé Canada

**QUESTION PERIOD NOTE**  
**NOTE POUR LA PÉRIODE DE**  
**QUESTIONS**

Date:	January 20, 2011
Classification :	<b>HECS PROTECTED - SESC PROTÉGÉ</b>

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**DRUGS - SALVIA DIVINORUM**

Français:

**DROGUES - SALVIA DIVINORUM**

---

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Media interest in Salvia divinorum is recurrent. Questions around this substance generally focus on its legality. Recently, a number of media reports have commented on a YouTube video which reportedly shows the young celebrity Miley Cyrus smoking Salvia divinorum. Canadian surveillance data indicates that this substance is being used by adolescents and young adults for its hallucinogenic properties, and there have also been several reports from scientific sources indicating that Salvia divinorum has a potential for abuse.

---

**ANTICIPATED QUESTION - QUESTION PRÉVUE**

English:

What is Health Canada doing to protect young Canadians from the potential adverse effects associated with the use of Salvia divinorum?

Français:

Quelles mesures Santé Canada prend-il pour protéger les jeunes Canadiens contre les effets indésirables possibles liés à l'utilisation de la Salvia divinorum?

---

English:

- Health Canada is proposing to regulate Salvia in order to protect the health and safety of Canadians, particularly youth.
- Health Canada has published a *Notice to Interested Parties* in *Canada Gazette*, Part I, to give Canadians the opportunity to provide comments on its proposal to regulate Salvia.
- The regulation of Salvia will make possession, trafficking, importation, exportation, and production illegal unless authorized by regulation.

Français:

---

## **BACKGROUND - CONTEXTE**

English:

### **BACKGROUND / CONTEXTE**

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, diviner's sage, magic mint, and puff. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs.

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- hallucinations
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- out-of-body experiences
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- short-term memory loss
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- slurred speech and awkward sentence patterns

Recent surveys indicate that Canadian youth are trying this substance which could be dangerous to their health. Results from the *Canadian Alcohol and Drug Use Monitoring Survey* (CADUMS) reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *Salvia divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24 years. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *Salvia divinorum* in the past year. The 2009 *Ontario Student Drug Use and Health Survey* (OSDUHS) indicated that 5.4% of Ontario students in grades 7-12 reported ever using *Salvia divinorum* and 4.4% of these students reported using this substance in the past year.

#### International Control of *S. divinorum*

Neither *Salvia divinorum* nor its main active ingredient salvinorin A are listed under the United Nations Drug Control Conventions; as a result, they do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions. The move to include *Salvia divinorum* and salvinorin A in Schedule III to the CDSA is consistent with actions taken by several countries (e.g. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Some individual U.S. states have also implemented laws restricting their use, sale and/or distribution.

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- Extent of actual abuse of the substance in Canada and internationally; and
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Health Canada recently concluded its assessment of *S. divinorum* and its main active ingredient salvinorin A against the aforementioned factors and now proposes to include both substances in Schedule III to the CDSA.

The regulation of *Salvia divinorum* will allow law enforcement to take action against illegal activities involving this substance. The possession, trafficking, importation, exportation and production of *Salvia divinorum* and salvinorin A will be illegal unless authorized by regulation.

The plant *Salvia divinorum* is not currently regulated under the *Controlled Drugs and Substances Act* (CDSA) and therefore the plant is not considered to be "banned" nor are activities with it considered to be illegal in Canada. However, as *Salvia divinorum* is a plant with hallucinogenic properties when consumed by humans, it meets the definition of a natural health product (NHP) under the *Natural Health Products Regulations* when marketed as a hallucinogen. To date, Health Canada has not licensed for sale any natural health product which contains *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products containing *Salvia divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

ATTACHMENTS / PIÈCE(S)-JOINTE(S)

Contact/Personne ressource : Denis Arsenault/HC-SC/GC/CA	Tel. no./No de tél. 613-957-6828	Approved by/ Approuvé par Paul Glover, ADM (HECS/SESC)	Tel. no./No. de tél. 946-6701
	Mobile/ Cellulaire: 613-296-4239	Title/ Titre:	Mobile/ Cellulaire:
Alternate/ Secondaire: Jocelyn Kula	Telephone/ Téléphone: 613-952-2177		
	Mobile/ Cellulaire: 613-797-2103		

**Date Prepared/Préparé le :** 2010-09-07

**Prepared by/Préparé par :** Stephanie Chandler **Phone/ No de tél. :** 613-946-0124

**Office/Bureau :** CSTD - Office of Controlled Substances

**Date Contact Signed/  
Signature de la personne  
ressource :**

Contact Signed - Signé

**D.G. Verification/  
Vérification par le D.E. :**

Cathy Sabiston

D.G. Approved / Approuvé D.E.

**Date D.G. Verified/  
Date vérifié par le D.E. :**

**Programme :** Controlled Substances and Tobacco Directorate

**ADM Approved/ Approbation  
par le SMA :** Paul Glover  
(946-6701)

**Branch/ Direction générale :** HECS/SESC

**Department/ Ministère :** Health Canada / Santé Canada



**Fw: Salvia Event is on**

Jocelyn Kula to: Denis Arsenault, Stephanie Chandler

2011-01-21 10:13 AM

stay tuned.....and this means hold off on NOI package until further notice.....  
(and am looking at IYH right now)

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224  
----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2011-01-21 10:12 AM -----

From: Martina Vorel/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Date: 2011-01-21 08:59 AM  
Subject: Re: Salvia Event is on

---

Should have mentioned that I'll let comms know. Thanks.  
Martina Vorel

----- Original Message -----

**From:** Martina Vorel  
**Sent:** 2011-01-21 08:58 AM EST  
**To:** Jocelyn Kula  
**Subject:** Re: Salvia Event is on

Hi Jocelyn,

An event will be needed. MO advised that comms should contact Tim for direction.

Thanks.

Jocelyn Kula

----- Original Message -----

**From:** Jocelyn Kula  
**Sent:** 2011-01-20 07:59 PM EST  
**To:** Martina Vorel

---

Jocelyn  
Sent by blackberry

Jocelyn Kula  
A/ Director/ Directrice par interim  
Office of Controlled Substances/ Bureau des substances contrôllées  
Martina Vorel

----- Original Message -----

**From:** Martina Vorel  
**Sent:** 2011-01-20 07:55 PM EST  
**To:** Jocelyn Kula  
**Subject:** Re: Salvia Event is on

FYI - MO advised they will discuss in the morning at our staff meeting. I will let you know for sure then.  
Martina Vorel

----- Original Message -----

**From:** Martina Vorel  
**Sent:** 2011-01-20 07:45 PM EST  
**To:** Jocelyn Kula  
**Subject:** Re: Salvia Event is on

Ok, thanks for this. It appears there is some confusion in MO.....am trying to confirm things.  
Jocelyn Kula

----- Original Message -----

**From:** Jocelyn Kula  
**Sent:** 2011-01-20 07:18 PM EST  
**To:** Martina Vorel  
**Subject:** Fw: Salvia Event is on

???

Sent by blackberry

Jocelyn Kula  
A/ Director/ Directrice par interim  
Office of Controlled Substances/ Bureau des substances contrôllées  
Christine Roush

----- Original Message -----

**From:** Christine Roush  
**Sent:** 2011-01-20 05:21 PM EST  
**To:** Jocelyn Kula  
**Cc:** Dave Stephens; Cathy A Sabiston; Stephanie Szick; Denis Arsenault;  
Stephanie Chandler; Dave Stephens  
**Subject:** Salvia Event is on

Hi Jocelyn,

We have heard that it has been confirmed by MO that they would like an event the first week of February regarding the proposal to schedule Salvia. They also said that they **do not want the NOI to be published next week**. Could you please let us know when the next earliest date would be for publishing the NOI to Canada Gazette I? MO would prefer the publishing to happen after the event. Our DG, Comms has asked MO to schedule a planning meeting as soon as possible. I hope this helps to clarify things a bit.

Christine Roush  
Senior Communications Advisor/

---

From: Dave Stephens/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Christine Roush/HC-SC/GC/CA@HWC  
Date: 2011-01-20 04:11 PM  
Subject: Re: Fw: Salvia Announcement

---

and MO is now calling PMO for confirmation

Dave Stephens  
Senior Communications Executive-Gestionnaire Principal des Communications HECSB/DGSCSE  
6th Floor, Room 6-033, 269 Laurier Ave. W., Ottawa, ON  
Tel: (613) 946-8107  
Cell: (613) 859-3581



**Fw: For Approval: Salvia Media Lines**

Jocelyn Kula to: Stephanie Chandler, Denis Arsenault

2011-01-21 11:37 AM

sorry, thought you had already been copied

---

Jocelyn Kula

Acting Director/ Directrice par intérim

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs

Health Canada/ Santé Canada

Tel: (613) 952-2177 Fax: (613) 946-4224

----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2011-01-21 11:37 AM -----

From: Suzanne Desjardins/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Cc: Jocelyn Kula/HC-SC/GC/CA@HWC  
Date: 2011-01-20 08:19 AM  
Subject: Re: For Approval: Salvia Media Lines

Hi Christine,

The first bullet in the supplementary messages is somewhat problematic. We do know enough about these substances to want to control them. They are potent hallucinogens. So I would recommend the following changes:

- Canadians should not use products containing *Salvia divinorum* and/or salvinorin A because they are hallucinogenic and very little is known about the long-term effects of these substances and their potential effects on the brain and body.

Also,

For A3 text similar to the highlight report should be used (as youth are not more likely to... they report higher prevalence)

A3 - Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *Salvia divinorum* at least once in their lifetime with a much higher rate of use (7.3%) in youth aged 15-24.

Thanks

Suzanne

Christine Roush

Hi Suzanne - not sure if you were copied on my...

2011-01-19 05:11:28 PM

From: Christine Roush/HC-SC/GC/CA  
To: Suzanne Desjardins/HC-SC/GC/CA@HWC  
Date: 2011-01-19 05:11 PM  
Subject: For Approval: Salvia Media Lines

Hi Suzanne - not sure if you were copied on my earlier email, but the MO wants to do an announcement around the NOI for Salvia on Jan. 28th. Jocelyn has approved the revised media lines below, so could you please also review and let me know if you are OK with them. We have also dusted off the It's Your Health article and are updating it in anticipation of posting it to the HC website for the 28th. We are also preparing a news release to announce the NOI, and we will share this with you when ready.

Thanks,

[attachment "Salvia MLs\_Jan 19(3)\_ENG.doc" deleted by Suzanne Desjardins/HC-SC/GC/CA]

Christine Roush  
Senior Communications Advisor/

From: Christine Roush/HC-SC/GC/CA  
To: Stephanie Chandler/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Nicole Prentice/HC-SC/GC/CA@HWC  
Date: 2011-01-19 04:49 PM  
Subject: Re: Salvia Media Lines

---

Thanks Stephanie - we have communication contacts in both RCMP, Justice and Public Safety and I will give them all a head's up about this announcement. I will send the MLs to Suzanne Desjardins now for her approval, and also start the approvals in HPFB too. The clean version is below.

[attachment "Salvia MLs\_Jan 19(3)\_ENG.doc" deleted by Suzanne Desjardins/HC-SC/GC/CA]

Christine Roush  
Senior Communications Advisor/

Stephanie Chandler	Hi Christine, Here are the revised media lines...	2011-01-19 03:39:45 PM
Christine Roush	HPFB will need to approve the lines and we can...	2011-01-18 05:07:42 PM
Stephanie Chandler	Hi Christine, We will work on that question, ho...	2011-01-18 04:58:22 PM
Christine Roush	Hi Stephanie, I have reviewed the MLs and mad...	2011-01-18 03:36:37 PM
Stephanie Chandler	Hi Christine, With regards to our earlier conver...	2011-01-18 02:53:10 PM



**Fw: Q about Salvia MLs**

Christine Roush to: Stephanie Chandler  
Cc: Nicole Prentice

2011-01-21 11:43 AM

Here are the revised MLs that are still with HPFB for approval. The lines have been approved by Jocelyn and Suzanne.



Salvia MLs\_Jan20(4)\_(revok)ENG.doc

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
Health Canada/Santé Canada  
Tel/Tél : (613) 954-0712/Cell: (613) 219-7194  
Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca

----- Forwarded by Christine Roush/HC-SC/GC/CA on 2011-01-21 11:42 AM -----

From: Nicole Prentice/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Date: 2011-01-21 10:51 AM  
Subject: Fw: Q about Salvia MLs

FYI - Can you respond?

**Nicole Prentice**

Junior Communications Officer | Agente junior des Communications  
Regulatory Communications and Media Relations Division | Division des communications  
réglementaires et des relations avec les médias  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires  
publiques, de la consultation et des communications  
Health Canada | Santé Canada  
Tel: 613.941.3107  
Fax: 613.948.8085

----- Forwarded by Nicole Prentice/HC-SC/GC/CA on 2011-01-21 10:50 AM -----

From: Stephanie Chandler/HC-SC/GC/CA  
To: Nicole Prentice/HC-SC/GC/CA@HWC  
Date: 2011-01-21 09:00 AM  
Subject: Q about Salvia MLs

Hi Nicole,

I received some comments on the NOI from Suzanne Desjardins, and she would like us to revise some sentences to reflect the media lines which she approved, however I have not seen this version. Would you be able to send me a copy of the media lines which she has approved (only for the purposes of

revising the NOI)?

Thanks,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca



**DRAFT**  
19/01/2011

**Media Lines**  
***Salvia divinorum***

**Issue**

There is ongoing media interest regarding the availability of *Salvia divinorum* in Canada as well as Canadian surveillance data suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has concluded that *Salvia divinorum* and its main active ingredient salvinorin A should be regulated under the *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth.

**Key Messages:**

- Health Canada is proposing to regulate both *Salvia divinorum* and its main active ingredient salvinorin A under Schedule III to the *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth.
- As a first step, Health Canada published a *Notice to Interested Parties* (NOI) in *Canada Gazette*, Part I on January 29, 2011. The NOI is intended to give Canadians the opportunity to provide comments on its proposal to regulate *Salvia divinorum* and salvinorin A as controlled substances.
- The inclusion of *Salvia divinorum* and salvinorin A in Schedule III to the CDSA will make possession, trafficking, importation, exportation, and production (or cultivation) illegal unless authorized by regulation.

**Supplementary Messages:**

- Canadians should not use products containing *Salvia divinorum* and/or salvinorin A because they are hallucinogenic and little is known about the long-term effects of these substances on the brain and body.
- The plant *Salvia divinorum* is not currently regulated under the CDSA and therefore it is not considered to be "banned", nor are activities with it considered to be illegal in Canada.
- However, as *Salvia divinorum* is a plant with hallucinogenic properties when consumed by humans, it would meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations* when marketed as a hallucinogen.

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Tobacco\Controlled  
Substances\OCS Misc  
Substances\Salvia\Salvia MLs\_Jan  
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Deleted: 2011-01-20

C:\Windows\Temp\notesD3FEF1\Salvia MLs\_Jan20(4) (revok)ENG.doc

Last saved by Christine Roush

Created by Christine Roush  
2011-01-24

**DRAFT**

19/01/2011

- To date, Health Canada has not authorized for sale any natural health products which contain *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products containing *Salvia divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

#### Questions and Answers:

#### **Q1 – What is involved in regulating *Salvia divinorum* as a controlled substance and what stage is it at?**

A1 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada recently concluded its assessment of *Salvia divinorum* and salvinorin A against the aforementioned factors and proposes to include both substances in Schedule III to the CDSA. The first step in the process of regulating a substance under the CDSA is the publication of a *Notice to Interested Parties* (NOI) in *Canada Gazette*, Part I. Any comments received will be considered during the preparation of a regulatory proposal. There will be additional opportunities for comment as the federal regulatory process progresses.

The regulation of these products will reduce the potential risks to the health and safety of Canadians associated with their ready availability, with their increased use and their unknown effects. The scheduling of *Salvia divinorum* and salvinorin A will also eliminate the current perception that these substances are a safe alternative to other illegal drugs.

#### **Q2 – Are *Salvia divinorum* and/or salvinorin A controlled internationally? How are these substances regulated in other countries?**

A2 - Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions; as a result, they do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

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**DRAFT**  
19/01/2011

The move to include *Salvia divinorum* and salvinorin A in Schedule III to the CDSA is consistent with actions taken by several countries (e.g., Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Some individual U.S. states have implemented laws restricting their use, sale and/or distribution.

**Q3 – Is there any research on the use of *Salvia divinorum* in Canada?**

A3 - Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *Salvia divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *Salvia divinorum* in the past year. The 2009 *Ontario Student Drug Use and Health Survey (OSDUHS)* indicated that 5.4% of Ontario students in grades 7-12 reported ever using *Salvia divinorum* and 4.4% of these students reported using this substance in the past year.

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**Q4 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why isn't it illegal?**

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A4 – Health Canada proposes to include *Salvia divinorum* and salvinorin A under Schedule III to the CDSA. Further to the regulation of these substances under the CDSA, the following activities will be illegal unless authorized by regulation: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation). Law enforcement agencies will also be able to take action against suspected illegal activities involving these substances.

As a plant with hallucinogenic properties, however, *Salvia divinorum* meets the definition of a natural health product under the *Natural Health Products Regulations (NHPR)* when marketed as a hallucinogen. To date, Health Canada has not authorized for sale any natural health products which contain *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products may be subject to compliance and enforcement action under the *Food and Drugs Act*.

**Q5 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A5 – Once *Salvia divinorum* and salvinorin A are included in Schedule III to the CDSA, law enforcement will be able to take appropriate action in response to suspected illegal activities with these substances.

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19/01/2011

Currently however, *Salvia divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. Complaints about the unauthorized sale of drugs containing *Salvia divinorum* and/or salvinorin A can be referred to the Health Products and Food Branch Inspectorate at 1-800-267-9675.

**Q6 - Has Health Canada issued any kind of warning to Canadians about *Salvia divinorum*?**

A6 - Health Canada has developed an *It's Your Health* article about *Salvia divinorum* to help inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at:

**Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

Data from the 2008-2009 Youth Smoking Survey indicates that:

- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;
- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year; and
- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using Salvia in their lifetime (0.2% in the past year); and
- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

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19/01/2011

Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that:

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;
- 5.4% of students (grades 7-12) ever used *Salvia divinorum*; and
- the use of *Salvia divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

**Prepared by:** Stephanie Chandler and Denis Arsenault, OCS, CSTD  
Reviewed and revised by: Christine Roush, Senior Communications Advisor, HECS, Communications

**Input by:** Lisa Mackay IYH/PACCB,  
Suzanne Desjardins HECSB/ODARS,  
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Duc Vu, Director, Marketed Biologics, Biotechnology and Natural Health Products Bureau, MHPD (pending)  
Kim Dayman-Rutkas, Director, HPFBI (pending)  
Jocelyn Kula, A/Director, OCS, CSTD, HECS (Approved Jan 19, 2011)  
Suzanne Desjardins, Director, ODARS, CSTD, HECS (Approved Jan 20, 2011)  
Cathy Sabiston, DG, CSTD, HECS (pending)  
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Nancy Richards, DG, NHPD (pending)  
Diana Dowthwaite, DG, HPFBI (pending)  
Ken Polk, Communications Executive, HPFB (pending)  
Jean Tessier, Senior Media Relations, PACCB (pending)  
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Anne Lamar, ADM, PACCB (pending)

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19/01/2011

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2011-01-24  
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**Re: Salvia MLs** 

Christine Roush to: Jocelyn Kula

2011-01-21 04:12 PM

Cc: Dave Stephens, Denis Arsenault, Stephanie Chandler, Stephanie Szick

---

History: This message has been forwarded.

Hi Jocelyn,

I have HPFB approval of the Salvia MLs and thought you might like to review quickly their comments and changes and let me know if you are OK with them. I gather nothing is moving forward to Cathy until we have more direction from MO. The draft NR is still in your shop, and we have started drafting a Ministerial Event Proposal.

Cheers,



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Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
Health Canada/Santé Canada  
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**DRAFT**  
21/01/2011

**Media Lines**  
***Salvia divinorum***

**Issue**

There is ongoing media interest regarding the availability of *Salvia divinorum* in Canada as well as Canadian surveillance data suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has concluded that *Salvia divinorum* and its main active ingredient salvinorin A should be regulated under the *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth.

**Key Messages:**

- Health Canada is proposing to regulate both *Salvia divinorum* and its main active ingredient salvinorin A under Schedule III to the *Controlled Drugs and Substances Act* (CDSA).
- After reviewing available information and reports that suggest this substance has the potential for abuse, especially among young people, we are taking these steps to protect the health and safety of Canadians, particularly youth, from the potentially harmful effects of this substance
- Canadians should not use products containing *Salvia divinorum* and/or salvinorin A because they are hallucinogenic and little is known about the long-term effects of these substances on the brain and body.
- The inclusion of *Salvia divinorum* and salvinorin A in Schedule III to the CDSA will make possession, trafficking, importation, exportation, and production (or cultivation) illegal unless authorized by regulation.

**Comment [D1]:** Suggest to add a line about why there is a risk to the health of Canadians. Abuse potential? Addiction?

**Supplementary Messages:**

- The plant *Salvia divinorum* is not currently regulated under the CDSA and therefore it is not considered to be "banned", nor are activities with it considered to be illegal in Canada.
- However, as *Salvia divinorum* is a plant with hallucinogenic properties when consumed by humans, it would meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations* when marketed as a hallucinogen.
- To date, Health Canada has not authorized for sale any natural health products which contain *Salvia divinorum* as an ingredient. The sale of unauthorized

**Comment [D2]:** Suggest to remove. It is considered an NHP and subject to the NHPR.

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21/01/2011

natural health products containing *Salvia divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act and its associated regulations*.

**Questions and Answers:**

**Q1 – What is involved in regulating *Salvia divinorum* as a controlled substance and what stage is it at?**

A1 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada recently concluded its assessment of *Salvia divinorum* and salvinorin A against the aforementioned factors and proposes to include both substances in Schedule III to the CDSA. The first step in the process of regulating a substance under the CDSA is the publication of a *Notice to Interested Parties* (NOI) in *Canada Gazette*, Part I. Any comments received will be considered during the preparation of a regulatory proposal. There will be additional opportunities for comment as the federal regulatory process progresses.

The regulation of these products will reduce the potential risks to the health and safety of Canadians associated with their ready availability, with their increased use and their unknown effects. The scheduling of *Salvia divinorum* and salvinorin A will also eliminate the current misconception that these substances are a safe alternative to other illegal drugs.

**Comment [D3]:** Replace with "misconception"

**Q2 – Are *Salvia divinorum* and/or salvinorin A controlled internationally? How are these substances regulated in other countries?**

A2 - Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions; as a result, there is no requirement for them to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

**Comment [D4]:** Replace with "there is no requirement for them to be regulated"

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The move to include *Salvia divinorum* and salvinorin A in Schedule III to the CDSA is consistent with actions taken by several countries (e.g., Australia, Belgium, Denmark,

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Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Some individual U.S. states have implemented laws restricting their use, sale and/or distribution.

**Q3 – Is there any research on the use of *Salvia divinorum* in Canada?**

A3 - Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *Salvia divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *Salvia divinorum* in the past year. The 2009 *Ontario Student Drug Use and Health Survey (OSDUHS)* indicated that 5.4% of Ontario students in grades 7-12 reported ever using *Salvia divinorum* and 4.4% of these students reported using this substance in the past year.

**Q4 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why isn't it illegal?**

A4 – Health Canada proposes to include *Salvia divinorum* and salvinorin A under Schedule III to the CDSA. Further to the regulation of these substances under the CDSA, the following activities would be illegal unless authorized by regulation: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation). Law enforcement agencies would also be able to take action against suspected illegal activities involving these substances.

**Comment [D5]:** It is considered an NHP – it is illegal? It is a contravention of the FDR/NHPR to sell and unlicensed and unapproved product. No licences have been granted for these products.

However, as a plant with hallucinogenic properties, *Salvia divinorum* currently meets the definition of a natural health product under the *Natural Health Products Regulations (NHPR)* when marketed as a hallucinogen. To date, Health Canada has not authorized for sale any natural health products which contain *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products may be subject to compliance and enforcement action in accordance with the *Food and Drugs Act and its associated regulations*.

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**Q5 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A5 – Once *Salvia divinorum* and salvinorin A are included in Schedule III to the CDSA, law enforcement will be able to take appropriate action in response to suspected illegal activities with these substances.

Currently however, *Salvia divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement

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action by Health Canada. For more information on how to submit a consumer complaint about the unauthorized sale of drugs containing *Salvia divinorum* and/or salvinorin A, visit: [www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_44\\_consumer\\_consommateur\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_44_consumer_consommateur_cp-pc-eng.php).

**Q6 - Has Health Canada issued any kind of warning to Canadians about *Salvia divinorum*?**

A6 - Health Canada has developed an *It's Your Health* article about *Salvia divinorum* to help inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at:

**Comment [D6]:** No link here. Is this coming?

**Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

Data from the 2008-2009 Youth Smoking Survey indicates that:

- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;
- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year; and
- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using Salvia in their lifetime (0.2% in the past year); and
- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

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- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;
- 5.4% of students (grades 7-12) ever used *Salvia divinorum*; and
- the use of *Salvia divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

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**QUESTION PERIOD NOTE**  
**NOTE POUR LA PÉRIODE DE**  
**QUESTIONS**

Date:	January 20 <sup>21</sup> , 2011
Classification :	HECS PROTECTED - SESC PROTÉGÉ

---

**SUBJECT - SUJET**

English:

**DRUGS - SALVIA DIVINORUM**

Français:

**DROGUES - SALVIA DIVINORUM**

---

**SYNOPSIS - SOMMAIRE**

English:

Media interest in Salvia divinorum is recurrent. Questions around this substance generally focus on its legality. Recently, a number of media reports have commented on a YouTube video which reportedly shows the young celebrity Miley Cyrus smoking Salvia divinorum. Canadian surveillance data indicates that this substance is being used by adolescents and young adults for its hallucinogenic properties, and there have also been several reports from scientific sources indicating that Salvia divinorum has a potential for abuse.

---

**ANTICIPATED QUESTION - QUESTION PRÉVUE**

English:

What is Health Canada doing to protect young Canadians from the potential adverse effects associated with the use of Salvia divinorum?

Français:

Quelles mesures Santé Canada prend-il pour protéger les jeunes Canadiens contre les effets indésirables possibles liés à l'utilisation de la Salvia divinorum?

---

English:

- Health Canada is proposing to regulate Salvia in order to protect the health and safety of Canadians, particularly youth.
- Health Canada has published a *Notice to Interested Parties* in *Canada Gazette*, Part I, to give Canadians the opportunity to provide comments on its proposal to regulate Salvia.
- The regulation of Salvia will make possession, trafficking, importation, exportation, and production illegal unless authorized by regulation.

Français:

---

## **BACKGROUND - CONTEXTE**

English:

### **BACKGROUND / CONTEXTE**

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, diviner's sage, magic mint, and puff. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs.

Both the plant *S. divinorum* and its main active ingredient salvinin A are known to have physical and mental effects which are often described as unpleasant, including:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination

- slurred speech and awkward sentence patterns

Recent surveys indicate that Canadian youth are trying this substance which could be dangerous to their health. Results from the *Canadian Alcohol and Drug Use Monitoring Survey* (CADUMS) reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *Salvia divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24 years. The results from the Canadian 2008-2009 *Youth Smoking Survey* also show that 5% of 15 year olds have used *Salvia divinorum* in the past year. The 2009 *Ontario Student Drug Use and Health Survey* (OSDUHS) indicated that 5.4% of Ontario students in grades 7-12 reported ever using *Salvia divinorum* and 4.4% of these students reported using this substance in the past year.

#### International Control of *S. divinorum*

Neither *Salvia divinorum* nor its main active ingredient salvinorin A are listed under the United Nations Drug Control Conventions; as a result, they do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions. The move to include *Salvia divinorum* and salvinorin A in Schedule III to the CDSA is consistent with actions taken by several countries (e.g. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Some individual U.S. states have also implemented laws restricting their use, sale and/or distribution.

#### Current Situation in Canada

Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted, namely:

- International requirements and trends in control and/or scheduling;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e. therapeutic, scientific, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada recently concluded its assessment of *S. divinorum* and its main active ingredient salvinorin A against the aforementioned factors and now proposes to include both substances in Schedule III to the CDSA.

The regulation of *Salvia divinorum* will allow law enforcement to take action against illegal activities involving this substance. The possession, trafficking, importation, exportation and production of *Salvia divinorum* and salvinorin A will be illegal unless authorized by regulation.

The plant *Salvia divinorum* is not currently regulated under the *Controlled Drugs and Substances Act* (CDSA) and therefore the plant is not considered to be "banned" nor are activities with it considered to be illegal in Canada. However, as *Salvia divinorum* is a plant with hallucinogenic properties when consumed by humans, it meets the definition of a natural health product (NHP) under the *Natural Health Products Regulations* when marketed as a hallucinogen. To date, Health Canada has not licensed for sale any natural health product which contains *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products containing *Salvia divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

ATTACHMENTS / PIÈCE(S)-JOINTE(S)



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**Date Prepared/Préparé le :** 2010-09-07

**Prepared by/Préparé par :** Stephanie Chandler **Phone/ No de tél. :** 613-946-0124

**Office/Bureau :** CSTD - Office of Controlled Substances

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**D.G. Verification/  
Vérification par le D.E. :** Cathy Sabiston  D.G. Approved / Approuvé D.E.

**Date D.G. Verified/  
Date vérifié par le D.E. :**

**Programme :** Controlled Substances and Tobacco Directorate

**ADM Approved/ Approbation  
par le SMA :** Paul Glover  
(946-6701)

**Branch/ Direction générale :** HECS/SESC

**Department/ Ministère :** Health Canada / Santé Canada

Scientific reports ~~have~~ also suggest that it has the potential for abuse.

### Salvia divinorum

#### Issue

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff, incense special, and salvia.

Recent ~~there have been~~ reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs. [As of DATE 2011] Health Canada has not authorized for sale any products containing *S. divinorum*.

Health Canada recommends that you avoid using this plant because ~~very little is known about the effects it may have on your body and/or brain functions.~~ There is also no way to predict how it will affect you with each use.

Moreover, ~~Canadian surveillance data and scientific reports have indicated that *S. divinorum* has the potential for abuse.~~ As a result, Health Canada is proposing to regulate both *S. divinorum* and its main active ingredient, salvinorin A under Schedule III to the Controlled Drugs and Substances Act (CDSA) in order to protect the health and safety of Canadians, particularly youth.

wld recommen to delete, seems out of place here ....

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In light of this information

#### Risks Associated with the Use of *Salvia divinorum*

*S. divinorum* is known to have both physical and mental effects. The effects of *S. divinorum*, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product
- how much is used
- the purity of the product (products that contain *S. divinorum* may be mixed with other substances)

They are hallucinogenic and very little is know about the long term effects of these substances on the brain and body.  
(consistent with Suzanne's comments on media lines)

Gain why advertise that is still legal?  
DR perhaps rephrase so that appears as  
In the long term, Health Canada is taking steps to regulate S. div. and Salv A under ie C.D. - S. A. - "

- how it is taken, for example, whether the product is chewed, swallowed or smoked
- the user's mood and expectations

While scientists know which brain receptors are targeted by the active ingredient, salvinorin A, very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or if it can cause permanent damage
- how it interacts with other substances, including other drugs, natural health products and alcohol
- the potential of *S. divinorum* to produce physical dependence and/or addiction

### Minimizing Your Risk

Hallucinogens like *S. divinorum* work by modifying functions in the brain. Health Canada recommends that you avoid using *S. divinorum* because very little is known about the effects it may have on your body and/or brain functions. There is also no way to predict how it will affect you with each use. Just because a drug is plant-based or "natural", does not mean that it is safe.

Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs, such as marijuana, cocaine, ecstasy, LSD and other substances that distort reality. See the "Need More Info?" section below for links to resources that can help you with this.

### Legal Status of *Salvia divinorum*

#### In Canada

As *S. divinorum* is a plant with hallucinogenic properties when consumed by humans, it currently meets the definition of a natural health product (NHP) under the *Natural Health Products Regulations* when marketed as a hallucinogen. As of ~~DATE~~ 2011, Health Canada has not authorized for sale any natural health products which contain *S. divinorum* as an ingredient. The sale of unauthorized natural health products containing *S. divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

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While ~~neither~~ *S. divinorum* ~~nor~~ salvinorin A ~~are~~ <sup>are</sup> currently regulated under the *Controlled Drugs and Substances Act* (CDSA), ~~However, after reviewing the available information regarding these substances, Health Canada is proposing to add *S. divinorum* and its main active ingredient, salvinorin A, to Schedule III to the CDSA. Because of their~~ <sup>its</sup> hallucinogenic properties, products containing *S. divinorum* or salvinorin A meet the definition of a Natural Health Product (NHP) in accordance with the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*. It is illegal to sell drugs or NHPs in Canada, unless they have been reviewed and authorized

now developing a regulatory proposal that would add....

for sale by Health Canada. In the case of NHPs, they need to be labelled with one of the following:

- \*a Natural Product Number (NPN); or
- \*an Exemption Number (EN); or
- \*a Drug Identification Number – Homeopathic Medicine Number (DIN-HM).

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As of ~~DATE~~ 2010 no products containing *S. divinorum* or salvinorin A have been authorized by Health Canada for sale. The sale of unauthorized drugs and NHPs is illegal, and may be subject to compliance and enforcement actions by the Department.

Neither *S. divinorum* nor salvinorin A are currently regulated under the *Controlled Drugs and Substances Act* (CDSA). Health Canada is currently considering the available information to determine whether regulation as a controlled substance is warranted.

#### In Other Countries

Several countries including but not limited to Australia, Belgium, Germany, ~~Italy~~ Italy and ~~Japan, etc.~~, have placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A.

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In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on their sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution. ~~For example,~~ In some states, for example, it is illegal for *S. divinorum* to be sold to anyone under the age of 18.

#### **Background**

The leaves of this plant have been used traditionally by the Mazatec people for medicinal and mystical purposes.

Products that claim to contain *S. divinorum* or its main active ingredient, salvinorin A are widely available on the Internet and are sold in various “head shops” and natural food stores. The products are sold in a number of forms, including fresh or dried leaves, liquids or seeds and plant cuttings for growing purposes.

Results from the Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *S. divinorum* at least once in their lifetime, and that youth aged 15-24 were much more likely to have used it than adults aged 25 years and older. The results from the Canadian 2008-2009 Youth Smoking Survey also show that 5% of 15 year olds have used *S. divinorum* in the past year. The 2009 Ontario Student Drug Use and Health Survey (OSDUHS) indicated that 5.4% of Ontario students in grades 7-12 reported ever using *S. divinorum* and 4.4% of these students reported using this substance in the past year. Results from the Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that, in 2009, less than 2% of Canadians age 15 and older reported having used *S. divinorum* at least once in their lifetime. Youth, ages 15-24 were much more likely to

have used it than adults. The results from the Canadian 2008-2009 Youth Smoking Survey show that 5% of 15yr olds have used *S. divinorum* in the past year. For more information on these surveys, see the *Need More Info* section below.

and particularly, the risk to youth,

as controlled substances.

### Health Canada's Role

Health Canada continues to collect and consider safety information regarding *S. divinorum* and will continue to consult with key stakeholders including health officials in other countries and law enforcement officials here at home. In light of the ~~potential~~ health and safety risks associated with the use of *S. divinorum*, Health Canada ~~proposes to~~ <sup>is taking steps to</sup> include *S. divinorum* and salvinorin A under Schedule III of the CDSA. As a first step in ~~the process of regulating these substances,~~ <sup>regulate</sup> Health Canada issued a *Notice to Interested Parties* (NOI) on January 29, 2011, ~~outlining its proposal to schedule these substances under the CDSA~~. This will assist in determining Health Canada's future approach to decision-making regarding the regulation of *S. divinorum* in Canada. In the interim, Health Canada also ~~will~~ continues to monitor the sale of unauthorized health products, ~~including those that contain *S. divinorum* or its main active ingredient salvinorin A,~~ <sup>It</sup> and will take appropriate action when ~~the Department~~ <sup>should it</sup> becomes aware of any unauthorized health products that may pose a risk to Canadians.

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### Need More Info?

- Complaints about the ~~illegal~~ unauthorized sale of drugs containing *S. divinorum* can be made to the **Health Products and Food Branch Inspectorate** at: [http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_44\\_consumer\\_consommateur\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_44_consumer_consommateur_cp-pc-eng.php)  
Tel: 1-800-267-9675.
- You can report any adverse reactions to the Canada Vigilance Program by one of the following three ways:  
Report online at the MedEffect™ Canada website at: <http://www.hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>  
Call toll-free at 1-866-234-2345  
Complete a Canada Vigilance Reporting Form and either:  
Fax toll-free to 1-866-678-6789  
Mail to: Canada Vigilance Program  
Health Canada  
AL 0701C  
Ottawa, ON K1A 0K9  
To have postage pre-paid, download the postage paid label from the MedEffect™ Canada website. The Canada Vigilance Reporting Form and the adverse reaction reporting guidelines may also be obtained via this website at : [http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei\\_form-eng.php](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei_form-eng.php)
- For information about the Government of Canada's Anti-Drug Strategy, go to: [www.nationalantidrugstrategy.gc.ca/](http://www.nationalantidrugstrategy.gc.ca/)

National

The Prevention section on this site has a number of helpful resources for parents, including:

- **Tips on Talking to Your Teenager**, at: [www.hc-sc.gc.ca/hc-ps/pubs/adp-adp/talk-aborder/index-eng.php](http://www.hc-sc.gc.ca/hc-ps/pubs/adp-adp/talk-aborder/index-eng.php)
- **What to Do if Your Teen is Using Drugs**, at: [www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html](http://www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html)
- Health Canada's **Not4Me** youth drug prevention section at: <http://www.hc-sc.gc.ca/hc-ps/drugs-drogues/youth-jeunes/facts-faits/index-eng.php>
- Information on natural health products and the ***Natural Health Products Regulations*** can be found at: [www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php)

For more on the surveys that have collected information about *Salvia divinorum* use in Canada, see:

- **The 2008-2009 Youth Smoking Survey**, at: <http://www.yss.uwaterloo.ca/index.cfm?section=5&page=288>
- **The 2009 Canadian Alcohol and Drug Use Monitoring Survey**, at: <http://www.hc-sc.gc.ca/hc-ps/drugs-drogues/stat/index-eng.php>
- **The 2009 Ontario Student Drug Use and Health Survey**, at: [http://www.camh.net/News\\_events/News\\_releases\\_and\\_media\\_advisories\\_and\\_ackgrounders/osduhs2009\\_advisory.html](http://www.camh.net/News_events/News_releases_and_media_advisories_and_ackgrounders/osduhs2009_advisory.html)

Additional Resources:

- U.S. Drug Enforcement Administration: **Drugs and Chemicals of Concern: *Salvia divinorum* and Salvinorin A** at: [www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)
- U.S. Department of Health & Human Services, **National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006** at: [www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf](http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf)
- For additional articles on health and safety issues go to the ***It's Your Health*** web section at: [www.healthcanada.gc.ca/iyh](http://www.healthcanada.gc.ca/iyh)

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

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## Salvia divinorum

### Issue

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff, incense special, and salvia.

Recent Canadian surveillance data indicates that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. Scientific reports also suggest that it has the potential for abuse. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs.

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Canadians should not use products containing *S. divinorum* and/or salvinorin A because they are hallucinogenic and little is known about the long-term effects of these substances on the brain and body. There is also no way to predict how it will affect you with each use.

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In light of this information, Health Canada is proposing to regulate both *S. divinorum* and its main active ingredient salvinorin A under Schedule III to the *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth.

**Deleted:** As of [REDACTED] 2010 Health Canada has not authorized for sale any products containing *S. divinorum*.

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### **Risks Associated with the Use of *Salvia divinorum***

*S. divinorum* is known to have both physical and mental effects. The effects of *S. divinorum*, which vary from person to person, are often described as unpleasant and may include the following:

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Health Canada recommends that you avoid using this plant because very little is known about the effects it may have on your body and/or brain functions. There is also no way to predict how it will affect you with each use.

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product
- how much is used
- the purity of the product (products that contain *S. divinorum* may be mixed with other substances)

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- how it is taken, for example, whether the product is chewed, swallowed or smoked
- the user's mood and expectations

While scientists know which brain receptors are targeted by the active ingredient, salvinorin A, very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or if it can cause permanent damage
- how it interacts with other substances, including other drugs, natural health products and alcohol
- the potential of *S. divinorum* to produce physical dependence and/or addiction

### Minimizing Your Risk

Hallucinogens like *S. divinorum* work by modifying functions in the brain. Health Canada recommends that you avoid using *S. divinorum* because very little is known about the effects it may have on your body and/or brain functions. There is also no way to predict how it will affect you with each use. Just because a drug is plant-based or "natural", does not mean that it is safe.

Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs, such as marijuana, cocaine, ecstasy, LSD and other substances that distort reality. See the "Need More Info?" section below for links to resources that can help you with this.

### Legal Status of *Salvia divinorum*

#### In Canada

As *S. divinorum* is a plant with hallucinogenic properties when consumed by humans, it currently meets the definition of a natural health product (NHP) under the *Natural Health Products Regulations* when marketed as a hallucinogen. As of [redacted] 2011, Health Canada has not authorized for sale any natural health products which contain *S. divinorum* as an ingredient. The sale of unauthorized natural health products containing *S. divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

While *S. divinorum* and salvinorin A are not currently regulated under the *Controlled Drugs and Substances Act* (CDSA), Health Canada is now developing a regulatory proposal that would add *S. divinorum* and salvinorin A to Schedule III to the CDSA.

#### In Other Countries

Several countries including but not limited to Australia, Belgium, Germany, Italy and Japan, have placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A.

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Deleted: As of [redacted] 2010 no products containing *S. divinorum* or salvinorin A have been authorized by Health Canada for sale. The sale of unauthorized drugs and NHPs is illegal, and may be subject to compliance and enforcement actions by the Department. ¶

¶ Neither *S. divinorum* nor salvinorin A are currently regulated under the *Controlled Drugs and Substances Act* (CDSA). Health Canada is currently considering the available information to determine whether regulation as a controlled substance is warranted. ¶

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In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on their sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution. In some states, for example, it is illegal for *S. divinorum* to be sold to anyone under the age of 18.

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### Background

The leaves of this plant have been used traditionally by the Mazatec people for medicinal and mystical purposes.

Products that claim to contain *S. divinorum* or its main active ingredient, salvinorin A are widely available on the Internet and are sold in various "head shops" and natural food stores. The products are sold in a number of forms, including fresh or dried leaves, liquids or seeds and plant cuttings for growing purposes.

Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *S. divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *S. divinorum* in the past year. The 2009 *Ontario Student Drug Use and Health Survey (OSDUHS)* indicated that 5.4% of Ontario students in grades 7-12 reported ever using *S. divinorum* and 4.4% of these students reported using this substance in the past year. For more information on these surveys, see the *Need More Info* section below.

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### Health Canada's Role

In light of the health and safety risks associated with the use of *S. divinorum*, Health Canada is taking steps to regulate *S. divinorum* and salvinorin A as controlled substances. As a first step in this process, Health Canada issued a *Notice to Interested Parties (NOI)* on February 5, 2011. In the interim, Health Canada will continue to monitor the sale of unauthorized health products that contain *S. divinorum* or its main active ingredient salvinorin A. It will take appropriate action should it become aware of any unauthorized health products that may pose a risk to Canadians.

and particularly the risks to youth

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### Need More Info?

- Complaints about the unauthorized sale of drugs containing *S. divinorum* can be made to the **Health Products and Food Branch Inspectorate** at: [http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_44\\_consumer\\_consommateur\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_44_consumer_consommateur_cp-pc-eng.php)  
Tel: 1-800-267-9675.

- You can report any adverse reactions to the Canada Vigilance Program by one of the following three ways:  
Report online at the MedEffect™ Canada website at: <http://www.hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>  
Call toll-free at 1-866-234-2345  
Complete a Canada Vigilance Reporting Form and either:  
Fax toll-free to 1-866-678-6789  
Mail to: Canada Vigilance Program  
Health Canada  
AL 0701C  
Ottawa, ON K1A 0K9  
To have postage pre-paid, download the postage paid label from the MedEffect™ Canada website. The Canada Vigilance Reporting Form and the adverse reaction reporting guidelines may also be obtained via this website at : [http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei\\_form-eng.php](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei_form-eng.php)
- For information about the Government of Canada's National Anti-Drug Strategy, go to: [www.nationalantidrugstrategy.gc.ca/](http://www.nationalantidrugstrategy.gc.ca/)  
The Prevention section on this site has a number of helpful resources for parents, including:
  - **Tips on Talking to Your Teenager**, at: [www.hc-sc.gc.ca/hc-ps/pubs/adp-adp/talk-aborder/index-eng.php](http://www.hc-sc.gc.ca/hc-ps/pubs/adp-adp/talk-aborder/index-eng.php)
  - **What to Do if Your Teen is Using Drugs**, at: [www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html](http://www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html)
  - Health Canada's **Not4Me** youth drug prevention section at: <http://www.hc-sc.gc.ca/hc-ps/drugs-drogues/youth-jeunes/facts-faits/index-eng.php>
- Information on natural health products and the Natural Health Products Regulations can be found at: [www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php)

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For more on the surveys that have collected information about *Salvia divinorum* use in Canada, see:

- **The 2008-2009 Youth Smoking Survey**, at: <http://www.yss.uwaterloo.ca/index.cfm?section=5&page=288>
- **The 2009 Canadian Alcohol and Drug Use Monitoring Survey**, at: <http://www.hc-sc.gc.ca/hc-ps/drugs-drogues/stat/index-eng.php>
- **The 2009 Ontario Student Drug Use and Health Survey**, at: [http://www.camh.net/News\\_events/News\\_releases\\_and\\_media\\_advisories\\_and\\_backgrounders/osduhs2009\\_advisory.html](http://www.camh.net/News_events/News_releases_and_media_advisories_and_backgrounders/osduhs2009_advisory.html)

Additional Resources:

- U.S. Drug Enforcement Administration: **Drugs and Chemicals of Concern: *Salvia divinorum* and *Salvinorin A*** at: [www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)

- U.S. Department of Health & Human Services, **National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006** at:  
[www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf](http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf)
- For additional articles on health and safety issues go to the **It's Your Health** web section at: [www.healthcanada.gc.ca/iyh](http://www.healthcanada.gc.ca/iyh)

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

Original:

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Catalogue#

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Version/date: Draft 17. September 8, 2010.

PACCB IYH - Lisa Mackay: 613-954-0105 – [Lisa.Mackay@hc-sc.gc.ca](mailto:Lisa.Mackay@hc-sc.gc.ca)

Comments from: HECSB - CSTD (OCS&ODARS) & HPFB – NHPD, MHPD & HPFBI

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HPFBI : Collin Pinto  
HPFB comms: Elizabeth Keeping, Blossom Leung

Health Canada

2011-XX

# News Release

## The Government of Canada Proposes to Regulate *Salvia Divinorum* and Salvinorin A as Controlled Substances

January 28, 2011  
For immediate release

**OTTAWA** – Today, the Honourable Leona Aglukkaq, Minister of Health announced that the Government of Canada intends to regulate *Salvia divinorum* and salvinorin A, also known as Salvia, as controlled substances. A Notice to Interested Parties outlining Health Canada's proposal will be published in *Canada Gazette*, Part I, on February 5, 2011.

"After reviewing Canadian surveillance data and scientific reports that suggest this substance has the potential for abuse, especially among young people, we are taking these steps to protect the health and safety of Canadians from the potentially harmful effects of this substance," said Minister Aglukkaq. "The use of this substance is of concern to Health Canada as very little is known about its long-term effects on the brain and body," added Aglukkaq.

The Notice to Interested Parties will propose that ~~*Salvia divinorum* and its main active ingredient salvinorin A~~ be added to Schedule III to the *Controlled Drugs and Substances Act*. This means that activities such as possession, trafficking, importation, exportation, and production will be illegal unless authorized by regulation. ~~The regulation of *Salvia divinorum* and salvinorin A will also enable law enforcement agencies to take action against suspected illegal activities involving these substances.~~

Interested parties are encouraged to submit any comments regarding the Notice to Interested Parties by March 7, 2011.

For more information on *Salvia divinorum*, please visit: *It's Your Health - Salvia divinorum*: XXX

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Media Enquiries:  
Health Canada

Également disponible en français

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Regulating Salvia as a controlled substance will

(613) 957-2983

Jenny Van Alstyne  
Office of the Honourable Leona Aglukkaq  
Federal Minister of Health  
(613) 957-0200

**Public Enquiries:**  
(613) 957-2991  
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The Notice to Interested Parties will be published in <i>Canada Gazette</i> , Part I, on January 29, 2011.		
<b>Page 1: [2] Comment [h1]</b>	<b>hcuser</b>	<b>2011-01-19 4:06:00 PM</b>
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<b>Page 1: [3] Comment [h2]</b>	<b>hcuser</b>	<b>2011-01-20 4:47:00 PM</b>
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Health Canada  
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20110-

# News Release

## The Government of Canada Proposes to Regulate Salvia Divinorum and Salvinorin A as Controlled Substances

January 28, 2011  
For immediate release

OTTAWA – Today, the Honourable Leona Aglukkaq, Minister of Health ~~announced that released a Notice to Interested Parties, also known as a Notice of Intent, would be published in the Canada Gazette, Part I, on January 29, 2011. The Notice outlines Health Canada's proposal to regulate Salvia divinorum and salvinorin A, also known as Salvia, as controlled substances.~~

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This Notice will provide interested stakeholders with the opportunity to comment on Health Canada's proposal to add the plant *Salvia divinorum* (*S. divinorum*) and its main active ingredient salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA).

"After reviewing available information Canadian surveillance data and scientific reports that suggest this substance has the potential for abuse, especially among young people, we are taking these steps to protect the health and safety of Canadians, particularly youth, from the potentially harmful effects of this substance," said Minister Aglukkaq. "The use of this substance is a serious concern for all Canadians to Health Canada because as not enough very little is known about the long-term effects of *Salvia divinorum*," added Aglukkaq.

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*on the brain and body.*

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Including these substances within the *Controlled Drugs and Substances Act* will make possession, trafficking, importation, exportation, and production (or cultivation) illegal unless authorized by regulation. Also, the regulation of *S. divinorum* and salvinorin A under the CDSA will also enable law enforcement agencies to take action against suspected illegal activities involving these substances.

The Notice to Interested Parties will be published in *Canada Gazette*, Part I, on January 29, 2011. Interested parties are encouraged to submit any comments regarding the Notice to Interested Parties before February 28, 2011.

*[DATE]*

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*The NOI will propose that Salvia be added to Schedule III to the CDSA. This means that all activities, e.g. possession, trafficking, importation... will be illegal unless authorized by regulation. Regulating Salvia as a controlled substance will also*



For more information on *Salvia divinorum*, please visit: *It's Your Health - Salvia divinorum*: XXX

**Comment [h2]:** Weblink – OCS is waiting for confirmation from DGO whether this will be posted next week

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**Media Enquiries:**  
Health Canada  
(613) 957-2983

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Jenny Van Alstyne  
Office of the Honourable Leona Aglukkaq  
Federal Minister of Health  
(613) 957-0200

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21/01/2011

## Media Lines *Salvia divinorum*

### Issue

There is ongoing media interest regarding the availability of *Salvia divinorum* in Canada as well as Canadian surveillance data suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has concluded that *Salvia divinorum* and its main active ingredient salvinorin A should be regulated under the *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth.

### Key Messages:

- Health Canada is proposing to regulate both *Salvia divinorum* and its main active ingredient salvinorin A under Schedule III to the *Controlled Drugs and Substances Act* (CDSA).
- After reviewing available information and reports that suggest this substance has the potential for abuse, especially among young people, we are taking these steps to protect the health and safety of Canadians, particularly youth, from the potentially harmful effects of this substance
- Canadians should not use products containing *Salvia divinorum* and/or salvinorin A because they are hallucinogenic and little is known about the long-term effects of these substances on the brain and body.
- The inclusion of *Salvia divinorum* and salvinorin A in Schedule III to the CDSA will make possession, trafficking, importation, exportation, and production (or cultivation) illegal unless authorized by regulation.

### Supplementary Messages:

- The plant *Salvia divinorum* is not currently regulated under the CDSA and therefore it is not considered to be "banned", nor are activities with it considered to be illegal in Canada.
- However, as *Salvia divinorum* is a plant with hallucinogenic properties when consumed by humans, it would meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations* when marketed as a hallucinogen.
- To date, Health Canada has not authorized for sale any natural health products which contain *Salvia divinorum* as an ingredient. The sale of unauthorized

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21/01/2011

natural health products containing *Salvia divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act and its associated regulations*.

**Questions and Answers:**

**Q1 – What is involved in regulating *Salvia divinorum* as a controlled substance and what stage is it at?**

A1 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act (CDSA)* is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada recently concluded its assessment of *Salvia divinorum* and salvinorin A against the aforementioned factors and proposes to include both substances in Schedule III to the CDSA. The first step in the process of regulating a substance under the CDSA is the publication of a *Notice to Interested Parties (NOI)* in *Canada Gazette, Part I*. Any comments received will be considered during the preparation of a regulatory proposal. There will be additional opportunities for comment as the federal regulatory process progresses.

The regulation of these products will reduce the potential risks to the health and safety of Canadians associated with their ready availability, with their increased use and their unknown effects. The scheduling of *Salvia divinorum* and salvinorin A will also eliminate the current misconception that these substances are a safe alternative to other illegal drugs.

**Q2 – Are *Salvia divinorum* and/or salvinorin A controlled internationally? How are these substances regulated in other countries?**

A2 - Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions; as a result, there is no requirement for them to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

The move to include *Salvia divinorum* and salvinorin A in Schedule III to the CDSA is consistent with actions taken by several countries (e.g., Australia, Belgium, Denmark,

**Comment [D5]:** Replace with "misconception"

**Comment [S6]:** OK with this change.

**Comment [D7]:** Replace with "there is no requirement for them to be regulated"

**Comment [S8]:** OK with this change.

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Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Some individual U.S. states have implemented laws restricting their use, sale and/or distribution.

**Q3 – Is there any research on the use of *Salvia divinorum* in Canada?**

A3 - Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *Salvia divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *Salvia divinorum* in the past year. The 2009 *Ontario Student Drug Use and Health Survey (OSDUHS)* indicated that 5.4% of Ontario students in grades 7-12 reported ever using *Salvia divinorum* and 4.4% of these students reported using this substance in the past year.

**Q4 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why isn't it illegal?**

A4 – The move to regulate *Salvia divinorum* and salvinorin A as controlled substances is based on surveillance data from surveys such as the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)*, *Youth Smoking Survey (YSS)* and the *Ontario Student Drug Use and Health Survey (OSDUHS)* which only became available in 2010,

In the interim, as *Salvia divinorum* is a plant with hallucinogenic properties, it currently meets the definition of a natural health product under the *Natural Health Products Regulations (NHPR)* when marketed as a hallucinogen. To date, Health Canada has not authorized for sale any natural health products which contain *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products may be subject to compliance and enforcement action in accordance with the *Food and Drugs Act* and its associated regulations.

**Q5 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A5 – Once *Salvia divinorum* and salvinorin A are included in Schedule III to the CDSA, law enforcement will be able to take appropriate action in response to suspected illegal activities with these substances.

Currently however, *Salvia divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. For more information on how to submit a consumer complaint about the unauthorized sale of drugs containing *Salvia divinorum* and/or salvinorin A,

**Comment [D9]:** It is considered an NHP – it is illegal? It is a contravention of the FDR/NHPR to sell and unlicensed and unapproved product. No licences have been granted for these products.

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visit: [www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_44\\_consumer\\_consommateur\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_44_consumer_consommateur_cp-pc-eng.php).

**Q6 - Has Health Canada issued any kind of warning to Canadians about *Salvia divinorum*?**

A6 - Health Canada has developed an *It's Your Health* article about *Salvia divinorum* to help inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at:

**Comment [D10]:** No link here. Is this coming?

**Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

Data from the 2008-2009 Youth Smoking Survey indicates that:

- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;
- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year; and
- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using Salvia in their lifetime (0.2% in the past year); and
- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that:

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;

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- 5.4% of students (grades 7-12) ever used *Salvia divinorum*; and
- the use of *Salvia divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

**Prepared by:** Stephanie Chandler and Denis Arsenault, OCS, CSTD  
Reviewed and revised by: Christine Roush, Senior Communications Advisor, HECS, Communications

**Input by:** Lisa Mackay IYH/PACCB,  
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**Approved by:**

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Duc Vu, Director, Marketed Biologics, Biotechnology and Natural Health Products Bureau, MHPD (pending)  
Kim Dayman-Rutkas, Director, HPFBI (pending)  
Jocelyn Kula, A/Director, OCS, CSTD, HECS (Approved Jan 19, 2011)  
Suzanne Desjardins, Director, ODARS, CSTD, HECS (Approved Jan 20, 2011)  
Cathy Sabiston, DG, CSTD, HECS (pending)  
Chris Turner, DG, MHPD (pending)  
Scott Sawler, DG, NHPD (pending)  
Diana Dowthwaite, DG, HPFBI (pending)  
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Ken Polk, A/Director, Public Affairs, PACCB (pending)  
Charles Mojsej, DG, PACCB (pending)

HECS Legal (pending)  
HPFB Legal (pending)  
Paul Glover, ADM, HECSB (pending)  
Meena Ballantyne, ADM, HPFB (pending)  
Anne Lamar, ADM, PACCB (pending)  
DMO (pending)  
MO (pending)  
PCO (pending)

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Warren Braun, Director, Strategic Communications, PACCB (pending)¶  
Peter Yendal

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21/01/2011

**Media Lines**  
**Salvia divinorum**

**Issue**

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**Key Messages:**

- Health Canada is proposing to regulate both *Salvia divinorum* and its main active ingredient salvinorin A under Schedule III to the *Controlled Drugs and Substances Act* (CDSA).
- After reviewing available information and reports that suggest this substance has the potential for abuse, especially among young people, we are taking these steps to protect the health and safety of Canadians, particularly youth, from the potentially harmful effects of this substance
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**Supplementary Messages:**

- The plant *Salvia divinorum* is not currently regulated under the CDSA and therefore it is not considered to be "banned", nor are activities with it considered to be illegal in Canada.
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21/01/2011

natural health products containing *Salvia divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act and its associated regulations*.

**Questions and Answers:**

**Q1 – What is involved in regulating *Salvia divinorum* as a controlled substance and what stage is it at?**

A1 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada recently concluded its assessment of *Salvia divinorum* and salvinorin A against the aforementioned factors and proposes to include both substances in Schedule III to the CDSA. The first step in the process of regulating a substance under the CDSA is the publication of a *Notice to Interested Parties* (NOI) in *Canada Gazette*, Part I. Any comments received will be considered during the preparation of a regulatory proposal. There will be additional opportunities for comment as the federal regulatory process progresses.

The regulation of these products will reduce the potential risks to the health and safety of Canadians associated with their ready availability, with their increased use and their unknown effects. The scheduling of *Salvia divinorum* and salvinorin A will also eliminate the current misconception that these substances are a safe alternative to other illegal drugs.

**Q2 – Are *Salvia divinorum* and/or salvinorin A controlled internationally? How are these substances regulated in other countries?**

A2 - Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions; as a result, there is no requirement for them to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

The move to include *Salvia divinorum* and salvinorin A in Schedule III to the CDSA is consistent with actions taken by several countries (e.g., Australia, Belgium, Denmark,

**Comment [D5]:** Replace with "misconception"

**Comment [S6]:** OK with this change

**Comment [D7]:** Replace with "there is no requirement for them to be regulated"

**Comment [S8]:** OK with this change

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21/01/2011

Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Some individual U.S. states have implemented laws restricting their use, sale and/or distribution.

**Q3 – Is there any research on the use of *Salvia divinorum* in Canada?**

A3 - Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *Salvia divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *Salvia divinorum* in the past year. The 2009 *Ontario Student Drug Use and Health Survey (OSDUHS)* indicated that 5.4% of Ontario students in grades 7-12 reported ever using *Salvia divinorum* and 4.4% of these students reported using this substance in the past year.

**Q4 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why isn't it illegal?**

A4 – The move to regulate *Salvia divinorum* and salvinorin A as controlled substances is based on surveillance data from surveys such as the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)*, *Youth Smoking Survey (YSS)* and the *Ontario Student Drug Use and Health Survey (OSDUHS)* which only became available in 2010.

In the interim, as *Salvia divinorum* is a plant with hallucinogenic properties, it currently meets the definition of a natural health product under the *Natural Health Products Regulations (NHPR)* when marketed as a hallucinogen. To date, Health Canada has not authorized for sale any natural health products which contain *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products may be subject to compliance and enforcement action in accordance with the *Food and Drugs Act* and its associated regulations.

**Q5 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A5 – Once *Salvia divinorum* and salvinorin A are included in Schedule III to the CDSA, law enforcement will be able to take appropriate action in response to suspected illegal activities with these substances.

Currently however, *Salvia divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. For more information on how to submit a consumer complaint about the unauthorized sale of drugs containing *Salvia divinorum* and/or salvinorin A,

**Comment [D9]:** It is considered an NHP – it is illegal? It is a contravention of the FDR/NHPR to sell and unlicensed and unapproved product. No licences have been granted for these products.

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21/01/2011

visit: [www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_44\\_consumer\\_consommateur\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_44_consumer_consommateur_cp-pc-eng.php)

### Q6 - Has Health Canada issued any kind of warning to Canadians about *Salvia divinorum*?

A6 - Health Canada has developed an *It's Your Health* article about *Salvia divinorum* to help inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at:

Comment [D10]: No link here. Is this coming?

#### Background

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

Data from the 2008-2009 Youth Smoking Survey indicates that:

- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;
- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year; and
- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using Salvia in their lifetime (0.2% in the past year); and
- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that:

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;

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- 5.4% of students (grades 7-12) ever used *Salvia divinorum*; and
- the use of *Salvia divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

**Prepared by:** Stephanie Chandler and Denis Arsenault, OCS, CSTD  
 Reviewed and revised by: Christine Roush, Senior Communications Advisor, HECS, Communications

**Input by:** Lisa Mackay IYH/PACCB,  
 Suzanne Desjardins HECSB/ODARS,  
 Hanan Abramovici HECSB/ODARS,  
 Bruna Brands HECSB/ODARS,  
 Jocelyn Kula, HECSB/OCS,  
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 Mano Murty HPFB/MHPD,  
 Robert Leitch HPFB/MHPD,  
 Shahid Perwaiz HPFB/MHPD,  
 Collin Pinto, HPFB/HPFBI

**Approved by:**  
 Robin Marles, Director, Bureau of Clinical Trials, NHPD (2011-01-20)  
 Duc Vu, Director, Marketed Biologics, Biotechnology and Natural Health Products Bureau, MHPD (pending)  
 Kim Dayman-Rutkas, Director, HPFBI (pending)  
 Jocelyn Kula, A/Director, OCS, CSTD, HECS (Approved Jan 19, 2011)  
 Suzanne Desjardins, Director, ODARS, CSTD, HECS (Approved Jan 20, 2011)  
 Cathy Sabiston, DG, CSTD, HECS (pending)  
 Chris Turner, DG, MHPD (pending)  
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 Meena Ballantyne, ADM, HPFB (pending)  
 Anne Lamar, ADM, PACCB (pending)  
 DMO (pending)  
 MO (pending)  
 PCO (pending)

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**Media Lines**  
***Salvia divinorum***

**Issue**

There is ongoing media interest regarding the availability of *Salvia divinorum* in Canada as well as Canadian surveillance data suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has concluded that *Salvia divinorum* and its main active ingredient salvinorin A should be regulated under the *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth.

**Key Messages:**

- Health Canada is proposing to regulate both *Salvia divinorum* and its main active ingredient salvinorin A under Schedule III to the *Controlled Drugs and Substances Act* (CDSA).
- After reviewing available information and reports that suggest this substance has the potential for abuse, especially among young people, we are taking these steps to protect the health and safety of Canadians, particularly youth, from the potentially harmful effects of this substance
- Canadians should not use products containing *Salvia divinorum* and/or salvinorin A because they are hallucinogenic and little is known about the long-term effects of these substances on the brain and body.
- The inclusion of *Salvia divinorum* and salvinorin A in Schedule III to the CDSA will make possession, trafficking, importation, exportation, and production (or cultivation) illegal unless authorized by regulation.

**Supplementary Messages:**

- The plant *Salvia divinorum* is not currently regulated under the CDSA and therefore it is not considered to be "banned", nor are activities with it considered to be illegal in Canada.
- However, as *Salvia divinorum* is a plant with hallucinogenic properties when consumed by humans, it would meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations* when marketed as a hallucinogen.
- To date, Health Canada has not authorized for sale any natural health products which contain *Salvia divinorum* as an ingredient. The sale of unauthorized

**Comment [D1]:** Suggest to add a line about why there is a risk to the health of Canadians. Abuse potential? Addiction?

**Comment [HC2R1]:** The second bullet says what the risk is.....could possibly reword first two bullets as follows: 1) After reviewing available information and reports that suggest this substance has the potential for abuse, especially among young people, HC is proposing to regulate *Salvia divinorum* and its main active ingredient as controlled substances. 2) The Government of Canada is taking these steps in order to protect the health and safety of Canadians, including youth, from its potentially harmful effects.

**Comment [D3]:** Suggest to remove. It is considered an NHP and subject to the NHPR.

**Comment [HC4]:** Technically I guess this comment is true (as we got the text from all those questions in previous media enquiries) if you consider the first bullet in this section only, but if you go on to read the remaining bullets, the choice of words is clarified? I would suggest that if HPFB does not like the order of bullets in this section, they suggest how to change things.....

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natural health products containing *Salvia divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act and its associated regulations*.

**Questions and Answers:**

**Q1 – What is involved in regulating *Salvia divinorum* as a controlled substance and what stage is it at?**

A1 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada recently concluded its assessment of *Salvia divinorum* and salvinorin A against the aforementioned factors and proposes to include both substances in Schedule III to the CDSA. The first step in the process of regulating a substance under the CDSA is the publication of a *Notice to Interested Parties* (NOI) in *Canada Gazette*, Part I. Any comments received will be considered during the preparation of a regulatory proposal. There will be additional opportunities for comment as the federal regulatory process progresses.

The regulation of these products will reduce the potential risks to the health and safety of Canadians associated with their ready availability, with their increased use and their unknown effects. The scheduling of *Salvia divinorum* and salvinorin A will also eliminate the current misconception that these substances are a safe alternative to other illegal drugs.

**Q2 – Are *Salvia divinorum* and/or salvinorin A controlled internationally? How are these substances regulated in other countries?**

A2 - Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions; as a result, there is no requirement for them to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

The move to include *Salvia divinorum* and salvinorin A in Schedule III to the CDSA is consistent with actions taken by several countries (e.g., Australia, Belgium, Denmark,

**Comment [D5]:** Replace with "misconception"

**Comment [HC6]:** OK with this suggestion

**Comment [D7]:** Replace with "there is no requirement for them to be regulated"

**Comment [HC8]:** OK with this change

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Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Some individual U.S. states have implemented laws restricting their use, sale and/or distribution.

**Q3 – Is there any research on the use of *Salvia divinorum* in Canada?**

A3 - Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *Salvia divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *Salvia divinorum* in the past year. The 2009 *Ontario Student Drug Use and Health Survey (OSDUHS)* indicated that 5.4% of Ontario students in grades 7-12 reported ever using *Salvia divinorum* and 4.4% of these students reported using this substance in the past year.

**Q4 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why hasn't it taken action until now?**

A4 – The move to regulate *Salvia divinorum* and salvinorin A as controlled substances is further to under Schedule III to the CDSA. Further to the regulation of these substances under the CDSA, the following activities would be illegal unless authorized by regulation: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation). Law enforcement agencies would also be able to take action against suspected illegal activities involving these substances.

However, as a plant with hallucinogenic properties, *Salvia divinorum* currently meets the definition of a natural health product under the *Natural Health Products Regulations (NHPR)* when marketed as a hallucinogen. To date, Health Canada has not authorized for sale any natural health products which contain *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products may be subject to compliance and enforcement action in accordance with the *Food and Drugs Act and its associated regulations*.

**Q5 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A5 – Once *Salvia divinorum* and salvinorin A are included in Schedule III to the CDSA, law enforcement will be able to take appropriate action in response to suspected illegal activities with these substances.

Currently however, *Salvia divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement

**Comment [D9]:** It is considered an NHP – it is illegal? It is a contravention of the FDR/NHPR to sell and unlicensed and unapproved product. No licences have been granted for these products.

**Comment [HC10]:** Stephanie- what do you think about reworking the answer to say the move to regulate S and Sal A as controlled substances is based on surveillance data that only became available in 2010. Then we would remove the staff about impacts of regulating as controlled substances, but then go straight to something about in the interim, S currently meets the definition of an NHP.... The Department has always had the ability to take compliance and enforcement action under the FDA etc.....

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action by Health Canada. For more information on how to submit a consumer complaint about the unauthorized sale of drugs containing *Salvia divinorum* and/or salvinorin A, visit: [www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_44\\_consumer\\_consommateur\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_44_consumer_consommateur_cp-pc-eng.php).

**Q6 - Has Health Canada issued any kind of warning to Canadians about *Salvia divinorum*?**

A6 - Health Canada has developed an *It's Your Health* article about *Salvia divinorum* to help inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at:

**Comment [D11]:** No link here. Is this coming?

### **Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

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Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using Salvia in their lifetime (0.2% in the past year); and
- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

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- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;
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- the use of *Salvia divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

**Prepared by:** Stephanie Chandler and Denis Arsenault, OCS, CSTD  
**Reviewed and revised by:** Christine Roush, Senior Communications Advisor, HECS, Communications

**Input by:** Lisa Mackay IYH/PACCB,  
Suzanne Desjardins HECSB/ODARS,  
Hanan Abramovici HECSB/ODARS,  
Bruna Brands HECSB/ODARS,  
Jocelyn Kula, HECSB/OCS,  
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Mano Murty HPFB/MHPD,  
Robert Leitch HPFB/MHPD,  
Shahid Perwaiz HPFB/MHPD,  
Collin Pinto, HPFB/HPFBI

**Approved by:**

Robin Marles, Director, Bureau of Clinical Trials, NHPD (2011-01-20)  
Duc Vu, Director, Marketed Biologics, Biotechnology and Natural Health Products Bureau, MHPD (pending)  
Kim Dayman-Rutkas, Director, HPFBI (pending)  
Jocelyn Kula, A/Director, OCS, CSTD, HECS (Approved Jan 19, 2011)  
Suzanne Desjardins, Director, ODARS, CSTD, HECS (Approved Jan 20, 2011)  
Cathy Sabiston, DG, CSTD, HECS (pending)  
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thank you

Lynne Lalancette-Vranckx

Executive Secretariat/Secrétariat exécutif  
Policy, Planning and Integration Directorate  
Room 6-004, 6th Floor, 269 Laurier Avenue W/Pièce 6-004, 6ième étage, 269 rue Laurier O  
Ottawa, Ontario  
K1A 0K9

Address Locator/Indice de l'adresse 4906A  
Telephone 613-952-5421 /Téléphone: 613-952-5421

Stephanie Szick

Just saw this -- - two things 1) how likely does it look to have the IYH article re...

01/24/2011 12:18:41 PM

From: Stephanie Szick/HC-SC/GC/CA  
To: Nicole Prentice/HC-SC/GC/CA@HWC  
Cc: Lynne Lalancette-Vranckx/HC-SC/GC/CA@HWC, Catherine Chabot/HC-SC/GC/CA@HWC, CSTD-DGO, Dave Stephens/HC-SC/GC/CA@HWC, Louise Bertrand/HC-SC/GC/CA@HWC, Christine Roush/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC  
Date: 01/24/2011 12:18 PM  
Subject: Re: rather urgent please. MIR entry

**Just saw this -- - two things**

- 1) how likely does it look to have the IYH article ready, coded and posted in both languages on the HC website by/before Saturday, Feb. 5/11??
- 2) The NOI is done and DG-approved - it is not in development -- it is also referenced in the main box at the top, so suggest deleting it.

Please see my changes in red in the bottom box.

Stephanie Szick  
Director General's Office / Bureau du directeur général  
Controlled Substances and Tobacco Directorate (CSTD) /  
Direction des substances contrôlées et de la lutte au tabagisme (DSCLT)  
Health Canada / Santé Canada  
Tel / Tél: (613) 948-8651

002499

Nicole Prentice

Hi, Comms changes are below in blue.

2011-01-24 11:46:04 AM

From: Nicole Prentice/HC-SC/GC/CA  
To: Lynne Lalancette-Vranckx/HC-SC/GC/CA@HWC  
Cc: Catherine Chabot/HC-SC/GC/CA@HWC, CSTD-DGO, Dave Stephens/HC-SC/GC/CA@HWC, Louise Bertrand/HC-SC/GC/CA@HWC, Stephanie Szick/HC-SC/GC/CA@HWC, Christine Roush/HC-SC/GC/CA@HWC  
Date: 2011-01-24 11:46 AM  
Subject: Re: rather urgent please. MIR entry

---

Hi,

Comms changes are below in blue.

**Nicole Prentice**

Junior Communications Officer | Agente junior des Communications

Regulatory Communications and Media Relations Division | Division des communications réglementaires et des relations avec les médias

Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la consultation et des communications

Health Canada | Santé Canada

Tel: 613.941.3107

Fax: 613.948.8085

Lynne Lalancette-Vranckx

Hello everyone, ADMO has asked us to include this entry back into the MIR. P...

2011-01-24 11:39:36 AM

From: Lynne Lalancette-Vranckx/HC-SC/GC/CA  
To: Nicole Prentice/HC-SC/GC/CA@HWC, Dave Stephens/HC-SC/GC/CA@HWC, Stephanie Szick/HC-SC/GC/CA@HWC, Louise Bertrand/HC-SC/GC/CA@HWC, CSTD-DGO  
Cc: Catherine Chabot/HC-SC/GC/CA@HWC  
Date: 2011-01-24 11:39 AM  
Subject: rather urgent please. MIR entry

---

Hello everyone,

ADMO has asked us to include this entry back into the MIR. Please note the date change. Can you also double check that the information is still correct.

002500

We would need this back as soon as possible.

thank you

February 4, 2011 (TBC)	<b>Publication of a Notice to Interested Parties, also known as a Notice of Intent (NOI), in the Canada Gazette, Part I, on the Proposal to Regulate Salvia divinorum and salvinorin A as Controlled Substances under the Controlled Drug and Substances Act - The NOI will provide stakeholders and other interested parties 30 days to provide comments, which will be reviewed and factored into a regulatory proposal in Spring 2011. The NOI is approved by the Director General, Controlled Substances and Tobacco Directorate.</b>		
	DETAILS (Please answer all questions)		SPECIFY
	What Branch/Agency/Department has the lead?	HECS B	
	Are other Branches/Agencies involved?	Yes	PACCB
	Should Health Canada have any concerns?	No	
	Is Health Canada providing a source of funding through a contribution? How much?	No	
	Is the activity likely to capture the media's interest and/or is the media invited to the event?	Yes	There is ongoing media coverage regarding the availability of Salvia Divinorum in Canada.
	When can DMO/MO expect the document/docket/embargo/advance copy of the report?		

	What supporting documents are being developed (i.e. media lines, Qs & As, Memo to the Minister, QP Note, Briefing Note, etc)?	Media lines, Qs&As, an IYH article?, news release and a Question Period note are in approvals. A Notice of Intent is in development and A speech will be prepared.
--	---	--

Lynne Lalancette-Vranckx

Executive Secretariat/Secrétariat exécutif  
Policy, Planning and Integration Directorate  
Room 6-004, 6th Floor, 269 Laurier Avenue W/Pièce 6-004, 6ième étage, 269 rue Laurier O  
Ottawa, Ontario  
K1A 0K9

Address Locator/Indice de l'adresse 4906A  
Telephone 613-952-5421 /Téléphone: 613-952-5421

**Re: Salvia docs** 

Christine Roush to: Jocelyn Kula

2011-01-27 06:19 PM

Cc: Stephanie Szick, Stephanie Chandler, Denis Arsenault

Thanks Jocelyn - your email below is clear. I will review these doc and put them into approval on Friday.

Have a great day off tomorrow.

Christine

Jocelyn Kula

----- Original Message -----

**From:** Jocelyn Kula

**Sent:** 2011-01-27 05:48 PM EST

**To:** Christine Roush

**Cc:** Stephanie Szick; Stephanie Chandler; Denis Arsenault

**Subject:** Salvia docs

Hi Christine

Please find attached the latest version of the media lines for Salvia, which incorporate our suggested changes further to comments from HPFB, and our comments on the draft NR you prepared.

[attachment "Salvia NR\_Jan 27\_OCS.doc" deleted by Christine Roush/HC-SC/GC/CA]

[attachment "Salvia MLs\_Jan27\_OCS.doc" deleted by Christine Roush/HC-SC/GC/CA]

For reference, I am attaching the QP note that we have updated in preparation for the house coming back into session.



(Note Cathy has not reviewed this yet but it is consistent with the media lines and the NOI text that have both been discussed with Cathy informally.)

What I don't seem to have is a copy of the updated NOI, so by copy of this message, I am asking Stephanie C to send it to you, as it has now been through Suzanne Desjardins' office for review.

Lastly, I am attaching a copy of the updated IYH (text now matches the key messages in the MLs and the gist of the NR etc.....). Please feel free to put this document back into approvals (I assume with HPFB) but please note that under no circumstances, should progress on this document impede publication of the NOI. We have clarified this with Cathy. If by some chance, the IYH can be ready for posting soon after the announcement/ NOI, so be it, but we are to plan for publication of the NOI on Sat. Feb 12.

[attachment "IYH Salvia divinatorum\_v19 Jan 27.doc" deleted by Christine Roush/HC-SC/GC/CA]

Please note that I am out of the office on annual leave tomorrow. Stephanie and Denis are around if you have questions however, and I am back in the office on Monday. From my perspective, the most pressing piece to move on is the NR and media lines, and Cathy's office knows to expect them sometime tomorrow.

Jocelyn

---

Jocelyn Kula

Acting Director/ Directrice par intérim

Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224



**Re: Salvia Announcement**   
Jocelyn Kula to: Christine Roush  
Cc: Stephanie Chandler, Denis Arsenault

2011-01-27 10:31 AM

well phew re. the event!  
yes, I am looking at docs right now

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
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Tel: (613) 952-2177 Fax: (613) 946-4224

---

Christine Roush      Jocelyn - since we have a tentative date from M...      2011-01-27 10:24:35 AM

From: Christine Roush/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Stephanie Chandler/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2011-01-27 10:24 AM  
Subject: Re: Salvia Announcement

---

**Jocelyn** - since we have a tentative date from MO for this announcement - Feb. 10th - can we get the products (News Release, MLs & Qs&As and It's Your Health article) moving through approvals now. We were told that there won't be an event, just a news release announcing the NOI.

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
Health Canada/Santé Canada  
Tel/Tél : (613) 954-0712/Cell: (613) 219-7194  
Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca

---

Jocelyn Kula      Thanks Christine, Was with my french tutor, but...      2011-01-21 05:47:06 PM  
Christine Roush

----- Original Message -----

**From:** Christine Roush  
**Sent:** 2011-01-21 04:12 PM EST  
**To:** Jocelyn Kula  
**Cc:** Dave Stephens; Denis Arsenault; Stephanie Chandler; Stephanie Szick  
**Subject:** Re: Salvia MLs

Hi Jocelyn,  
I have HPFB approval of the Salvia MLs and thought you might like to review quickly their comments and changes and let me know if you are OK with them. I gather nothing is moving forward to Cathy until we have more direction from MO. The draft NR is still in your shop, and we have started drafting a Ministerial Event Proposal.



Cheers,

[attachment "Salvia MLs\_Jan21(4)\_DCVIU16h07.doc" deleted by Jocelyn Kula/HC-SC/GC/CA]

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
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Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca



**Dates of CGI Publication of Salvia NOI**

Denis Arsenault to: Jocelyn Kula

Cc: Stephanie Chandler

2011-01-27 01:55 PM

Hi Jocelyn,

Just confirmed that the first date we could publish the salvia NOI after the event (currently proposed for February 10th) is Saturday, February 12th.

To get NOI published on the 12th, we need to get the package to *Canada Gazette* by noon on Friday, February 4th.

Denis

Denis Arsenault, A/Manager / Gestionnaire p.i.

Regulatory Policy Division /

Division des politiques réglementaires,

Office of Controlled Substances /

Bureau des substances contrôlées,

Health Canada / Santé Canada

Tel/Tél: (613) 957-6828

Fax / Télécopieur : (613) 946-4224

E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca

----- Forwarded by Denis Arsenault/HC-SC/GC/CA on 2011-01-27 01:54 PM -----

From: Jocelyn Kula/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Cc: Stephanie Chandler/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2011-01-27 10:31 AM  
Subject: Re: Salvia Announcement

well phew re. the event!  
yes, I am looking at docs right now

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

Christine Roush      Jocelyn - since we have a tentative date from M...      2011-01-27 10:24:35 AM

From: Christine Roush/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Stephanie Chandler/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2011-01-27 10:24 AM  
Subject: Re: Salvia Announcement

Jocelyn - since we have a tentative date from MO for this announcement - Feb. 10th - can we get the products (News Release, MLs & Qs&As and It's Your Health article) moving through approvals now. We

were told that there won't be an event, just a news release announcing the NOI.

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
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de la consultation et des communications  
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Tel/Tél : (613) 954-0712/Cell: (613) 219-7194  
Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca

Jocelyn Kula

Thanks Christine, Was with my french tutor, but...

2011-01-21 05:47:06 PM

Christine Roush



**Re: Salvia Products for Review**

Jocelyn Kula to: Stephanie Chandler

Cc: Denis Arsenault

2011-01-27 03:38 PM

these look great  
thanks  
will now send to Christine R

---

Jocelyn Kula

Acting Director/ Directrice par intérim

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs

Health Canada/ Santé Canada

Tel: (613) 952-2177 Fax: (613) 946-4224

---

Stephanie Chandler Hi Jocelyn, The following Salvia docs have be...

2011-01-27 03:16:29 PM

From: Stephanie Chandler/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC, CSTD-OCS-DO  
Date: 2011-01-27 03:16 PM  
Subject: Salvia Products for Review

---

Hi Jocelyn,

The following Salvia docs have been revised as requested.



IYH Salvia divinatorum\_v19 Jan 27.doc Salvia NR\_Jan 27\_OCS.doc Salvia MLs\_Jan27\_OCS.doc

And QP Note:

I have left printed copies in your office on your table.

Regards,

Stephanie

Stephanie Chandler

Junior Regulatory Project Officer

Regulatory Policy Division/ Division de la politique réglementaire

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs

Health Canada/ Santé Canada

Tel: (613) 946-0124, Fax: (613) 946-4224

E-Mail: stephanie.chandler@hc-sc.gc.ca

Health Canada

2011-XX

# News Release

## The Government of Canada Proposes to Regulate Salvia Divinorum and Salvinorin A as Controlled Substances

February 10, 2011

For immediate release

OTTAWA – Today, the Honourable Leona Aglukkaq, Minister of Health announced that the Government of Canada intends to regulate *Salvia divinorum* and salvinorin A, also known as Salvia, as controlled substances. A Notice to Interested Parties outlining Health Canada's proposal will be published in *Canada Gazette*, Part I, on February 12, 2011.

"After reviewing Canadian surveillance data and scientific reports that suggest this substance has the potential for abuse, especially among young people, we are taking these steps to protect the health and safety of Canadians from the potentially harmful effects of this substance," said Minister Aglukkaq. "The use of this substance is of concern to Health Canada as very little is known about its long-term effects on the brain and body," added Aglukkaq.

The Notice to Interested Parties will propose that *Salvia divinorum* and salvinorin A be added to Schedule III to the *Controlled Drugs and Substances Act*. This means that activities such as possession, trafficking, importation, exportation, and production will be illegal unless authorized by regulation. Regulating Salvia as a controlled substance will also enable law enforcement agencies to take action against suspected illegal activities involving this substance.

Interested parties are encouraged to submit any comments regarding the Notice to Interested Parties by March 14, 2011.

-30-

Media Enquiries:  
Health Canada  
(613) 957-2983

Également disponible en français

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Jenny Van Alstyne  
Office of the Honourable Leona Aglukkaq  
Federal Minister of Health  
(613) 957-0200

**Public Enquiries:**  
(613) 957-2991  
1-866 225-0709

Health Canada news releases are available on the Internet at  
[www.healthcanada.gc.ca/media](http://www.healthcanada.gc.ca/media)



Government  
of Canada

Gouvernement  
du Canada

Canada

<b>Page 1: [1] Deleted</b>	<b>STCHANDL</b>	<b>2011-01-21 11:39:00 AM</b>
This notice will provide interested stakeholders with the opportunity to comment on Health Canada's proposal to add the plant <i>Salvia divinorum</i> ( <i>S. divinorum</i> ) and its main active ingredient salvinorin A to Schedule III to the <i>Controlled Drugs and Substances Act</i> (CDSA).		
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Including these substances within the

<b>Page 1: [8] Deleted</b>	<b>STCHANDL</b>	<b>2011-01-25 11:42:00 AM</b>
<i>S. divinorum</i> and salvinorin A		
<b>Page 1: [9] Deleted</b>	<b>STCHANDL</b>	<b>2011-01-20 4:45:00 PM</b>
The Notice to Interested Parties will be published in <i>Canada Gazette</i> , Part I, on January 29, 2011.		
<b>Page 1: [10] Comment [h1]</b>	<b>hcuser</b>	<b>2011-01-19 4:06:00 PM</b>
Standard text from previous enquiries.		
<b>Page 1: [11] Deleted</b>	<b>STCHANDL</b>	<b>2011-01-27 2:49:00 PM</b>
For more information on <i>Salvia divinorum</i> , please visit: <i>It's Your Health - Salvia divinorum</i> : XXX		

DRAFT  
21/01/2011

**Media Lines**  
*Salvia divinorum*

**Issue**

There is ongoing media interest regarding the availability of *Salvia divinorum* in Canada as well as Canadian surveillance data suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has concluded that *Salvia divinorum* and its main active ingredient salvinorin A should be regulated under the *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth.

**Key Messages:**

- Health Canada is proposing to regulate both *Salvia divinorum* and its main active ingredient salvinorin A under Schedule III to the *Controlled Drugs and Substances Act* (CDSA).
- After reviewing available information and reports that suggest this substance has the potential for abuse, especially among young people, we are taking these steps to protect the health and safety of Canadians, particularly youth, from the potentially harmful effects of this substance
- Canadians should not use products containing *Salvia divinorum* and/or salvinorin A because they are hallucinogenic and little is known about the long-term effects of these substances on the brain and body.
- The inclusion of *Salvia divinorum* and salvinorin A in Schedule III to the CDSA will make possession, trafficking, importation, exportation, and production (or cultivation) illegal unless authorized by regulation.

**Supplementary Messages:**

- The plant *Salvia divinorum* is not currently regulated under the CDSA and therefore it is not considered to be "banned", nor are activities with it considered to be illegal in Canada, unless it is being sold as a hallucinogen. If this were the case, the product would meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations*.
- To date, Health Canada has not authorized for sale any natural health products which contain *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products containing *Salvia divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act and its associated regulations*.

**Comment [D1]:** Suggest to add a line about why there is a risk to the health of Canadians. Abuse potential? Addiction?

**Comment [S2]:** OCS feels that the second bullet addresses this. Could possibly reword first two bullets as follows: 1) After reviewing available information and reports that suggest this substance has the potential for abuse, especially among young people, Health Canada is proposing to regulate *Salvia divinorum* and its main active ingredient as controlled substances. 2) The Government of Canada is taking these steps in order to protect the health and safety of Canadians, including youth, from its potentially harmful effects.

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**Comment [D3]:** Suggest to remove. It is considered an NHP and subject to the NHPR.

**Comment [S4]:** We are simply responding to all the past media enquiries. In any case, the focus of these lines is to support issuance of NOI not highlight NHP status.

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¶ However, as *Salvia divinorum* is a plant with hallucinogenic properties when consumed by humans, it would meet the

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Last saved by Christine Roush

Created by Christine Roush  
2011-01-28



**DRAFT**  
21/01/2011

**Questions and Answers:**

**Q1 – What is involved in regulating *Salvia divinorum* as a controlled substance and what stage is it at?**

A1 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada recently concluded its assessment of *Salvia divinorum* and salvinorin A against the aforementioned factors and proposes to include both substances in Schedule III to the CDSA. The first step in the process of regulating a substance under the CDSA is the publication of a *Notice to Interested Parties* (NOI) in *Canada Gazette*, Part I. Any comments received will be considered during the preparation of a regulatory proposal. There will be additional opportunities for comment as the federal regulatory process progresses.

The regulation of these products will reduce the potential risks to the health and safety of Canadians associated with their ready availability, with their increased use and their unknown effects. The scheduling of *Salvia divinorum* and salvinorin A will also eliminate the current misconception that these substances are a safe alternative to other illegal drugs.

**Q2 – Are *Salvia divinorum* and/or salvinorin A controlled internationally? How are these substances regulated in other countries?**

A2 - Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions; as a result, there is no requirement for them to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

The move to include *Salvia divinorum* and salvinorin A in Schedule III to the CDSA is consistent with actions taken by several countries (e.g., Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Some

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Last saved by Christine Roush

Created by Christine Roush  
2011-01-28

DRAFT  
21/01/2011

individual U.S. states have implemented laws restricting their use, sale and/or distribution.

**Q3 – Is there any research on the use of *Salvia divinorum* in Canada?**

A3 - Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *Salvia divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *Salvia divinorum* in the past year. The 2009 *Ontario Student Drug Use and Health Survey (OSDUHS)* indicated that 5.4% of Ontario students in grades 7-12 reported ever using *Salvia divinorum* and 4.4% of these students reported using this substance in the past year.

**Q4 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why isn't it illegal?**

A4 – The move to regulate *Salvia divinorum* and salvinorin A as controlled substances is based on surveillance data from surveys such as the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)*, *Youth Smoking Survey (YSS)* and the *Ontario Student Drug Use and Health Survey (OSDUHS)*, some of which only became available in 2010.

In the interim, as *Salvia divinorum* is a plant with hallucinogenic properties, it currently meets the definition of a natural health product under the *Natural Health Products Regulations (NHPR)* when marketed as a hallucinogen. The sale of unauthorized natural health products may be subject to compliance and enforcement action in accordance with the *Food and Drugs Act* and its associated regulations.

**Q5 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A5 – Once *Salvia divinorum* and salvinorin A are included in Schedule III to the CDSA, law enforcement will be able to take appropriate action in response to suspected illegal activities with these substances.

Currently however, *Salvia divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. For more information on how to submit a consumer complaint about the unauthorized sale of drugs containing *Salvia divinorum* and/or salvinorin A, visit: [www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_44\\_consumer\\_consommateur\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_44_consumer_consommateur_cp-pc-eng.php).

**Comment [D5]:** It is considered an NHP – it is illegal? It is a contravention of the FDR/NHPR to sell and unlicensed and unapproved product. No licences have been granted for these products.

**Comment [S6]:** OCS feels that the second paragraph in this answer addresses the question

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Created by Christine Roush  
2011-01-28

**DRAFT**  
21/01/2011

**Q6 - Has Health Canada issued any kind of warning to Canadians about *Salvia divinorum*?**

A6 - Health Canada has developed an *It's Your Health* article about *Salvia divinorum* to help inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at:

**Comment [D7]:** No link here. Is this coming?

**Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

Data from the 2008-2009 Youth Smoking Survey indicates that:

- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;
- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year; and
- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using *Salvia* in their lifetime (0.2% in the past year); and
- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that:

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;
- 5.4% of students (grades 7-12) ever used *Salvia divinorum*; and
- the use of *Salvia divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

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2011-01-28

**DRAFT**  
21/01/2011

**Prepared by:** Stephanie Chandler and Denis Arsenault, OCS, CSTD  
Reviewed and revised by: Christine Roush, Senior Communications Advisor, HECS, Communications

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**Approved by:**  
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DMO (pending)  
MO (pending)  
PCO (pending)

**Deleted:** Ken Polk,  
**Deleted:** Jean Tessier, Senior Media Relations, PACCB (pending)¶  
Warren Braun, Director, Strategic Communications, PACCB (pending)¶  
Peter Yendal  
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2011-01-28

## Salvia divinorum

### Issue

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff, incense special, and salvia.

Certain websites promote the use of *S. divinorum* as a "legal" alternative to street drugs. Recent Canadian surveillance data indicates that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. Scientific reports also suggest that it has the potential for abuse.

Canadians should not use products containing *S. divinorum* and/or salvinorin A because they are hallucinogenic and little is known about the long-term effects of these substances on the brain and body. There is also no way to predict how it will affect you with each use.

In light of this information, Health Canada is proposing to regulate both *S. divinorum* and its main active ingredient salvinorin A under Schedule III to the *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth.

### Risks Associated with the Use of *Salvia divinorum*

*S. divinorum* is known to have both physical and mental effects. The effects of *S. divinorum*, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product
- how much is used
- the purity of the product (products that contain *S. divinorum* may be mixed with other substances)

**Comment [S1]:** Please note that OCS has clarified with Cathy that, while the IYH is important, it should not hold up the publication of the NOI. Its posting can follow soon after the NOI is published.

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**Deleted:** Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs.

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**Deleted:** As of [REDACTED] 2010 Health Canada has not authorized for sale any products containing *S. divinorum*.

**Deleted:** ¶ Health Canada recommends that you avoid using this plant because very little is known about the effects it may have on your body and/or brain functions. There is also no way to predict how it will affect you with each use.

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- how it is taken, for example, whether the product is chewed, swallowed or smoked
- the user's mood and expectations

While scientists know which brain receptors are targeted by the active ingredient, salvinorin A, very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or if it can cause permanent damage
- how it interacts with other substances, including other drugs, natural health products and alcohol
- the potential of *S. divinorum* to produce physical dependence and/or addiction

### Minimizing Your Risk

Hallucinogens like *S. divinorum* work by modifying functions in the brain. Health Canada recommends that you avoid using *S. divinorum* because very little is known about the effects it may have on your body and/or brain functions. There is also no way to predict how it will affect you with each use. Just because a drug is plant-based or "natural", does not mean that it is safe.

Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs, such as marijuana, cocaine, ecstasy, LSD and other substances that distort reality. See the "Need More Info?" section below for links to resources that can help you with this.

### Legal Status of *Salvia divinorum*

#### In Canada

As *S. divinorum* is a plant with hallucinogenic properties when consumed by humans, it currently meets the definition of a natural health product (NHP) under the *Natural Health Products Regulations* when marketed as a hallucinogen. As of [REDACTED] 2011, Health Canada has not authorized for sale any natural health products which contain *S. divinorum* as an ingredient. The sale of unauthorized natural health products containing *S. divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

While *S. divinorum* and salvinorin A are not currently regulated under the *Controlled Drugs and Substances Act* (CDSA), Health Canada is now developing a regulatory proposal that would add *S. divinorum* and salvinorin A to Schedule III to the CDSA.

#### In Other Countries

Several countries including but not limited to Australia, Belgium, Germany, Italy and Japan, have placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A.

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Deleted: hallucinogenic properties, products containing <i>S. divinorum</i> or salvinorin A meet the definition of a Natural Health Product (NHP) in accordance with the <i>Natural Health Products Regulations</i> and the definition of a drug under the <i>Food and Drugs Act</i> . It is illegal to sell drugs or NHPs in Canada, unless they have been reviewed and authorized for sale by Health Canada. In the case of NHPs, they need to be labelled with one of the following:¶ a Natural Product Number (NPN); or¶ an Exemption Number (EN); or¶ a Drug Identification Number - Homeopathic Medicine Number (DIN-HM). ¶
Deleted: As of [REDACTED] 2010 no products containing <i>S. divinorum</i> or salvinorin A have been authorized by Health Canada for sale. The sale of unauthorized drugs and NHPs is illegal, and may be subject to compliance and enforcement actions by the Department. ¶ Neither <i>S. divinorum</i> nor salvinorin A are currently regulated under the <i>Controlled Drugs and Substances Act</i> (CDSA). Health Canada is currently considering the available information to determine whether regulation as a controlled substance is warranted.¶
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In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on their sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution. In some states, for example, it is illegal for *S. divinorum* to be sold to anyone under the age of 18.

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### Background

The leaves of this plant have been used traditionally by the Mazatec people for medicinal and mystical purposes.

Products that claim to contain *S. divinorum* or its main active ingredient, salvinorin A are widely available on the Internet and are sold in various "head shops" and natural food stores. The products are sold in a number of forms, including fresh or dried leaves, liquids or seeds and plant cuttings for growing purposes.

Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *S. divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *S. divinorum* in the past year. The 2009 *Ontario Student Drug Use and Health Survey (OSDUHS)* indicated that 5.4% of Ontario students in grades 7-12 reported ever using *S. divinorum* and 4.4% of these students reported using this substance in the past year. For more information on these surveys, see the *Need More Info* section below.

Deleted: Results from the Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that, in 2009, less than 2% of Canadians age 15 and older reported having used *S. divinorum* at least once in their lifetime. Youth, ages 15-24 were much more likely to have used it than adults. The results from the Canadian 2008-2009 Youth Smoking Survey show that 5% of 15yr olds have used *S. divinorum* in the past year.

### Health Canada's Role

In light of the health and safety risks associated with the use of *S. divinorum* and particularly the risks to youth, Health Canada is taking steps to regulate *S. divinorum* and salvinorin A as controlled substances. As a first step in this process, Health Canada issued a *Notice to Interested Parties (NOI)* on February 5, 2011. In the interim, Health Canada will continue to monitor the sale of unauthorized health products that contain *S. divinorum* or its main active ingredient salvinorin A. It will take appropriate action should it become aware of any unauthorized health products that may pose a risk to Canadians.

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### Need More Info?

- Complaints about the unauthorized sale of drugs containing *S. divinorum* can be made to the **Health Products and Food Branch Inspectorate** at: [http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_44\\_consumer\\_consommateur\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_44_consumer_consommateur_cp-pc-eng.php)  
Tel: 1-800-267-9675.

- You can report any adverse reactions to the Canada Vigilance Program by one of the following three ways:  
Report online at the MedEffect™ Canada website at: <http://www.hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>  
Call toll-free at 1-866-234-2345  
Complete a Canada Vigilance Reporting Form and either:  
Fax toll-free to 1-866-678-6789  
Mail to: Canada Vigilance Program  
Health Canada  
AL 0701C  
Ottawa, ON K1A 0K9  
To have postage pre-paid, download the postage paid label from the MedEffect™ Canada website. The Canada Vigilance Reporting Form and the adverse reaction reporting guidelines may also be obtained via this website at : [http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei\\_form-eng.php](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei_form-eng.php)
- For information about the Government of Canada's National Anti-Drug Strategy, go to: [www.nationalantidrugstrategy.gc.ca/](http://www.nationalantidrugstrategy.gc.ca/)  
The Prevention section on this site has a number of helpful resources for parents, including:
  - **Tips on Talking to Your Teenager**, at: [www.hc-sc.gc.ca/hc-ps/pubs/adp-apd/talk-aborder/index-eng.php](http://www.hc-sc.gc.ca/hc-ps/pubs/adp-apd/talk-aborder/index-eng.php)
  - **What to Do if Your Teen is Using Drugs**, at:  
[www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html](http://www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html)
  - Health Canada's **Not4Me** youth drug prevention section at:  
<http://www.hc-sc.gc.ca/hc-ps/drugs-drogues/youth-jeunes/facts-faits/index-eng.php>
- Information on natural health products and the Natural Health Products Regulations can be found at: [www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php)

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For more on the surveys that have collected information about *Salvia divinorum* use in Canada, see:

- **The 2008-2009 Youth Smoking Survey**, at:  
<http://www.yss.uwaterloo.ca/index.cfm?section=5&page=288>
- **The 2009 Canadian Alcohol and Drug Use Monitoring Survey**, at:  
<http://www.hc-sc.gc.ca/hc-ps/drugs-drogues/stat/index-eng.php>
- **The 2009 Ontario Student Drug Use and Health Survey**, at:  
[http://www.camh.net/News\\_events/News\\_releases\\_and\\_media\\_advisories\\_and\\_ackgrounders/osduhs2009\\_advisory.html](http://www.camh.net/News_events/News_releases_and_media_advisories_and_ackgrounders/osduhs2009_advisory.html)

Additional Resources:

- U.S. Drug Enforcement Administration: **Drugs and Chemicals of Concern: Salvia divinorum and Salvinorin A** at:  
[www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)



- U.S. Department of Health & Human Services, **National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006** at:  
[www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf](http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf)
- For additional articles on health and safety issues go to the **It's Your Health** web section at: [www.healthcanada.gc.ca/iyh](http://www.healthcanada.gc.ca/iyh)

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

Original:

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Catalogue#

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PACCB IYH - Lisa Mackay: 613-954-0105 – [Lisa.Mackay@hc-sc.gc.ca](mailto:Lisa.Mackay@hc-sc.gc.ca)

Comments from: HECSB - CSTD (OCS&ODARS) & HPFB – NHPD, MHPD & HPFBI

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Arsenault, Hanan Abramovici, Bruna Brands  
HECSB comms: Christine Roush, Bronwyn Cline  
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Collins  
HPFB-MHPD: Scott Jordan, Robert Leitch, Mano Murty, Shahid Perwaiz  
HPFBI : Collin Pinto  
HPFB comms: Elizabeth Keeping, Blossom Leung

**QUESTION PERIOD NOTE**  
**NOTE POUR LA PÉRIODE DE QUESTIONS**

Date:	January 27, 2011
Classification :	HECS PROTECTED - SESC PROTÉGÉ

---

**SUBJECT - SUJET**

English:

**DRUGS - SALVIA DIVINORUM**

Français:

**DROGUES - SALVIA DIVINORUM**

---

**SYNOPSIS - SOMMAIRE**

English:

Media interest in Salvia divinorum is recurrent. Questions around this substance generally focus on its legality. Recently, a number of media reports have commented on a YouTube video which reportedly shows the young celebrity Miley Cyrus smoking Salvia divinorum. Canadian surveillance data indicates that this substance is being used by adolescents and young adults for its hallucinogenic properties, and there have also been several reports from scientific sources indicating that Salvia divinorum has a potential for abuse.

---

**ANTICIPATED QUESTION - QUESTION PRÉVUE**

English:

What is Health Canada doing to protect young Canadians from the potential adverse effects associated with the use of Salvia divinorum?

Français:

Quelles mesures Santé Canada prend-il pour protéger les jeunes Canadiens contre les effets indésirables possibles liés à l'utilisation de la Salvia divinorum?

---

English:

- Health Canada is proposing to regulate Salvia as a controlled substance in order to protect the health and safety of Canadians, particularly youth.
- Health Canada has published a *Notice to Interested Parties* in *Canada Gazette*, Part I, to give Canadians the opportunity to provide comments on its proposal to regulate Salvia as a controlled substance.
- The regulation of Salvia will make possession, trafficking, importation, exportation, and production illegal unless authorized by regulation.

Français:

---

## **BACKGROUND - CONTEXTE**

English:

### **BACKGROUND / CONTEXTE**

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, diviner's sage, magic mint, and puff. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs.

Both the plant *S. divinorum* and its main active ingredient salvinorin A are known to have physical and mental effects which are often described as unpleasant, including:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination

- slurred speech and awkward sentence patterns

Recent surveys indicate that Canadian youth are trying this substance which could be dangerous to their health. Results from the *Canadian Alcohol and Drug Use Monitoring Survey* (CADUMS) reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *Salvia divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24 years. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *Salvia divinorum* in the past year. The 2009 *Ontario Student Drug Use and Health Survey* (OSDUHS) indicated that 5.4% of Ontario students in grades 7-12 reported ever using *Salvia divinorum* and 4.4% of these students reported using this substance in the past year.

International Control of *S. divinorum*

Neither *Salvia divinorum* nor its main active ingredient salvinorin A are listed under the United Nations Drug Control Conventions; as a result, they do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions. The move to include *Salvia divinorum* and salvinorin A in Schedule III to the CDSA is consistent with actions taken by several countries (e.g. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Some individual U.S. states have also implemented laws restricting their use, sale and/or distribution.

Current Situation in Canada

The plant *Salvia divinorum* is not currently regulated under the *Controlled Drugs and Substances Act* (CDSA) and therefore the plant is not considered to be "banned" nor are activities with it considered to be illegal in Canada unless it is being sold as a hallucinogen. If this were the case, the product would meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations*. To date, Health Canada has not licensed for sale any natural health product which contains *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products containing *Salvia divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

In light of the surveillance data and scientific reports regarding its potential for abuse, Health Canada has determined that *S. divinorum* and Salvinorin A should be included in Schedule III to the CDSA. This means that the possession, trafficking, importation, exportation and production of *Salvia divinorum* and salvinorin A will be illegal unless authorized by regulation. The regulation of *Salvia divinorum* and Salvinorin A as controlled substances will allow law enforcement to take action against illegal activities involving this substance.

**ATTACHMENTS / PIÈCE(S)-JOINTE(S)**

Contact/Personne ressource : Denis Arsenault/HC-SC/GC/CA	Tel. no./No de tél. 613-957-6828	Approved by/ Approuvé par Paul Glover, ADM (HECS/SESC)	Tel. no./No. de tél. 946-6701
	Mobile/ Cellulaire: 613-296-4239	Title/ Titre:	Mobile/ Cellulaire:
Alternate/ Secondaire: Jocelyn Kula	Telephone/ Téléphone: 613-952-2177		
	Mobile/ Cellulaire: 613-797-2103		

**Date Prepared/Préparé le :** 2010-09-07

**Prepared by/Préparé par :** Stephanie Chandler **Phone/ No de tél. :** 613-946-0124

**Office/Bureau :** CSTD - Office of Controlled Substances

**Date Contact Signed/  
Signature de la personne  
ressource :**

Contact Signed - Signé

**D.G. Verification/  
Vérification par le D.E. :**

Cathy Sabiston

D.G. Approved / Approuvé D.E.

**Date D.G. Verified/  
Date vérifié par le D.E. :** 2011-01-28

**Programme :** Controlled Substances and Tobacco Directorate

**ADM Approved/ Approbation  
par le SMA :** Paul Glover  
(946-6701)

**Branch/ Direction générale :** HECS/SESC

**Department/ Ministère :** Health Canada / Santé Canada

## RPD Telephone Enquiry

**Date of Call:** January 27, 2011

**Subject:** Status of *Salvia divinorum* and whether we are assessing it

**Language of Correspondence:** English

s.19(1)

**Caller Name:** [REDACTED]

**Caller Organization:** Saskatchewan Drug Information Services

**Caller Telephone Number:** [REDACTED]

### CALL SUMMARY:

[REDACTED] of Saskatchewan Drug Information Services called to enquire as to the status of *Salvia divinorum* and when it is considered a natural health product as she felt that there had been confusion in media reports. [REDACTED] also inquired as to whether it was true that Health Canada is currently assessing this substance.


I informed [REDACTED] that as *Salvia divinorum* is not scheduled under the *Controlled Drugs and Substances Act* it is not considered to be illegal in itself. However, because *Salvia divinorum* is a plant with hallucinogenic properties and can affect brain function, it is considered a natural health product under the *Natural Health Product Regulations* when it is marketed as such.

I also informed the caller that Health Canada is currently assessing *S. divinorum* to determine what measures (if any) Health Canada should take in order to control this substance.

The caller also asked if there are any other plants that are the same species as *Salvia divinorum*. I stated that while *Salvia divinorum* is a type of sage, I did not have enough knowledge of plant species to adequately answer her question. I offered to find a contact for her that could be of assistance, but she said that it was not necessary.

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division  
Office of Controlled Substances



**Re: Fw: Salvia docs**   
Stephanie Szick to: Stephanie Chandler  
Cc: Denis Arsenault

2011-01-28 09:17 AM

Perfect. Thanks for this Stephanie  
We are having a DGO meeting this morning so I will track down this docket and bring to Cathy's attention for signature.

Will keep you posted.

Stephanie Szick  
Director General's Office / Bureau du directeur général  
Controlled Substances & Tobacco Directorate (CSTD) /  
Direction des substances contrôlées et de la lutte au tabagisme (DSCLT)  
Health Canada / Santé Canada  
Tel / Tél: (613) 948-8651

Stephanie Chandler Hi Stephanie, Suzanne Desjardins had some...

2011-01-28 09:09:32 AM

From: Stephanie Chandler/HC-SC/GC/CA  
To: Stephanie Szick/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2011-01-28 09:09 AM  
Subject: Re: Fw: Salvia docs

Hi Stephanie,

Suzanne Desjardins had some minor comments on the NOI, so it has been revised and translated. It was sent up to DGO in a docket yesterday. (Please note that there are 4 copies of the NOI in the docket - 2 French, 2 English - and all 4 require Cathy's signature.

And yes, in order for the NOI to be published on Feb 12th, it needs to be with Canada Gazette by noon Friday February 4th.

Regards,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

Stephanie Szick hi both, Can you confirm (and I need a memory r...

2011-01-28 08:13:21 AM

From: Stephanie Szick/HC-SC/GC/CA  
To: Denis Arsenault/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2011-01-28 08:13 AM

Subject: Fw: Salvia docs

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hi both,

Can you confirm (and I need a memory refresh I'm afraid!) -- Cathy has signed the NOI? I understand this needs to land with CG folks next Friday if we are to be in CG1 on Sat. Feb. 12.

If she hasn't -- let me know and we can get that today hopefully.

Thanks, Stephanie

----- Forwarded by Stephanie Szick/HC-SC/GC/CA on 2011-01-28 08:11 AM -----

From: Jocelyn Kula/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Cc: stephanie.szick@hc-sc.gc.ca, stephanie.chandler@hc-sc.gc.ca, Denis  
Arsenault/HC-SC/GC/CA@HWC  
Date: 2011-01-27 05:48 PM  
Subject: Salvia docs

---

Hi Christine

Please find attached the latest version of the media lines for Salvia, which incorporate our suggested changes further to comments from HPFB, and our comments on the draft NR you prepared.

[attachment "Salvia NR\_Jan 27\_OCS.doc" deleted by Stephanie Szick/HC-SC/GC/CA] [attachment "Salvia MLs\_Jan27\_OCS.doc" deleted by Stephanie Szick/HC-SC/GC/CA]

For reference, I am attaching the QP note that we have updated in preparation for the house coming back into session.



(Note Cathy has not reviewed this yet but it is consistent with the media lines and the NOI text that have both been discussed with Cathy informally.)

What I don't seem to have is a copy of the updated NOI, so by copy of this message, I am asking Stephanie C to send it to you, as it has now been through Suzanne Desjardins' office for review.

Lastly, I am attaching a copy of the updated IYH (text now matches the key messages in the MLs and the gist of the NR etc.....). Please feel free to put this document back into approvals (I assume with HPFB) but please note that under no circumstances, should progress on this document impede publication of the NOI. We have clarified this with Cathy. If by some chance, the IYH can be ready for posting soon after the announcement/ NOI, so be it, but we are to plan for publication of the NOI on Sat. Feb 12.

[attachment "IYH Salvia divinatorum\_v19 Jan 27.doc" deleted by Stephanie Szick/HC-SC/GC/CA]

Please note that I am out of the office on annual leave tomorrow. Stephanie and Denis are around if you have questions however, and I am back in the office on Monday. From my perspective, the most pressing piece to move on is the NR and media lines, and Cathy's office knows to expect them sometime tomorrow.

Jocelyn

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées



Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224



**Salvia Noi docket??**

Carmen Berube to: Stephanie Chandler, Denis Arsenault  
Cc: Arafo Talane

2011-01-28 09:44 AM

History: This message has been replied to.

FYI - Yesterday, Jocelyn told Arafo this could wait until today.  
Besides, the doors were locked upstairs as it was after 6 PM.

----- Forwarded by Carmen Berube/HC-SC/GC/CA on 2011-01-28 09:43 AM -----

From: Stephanie Chandler/HC-SC/GC/CA  
To: Carmen Berube/HC-SC/GC/CA@HWC  
Cc: Arafo Talane/HC-SC/GC/CA@HWC  
Date: 2011-01-28 09:33 AM  
Subject: Fw: Salvia Noi docket??

FYI The docket is with DGO now.

Thanks for your help,

**Stephanie**

----- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2011-01-28 09:31 AM -----

From: Stephanie Chandler/HC-SC/GC/CA  
To: Stephanie Szick/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2011-01-28 09:30 AM  
Subject: Re: Salvia Noi docket??

Sorry Stephanie. It appears it got left behind in DO yesterday... I just brought it up now.

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

Stephanie Szick hi again both, I've asked here - this hasn't lande...

2011-01-28 09:24:11 AM

From: Stephanie Szick/HC-SC/GC/CA  
To: Stephanie Chandler/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2011-01-28 09:24 AM  
Subject: Salvio Noi docket??

hi again both,  
I've asked here - this hasn't landed in DGO? Neither Paula nor Sonia are aware of it having come in...and  
nowhere here. Unless Jocelyn handed directly to Cathy? Could it still be in DO?  
We are having our meeting in a few minutes...any way you can bring it up in the next bit??

Stephanie Szick  
Director General's Office / Bureau du directeur général  
Controlled Substances & Tobacco Directorate (CSTD) /  
Direction des substances contrôlées et de la lutte au tabagisme (DSCLT)  
Health Canada / Santé Canada  
Tel / Tél: (613) 948-8651



**Re: Salvia docs**  
Christine Roush to: Stephanie Chandler

2011-01-28 09:55 AM

History: This message has been forwarded.

Thanks Stephanie - I will be putting the products into approval today, and will keep you copied on their progress.

Christine Roush  
Senior Communications Advisor/

Stephanie Chandler Hi Christine, Here is the revised version of the... 2011-01-28 09:11:30 AM

From: Stephanie Chandler/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Cc: Jocelyn Kula/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, stephanie.szick@hc-sc.gc.ca  
Date: 2011-01-28 09:11 AM  
Subject: Re: Salvia docs

Hi Christine,

Here is the revised version of the Salvia NOI as requested by Jocelyn.

[attachment "DRAFT Salvia NOI\_Jan 25 EN.wpd" deleted by Christine Roush/HC-SC/GC/CA]

Regards,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

Jocelyn Kula Hi Christine Please find attached the latest versi... 2011-01-27 05:48:46 PM

From: Jocelyn Kula/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Cc: stephanie.szick@hc-sc.gc.ca, stephanie.chandler@hc-sc.gc.ca, Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2011-01-27 05:48 PM  
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[attachment "Salvia NR\_Jan 27\_OCS.doc" deleted by Stephanie Chandler/HC-SC/GC/CA] [attachment

"Salvia MLs\_Jan27\_OCS.doc" deleted by Stephanie Chandler/HC-SC/GC/CA]

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(Note Cathy has not reviewed this yet but it is consistent with the media lines and the NOI text that have both been discussed with Cathy informally.)

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[attachment "IYH Salvia divinatorum\_v19 Jan 27.doc" deleted by Stephanie Chandler/HC-SC/GC/CA]

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Jocelyn

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

DRAFT  
2/1/2011  
PJ

**Media Lines**  
**Salvia divinorum**

**Issue**

There is ongoing media interest regarding the availability of *Salvia divinorum* in Canada as well as Canadian surveillance data suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has concluded that *Salvia divinorum* and its main active ingredient salvinorin A should be regulated under the *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth.

**Key Messages:**

- Health Canada is proposing to regulate both *Salvia divinorum* and its main active ingredient salvinorin A under Schedule III to the *Controlled Drugs and Substances Act* (CDSA).
- After reviewing available information and reports that suggest this substance has the potential for abuse, especially among young people, we are taking these steps to protect the health and safety of Canadians, particularly youth, from the potentially harmful effects of this substance
- Canadians should not use products containing *Salvia divinorum* and/or salvinorin A because they are hallucinogenic and little is known about the long-term effects of these substances on the brain and body.
- The inclusion of *Salvia divinorum* and salvinorin A in Schedule III to the CDSA will make possession, trafficking, importation, exportation, and production (or cultivation) illegal unless authorized by regulation.

**Comment [D1]:** Suggest to add a line about why there is a risk to the health of Canadians. Abuse potential? Addiction?

**Comment [S2]:** OCS feels that the second bullet addresses this. Could possibly reword first two bullets as follows: 1) After reviewing available information and reports that suggest this substance has the potential for abuse, especially among young people, Health Canada is proposing to regulate *Salvia divinorum* and its main active ingredient as controlled substances. 2) The Government of Canada is taking these steps in order to protect the health and safety of Canadians, including youth, from its potentially harmful effects.

**Supplementary Messages:**

• The plant *Salvia divinorum* is not currently regulated under the CDSA and therefore it is not considered to be "banned", nor are activities with it considered to be illegal in Canada.

*unless it is being sold as a hallucinogen*

• However, as *Salvia divinorum* is a plant with hallucinogenic properties when consumed by humans, it would meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations*, when marketed as a hallucinogen.

*gen. If this were the case, the product would meet the*

• To date, Health Canada has not authorized for sale any natural health products which contain *Salvia divinorum* as an ingredient. The sale of unauthorized

**Comment [D3]:** Suggest to remove. It is considered an NHP and subject to the NHPR.

**Comment [S4]:** Technically this comment is true (as we got the text from all those questions in previous media inquiries) if you consider the first bullet in the section only, but if you go on to read the remaining bullets the choice of words seems to be clarified. OCS would suggest that if HPPF does not like the order of bullets, they could suggest how to change them...

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Last saved by Christine Roush

Created by Christine Roush  
2011-01-25

*Add comment*  
*We are simply responding to all the past media enquiries. In any case, the*  
*002535*  
*for*

DRAFT  
21/01/2011

natural health products containing *Salvia divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act and its associated regulations*.

**Questions and Answers:**

**Q1 – What is involved in regulating *Salvia divinorum* as a controlled substance and what stage is it at?**

A1 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act (CDSA)* is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada recently concluded its assessment of *Salvia divinorum* and salvinorin A against the aforementioned factors and proposes to include both substances in Schedule III to the CDSA. The first step in the process of regulating a substance under the CDSA is the publication of a *Notice to Interested Parties (NOI)* in *Canada Gazette, Part I*. Any comments received will be considered during the preparation of a regulatory proposal. There will be additional opportunities for comment as the federal regulatory process progresses.

The regulation of these products will reduce the potential risks to the health and safety of Canadians associated with their ready availability, with their increased use and their unknown effects. The scheduling of *Salvia divinorum* and salvinorin A will also eliminate the current misconception that these substances are a safe alternative to other illegal drugs.

**Q2 – Are *Salvia divinorum* and/or salvinorin A controlled internationally? How are these substances regulated in other countries?**

A2 - Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions; as a result, there is no requirement for them to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

The move to include *Salvia divinorum* and salvinorin A in Schedule III to the CDSA is consistent with actions taken by several countries (e.g., Australia, Belgium, Denmark,

**Comment [D5]:** Replace with "misconception"

**Comment [S6]:** OK with this change

**Comment [D7]:** Replace with "there is no requirement for them to be regulated"

**Comment [S8]:** OK with this change

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Last saved by Christine Roush

Created by Christine Roush

2011-01-25

DRAFT  
21/01/2011

Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Some individual U.S. states have implemented laws restricting their use, sale and/or distribution.

Add comment  
OCS feels that  
2nd para in the  
answer  
addresses  
the question

**Q3 – Is there any research on the use of *Salvia divinorum* in Canada?**

A3 - Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *Salvia divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *Salvia divinorum* in the past year. The 2009 *Ontario Student Drug Use and Health Survey (OSDUHS)* indicated that 5.4% of Ontario students in grades 7-12 reported ever using *Salvia divinorum* and 4.4% of these students reported using this substance in the past year.

**Comment [D9]:** It is considered an NHP – it is illegal? It is a contravention of the FDR/NHPR to sell and unlicensed and unapproved product. No licences have been granted for these products.

**Deleted:** Health Canada proposes to include

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**Comment [S10]:** CADUMS included Salvia in 2008

**Q4 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why isn't it illegal?**

A4 – The move to regulate *Salvia divinorum* and salvinorin A as controlled substances is based on surveillance data from surveys such as the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)*, *Youth Smoking Survey (YSS)* and the *Ontario Student Drug Use and Health Survey (OSDUHS)*, some of which only became available in 2010.

**Deleted:** under Schedule III of the CDSA. Further to the regulation of these substances under the CDSA, the following activities would be illegal unless authorized by regulation: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation). Law enforcement agencies would also be able to take action against suspected illegal activities involving these substances.

In the interim, as *Salvia divinorum* is a plant with hallucinogenic properties, it currently meets the definition of a natural health product under the *Natural Health Products Regulations (NHPR)* when marketed as a hallucinogen. ~~To date, Health Canada has not authorized for sale any natural health products which contain *Salvia divinorum* as an ingredient.~~ The sale of unauthorized natural health products may be subject to compliance and enforcement action in accordance with the *Food and Drugs Act* and its associated regulations.

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**Field Code Changed**

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**Q5 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A5 – Once *Salvia divinorum* and salvinorin A are included in Schedule III to the CDSA, law enforcement will be able to take appropriate action in response to suspected illegal activities with these substances.

Currently however, *Salvia divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. For more information on how to submit a consumer complaint about the unauthorized sale of drugs containing *Salvia divinorum* and/or salvinorin A,

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Last saved by Christine Roush

Created by Christine Roush  
2011-01-25



**DRAFT**  
21/01/2011

visit: [www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_44\\_consumer\\_consommateur\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_44_consumer_consommateur_cp-pc-eng.php).

**Q6 - Has Health Canada issued any kind of warning to Canadians about *Salvia divinorum*?**

A6 - Health Canada has developed an *It's Your Health* article about *Salvia divinorum* to help inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at:

**Comment [D11]:** No link here. Is this coming?

**Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

Data from the 2008-2009 Youth Smoking Survey indicates that:

- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;
- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year; and
- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using Salvia in their lifetime (0.2% in the past year); and
- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that:

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;

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Last saved by Christine Roush

Created by Christine Roush  
2011-01-25

**DRAFT**  
21/01/2011

- 5.4% of students (grades 7-12) ever used *Salvia divinorum*; and
- the use of *Salvia divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

**Prepared by:** Stephanie Chandler and Denis Arsenault, OCS, CSTD  
Reviewed and revised by: Christine Roush, Senior Communications Advisor, HECS, Communications

**Input by:** Lisa Mackay IYH/PACCB,  
Suzanne Desjardins HECSB/ODARS,  
Hanan Abramovici HECSB/ODARS,  
Bruna Brands HECSB/ODARS,  
Jocelyn Kula, HECSB/OCS,  
Robin Marles HPFB/NHPD,  
Maggie Graham HPFB/NHPD,  
Stephanie Collins HPFB/NHPD,  
Mano Murty HPFB/MHPD,  
Robert Leitch HPFB/MHPD,  
Shahid Perwaiz HPFB/MHPD,  
Collin Pinto, HPFB/HPFBI

**Approved by:**  
Robin Marles, Director, Bureau of Clinical Trials, NHPD (2011-01-20)  
Duc Vu, Director, Marketed Biologics, Biotechnology and Natural Health Products Bureau, MHPD (pending)  
Kim Dayman-Rutkas, Director, HPFBI (pending)  
Jocelyn Kula, A/Director, OCS, CSTD, HECS (Approved Jan 19, 2011)  
Suzanne Desjardins, Director, ODARS, CSTD, HECS (Approved Jan 20, 2011)  
Cathy Sabiston, DG, CSTD, HECS (pending)  
Chris Turner, DG, MHPD (pending)  
Scott Sawler, DG, NHPD (pending)  
Diana Dowthwaite, DG, HPFBI (pending)  
Aldege Bellefeuille, Communications Executive, HPFB (pending)  
Ken Polk, A/Director, Public Affairs, PACCB (pending)  
Charles Mojsej, DG, PACCB (pending)

HECS Legal (pending)  
HPFB Legal (pending)  
Paul Glover, ADM, HECSB (pending)  
Meena Ballantyne, ADM, HPFB (pending)  
Anne Lamar, ADM, PACCB (pending)  
DMO (pending)  
MO (pending)  
PCO (pending)

**Deleted:** Ken Polk,

**Deleted:** Jean Tessier, Senior Media Relations, PACCB (pending)¶  
Warren Braun, Director, Strategic Communications, PACCB (pending)¶  
Peter Yendal

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2011-01-25

Health Canada

2011-XX

# News Release

## The Government of Canada Proposes to Regulate Salvia Divinorum and Salvinorin A as Controlled Substances

~~[DATE]~~ February 10, 2011  
~~February 6, 2011~~

For immediate release

OTTAWA – Today, the Honourable Leona Aglukkaq, Minister of Health announced that the Government of Canada intends to regulate *Salvia divinorum* and salvinorin A, also known as Salvia, as controlled substances. A Notice to Interested Parties outlining Health Canada's proposal will be published in *Canada Gazette*, Part I, on February 5, 2011.

“After reviewing Canadian surveillance data and scientific reports that suggest this substance has the potential for abuse, especially among young people, we are taking these steps to protect the health and safety of Canadians from the potentially harmful effects of this substance,” said Minister Aglukkaq. “The use of this substance is of concern to Health Canada as very little is known about its long-term effects on the brain and body,” added Aglukkaq.

The Notice to Interested Parties will propose that *Salvia* and *Salvinorin A* be added to Schedule III to the *Controlled Drugs and Substances Act*. This means that activities such as possession, trafficking, importation, exportation, and production will be illegal unless authorized by regulation. Regulating *Salvia* as a controlled substance will also enable law enforcement agencies to take action against suspected illegal activities involving this substance.

Interested parties are encouraged to submit any comments regarding the Notice to Interested Parties by ~~March 7, 2011~~.

For more information on *Salvia divinorum*, please visit: ~~It's Your Health - Salvia divinorum~~. ~~XXX~~

[change date]

no longer tied to IYH

Media Enquiries:  
Health Canada  
(613) 957-2983

Également disponible en français

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- Deleted: January
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- Deleted: released a Notice to Interested Parties, also known as a Notice of Intent, in the *Canada Gazette*, Part I, on the proposal to
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- Deleted: This notice will provide interested stakeholders with the opportunity to comment on Health Canada's proposal to add the plant *Salvia divinorum* (*S. divinorum*) and its main active ingredie ... [1]
- Deleted: available information
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- Deleted: a serious
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- Deleted: Also, the regulation of
- Deleted: *S. divinorum* an ... [8]
- Deleted: under the CDSA
- Deleted: ese
- Deleted: s
- Deleted: The Notice to ... [9]
- Comment [h1]: Stand ... [10]
- Deleted: efore
- Deleted: February
- Deleted: 27
- Comment [h2]: Webli ... [11]

Steph:  
As find  
out  
next  
pub date  
for  
CI

Jenny Van Alstyne  
Office of the Honourable Leona Aglukkaq  
Federal Minister of Health  
(613) 957-0200

**Public Enquiries:**  
(613) 957-2991  
1-866 225-0709

Health Canada news releases are available on the Internet at  
[www.healthcanada.gc.ca/media](http://www.healthcanada.gc.ca/media)



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du Canada

Canada

<b>Page 1: [1] Deleted</b>	<b>STCHANDL</b>	<b>2011-01-21 11:39:00 AM</b>
This notice will provide interested stakeholders with the opportunity to comment on Health Canada's proposal to add the plant <i>Salvia divinorum</i> ( <i>S. divinorum</i> ) and its main active ingredient salvinorin A to Schedule III to the <i>Controlled Drugs and Substances Act</i> (CDSA).		
<b>Page 1: [2] Formatted</b> Font: Times New Roman, 12 pt	<b>STCHANDL</b>	<b>2011-01-20 3:32:00 PM</b>
<b>Page 1: [3] Formatted</b> Font: Times New Roman, 12 pt	<b>STCHANDL</b>	<b>2011-01-20 3:32:00 PM</b>
<b>Page 1: [4] Formatted</b> Font: Times New Roman, 12 pt	<b>STCHANDL</b>	<b>2011-01-20 3:32:00 PM</b>
<b>Page 1: [5] Formatted</b> Font: Times New Roman, 12 pt	<b>STCHANDL</b>	<b>2011-01-20 3:32:00 PM</b>
<b>Page 1: [6] Formatted</b> Font: Times New Roman, 12 pt	<b>STCHANDL</b>	<b>2011-01-20 3:32:00 PM</b>
<b>Page 1: [7] Deleted</b>	<b>STCHANDL</b>	<b>2011-01-21 11:40:00 AM</b>

Including these substances within the

<b>Page 1: [8] Deleted</b> <i>S. divinorum</i> and salvinorin A	<b>STCHANDL</b>	<b>2011-01-25 11:42:00 AM</b>
<b>Page 1: [9] Deleted</b> The Notice to Interested Parties will be published in <i>Canada Gazette</i> , Part I, on January 29, 2011.	<b>STCHANDL</b>	<b>2011-01-20 4:45:00 PM</b>
<b>Page 1: [10] Comment [h1]</b> Standard text from previous enquiries.	<b>hcuser</b>	<b>2011-01-19 4:06:00 PM</b>
<b>Page 1: [11] Comment [h2]</b> Weblink – OCS is waiting for confirmation from DGO whether this will be posted next week	<b>hcuser</b>	<b>2011-01-20 4:47:00 PM</b>

looked great  
one minor change

## Salvia divinorum

### Issue

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff, incense special, and salvia.

move to be 1st sentence in para

Recent Canadian surveillance data indicates that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. Scientific reports also suggest that it has the potential for abuse. ~~Certain websites are also promoting~~ the use of *S. divinorum* as a "legal" alternative to street drugs.

Deleted: ly there have been reports suggesting

Canadians should not use products containing *S. divinorum* and/or salvininorin A because they are hallucinogenic and little is known about the long-term effects of these substances on the brain and body. There is also no way to predict how it will affect you with each use.

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In light of this information, Health Canada is proposing to regulate both *S. divinorum* and its main active ingredient salvininorin A under Schedule III to the *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth.

Deleted: As of [redacted] 2010 Health Canada has not authorized for sale any products containing *S. divinorum*.

Comment [S1]: Have removed as it repeats content of "Minimizing your Risk" section

### Risks Associated with the Use of *Salvia divinorum*

*S. divinorum* is known to have both physical and mental effects. The effects of *S. divinorum*, which vary from person to person, are often described as unpleasant and may include the following:

Deleted: ¶ Health Canada recommends that you avoid using this plant because very little is known about the effects it may have on your body and/or brain functions. There is also no way to predict how it will affect you with each use.

Deleted: ¶

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product
- how much is used
- the purity of the product (products that contain *S. divinorum* may be mixed with other substances)



Note, pls make sure Christine understands that we have clarified with Cathy that while the 1YH is important, it

Its posting can be done after

S 002543

- how it is taken, for example, whether the product is chewed, swallowed or smoked
- the user's mood and expectations

While scientists know which brain receptors are targeted by the active ingredient, salvinorin A, very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or if it can cause permanent damage
- how it interacts with other substances, including other drugs, natural health products and alcohol
- the potential of *S. divinorum* to produce physical dependence and/or addiction

### Minimizing Your Risk

Hallucinogens like *S. divinorum* work by modifying functions in the brain. Health Canada recommends that you avoid using *S. divinorum* because very little is known about the effects it may have on your body and/or brain functions. There is also no way to predict how it will affect you with each use. Just because a drug is plant-based or "natural", does not mean that it is safe.

Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs, such as marijuana, cocaine, ecstasy, LSD and other substances that distort reality. See the "Need More Info?" section below for links to resources that can help you with this.

### Legal Status of *Salvia divinorum*

#### In Canada

As *S. divinorum* is a plant with hallucinogenic properties when consumed by humans, it currently meets the definition of a natural health product (NHP) under the *Natural Health Products Regulations* when marketed as a hallucinogen. As of [REDACTED] 2011, Health Canada has not authorized for sale any natural health products which contain *S. divinorum* as an ingredient. The sale of unauthorized natural health products containing *S. divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

While *S. divinorum* and salvinorin A are not currently regulated under the *Controlled Drugs and Substances Act* (CDSA), Health Canada is now developing a regulatory proposal that would add *S. divinorum* and salvinorin A to Schedule III to the CDSA.

#### In Other Countries

Several countries including but not limited to Australia, Belgium, Germany, Italy and Japan, have placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A.

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**Deleted:** hallucinogenic properties, products containing *S. divinorum* or salvinorin A meet the definition of a Natural Health Product (NHP) in accordance with the *Natural Health Products Regulations* and the definition of a drug under the *Food and Drugs Act*. It is illegal to sell drugs or NHPs in Canada, unless they have been reviewed and authorized for sale by Health Canada. In the case of NHPs, they need to be labelled with one of the following: ¶ a Natural Product Number (NPN); or ¶ an Exemption Number (EN); or ¶ a Drug Identification Number - Homeopathic Medicine Number (DIN-HM). ¶

**Deleted:** As of [REDACTED] 2010 no products containing *S. divinorum* or salvinorin A have been authorized by Health Canada for sale. The sale of unauthorized drugs and NHPs is illegal, and may be subject to compliance and enforcement actions by the Department. ¶

¶ Neither *S. divinorum* nor salvinorin A are currently regulated under the *Controlled Drugs and Substances Act* (CDSA). Health Canada is currently considering the available information to determine whether regulation as a controlled substance is warranted. ¶

**Deleted:** Italy

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In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on their sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution. In some states, for example, it is illegal for *S. divinorum* to be sold to anyone under the age of 18.

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### Background

The leaves of this plant have been used traditionally by the Mazatec people for medicinal and mystical purposes.

Products that claim to contain *S. divinorum* or its main active ingredient, salvinorin A are widely available on the Internet and are sold in various "head shops" and natural food stores. The products are sold in a number of forms, including fresh or dried leaves, liquids or seeds and plant cuttings for growing purposes.

Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *S. divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *S. divinorum* in the past year. The 2009 *Ontario Student Drug Use and Health Survey (OSDUHS)* indicated that 5.4% of Ontario students in grades 7-12 reported ever using *S. divinorum* and 4.4% of these students reported using this substance in the past year. For more information on these surveys, see the *Need More Info* section below.

Deleted: Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, less than 2% of Canadians age 15 and older reported having used *S. divinorum* at least once in their lifetime. Youth, ages 15-24 were much more likely to have used it than adults. The results from the *Canadian 2008-2009 Youth Smoking Survey* show that 5% of 15yr olds have used *S. divinorum* in the past year.

### Health Canada's Role

In light of the health and safety risks associated with the use of *S. divinorum* and particularly the risks to youth, Health Canada is taking steps to regulate *S. divinorum* and salvinorin A as controlled substances. As a first step in this process, Health Canada issued a *Notice to Interested Parties (NOI)* on February 5, 2011. In the interim, Health Canada will continue to monitor the sale of unauthorized health products that contain *S. divinorum* or its main active ingredient salvinorin A. It will take appropriate action should it become aware of any unauthorized health products that may pose a risk to Canadians.

Deleted: Health Canada continues to collect and consider safety information regarding *S. divinorum* and will continue to consult with key stakeholders including health officials in other countries and law enforcement officials here at home.

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### Need More Info?

- Complaints about the unauthorized sale of drugs containing *S. divinorum* can be made to the **Health Products and Food Branch Inspectorate** at: [http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_44\\_consumer\\_consommateur\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_44_consumer_consommateur_cp-pc-eng.php)  
Tel: 1-800-267-9675.



- You can report any adverse reactions to the Canada Vigilance Program by one of the following three ways:  
Report online at the MedEffect™ Canada website at: <http://www.hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>  
Call toll-free at 1-866-234-2345  
Complete a Canada Vigilance Reporting Form and either:  
Fax toll-free to 1-866-678-6789  
Mail to: Canada Vigilance Program  
Health Canada  
AL 0701C  
Ottawa, ON K1A 0K9  
To have postage pre-paid, download the postage paid label from the MedEffect™ Canada website. The Canada Vigilance Reporting Form and the adverse reaction reporting guidelines may also be obtained via this website at : [http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei\\_form-eng.php](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei_form-eng.php)
- For information about the Government of Canada's National Anti-Drug Strategy, go to: [www.nationalantidrugstrategy.gc.ca/](http://www.nationalantidrugstrategy.gc.ca/)  
The Prevention section on this site has a number of helpful resources for parents, including:
  - **Tips on Talking to Your Teenager**, at: [www.hc-sc.gc.ca/hc-ps/pubs/adp-adp/talk-aborder/index-eng.php](http://www.hc-sc.gc.ca/hc-ps/pubs/adp-adp/talk-aborder/index-eng.php)
  - **What to Do if Your Teen is Using Drugs**, at:  
[www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html](http://www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html)
  - Health Canada's **Not4Me** youth drug prevention section at:  
<http://www.hc-sc.gc.ca/hc-ps/drugs-drogues/youth-jeunes/facts-faits/index-eng.php>
- Information on natural health products and the Natural Health Products Regulations can be found at: [www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php)

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For more on the surveys that have collected information about *Salvia divinorum* use in Canada, see:

- **The 2008-2009 Youth Smoking Survey**, at:  
<http://www.yss.uwaterloo.ca/index.cfm?section=5&page=288>
- **The 2009 Canadian Alcohol and Drug Use Monitoring Survey**, at:  
<http://www.hc-sc.gc.ca/hc-ps/drugs-drogues/stat/index-eng.php>
- **The 2009 Ontario Student Drug Use and Health Survey**, at:  
[http://www.camh.net/News\\_events/News\\_releases\\_and\\_media\\_advisories\\_and\\_b\\_ackgrounders/osduhs2009\\_advisory.html](http://www.camh.net/News_events/News_releases_and_media_advisories_and_b_ackgrounders/osduhs2009_advisory.html)

Additional Resources:

- U.S. Drug Enforcement Administration: **Drugs and Chemicals of Concern: Salvia divinorum and Salvinorin A** at:  
[www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)

- U.S. Department of Health & Human Services, **National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006** at:  
[www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf](http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf)
- For additional articles on health and safety issues go to the **It's Your Health** web section at: [www.healthcanada.gc.ca/iyh](http://www.healthcanada.gc.ca/iyh)

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

Original:

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Catalogue#

ISBN#


Version/date: Draft 17. September 8, 2010.

PACCB IYH - Lisa Mackay: 613-954-0105 – [Lisa.Mackay@hc-sc.gc.ca](mailto:Lisa.Mackay@hc-sc.gc.ca)

Comments from: HECSB - CSTD (OCS&ODARS) & HPFB – NHPD, MHPD & HPFBI

Contacts: HECSB: Jocelyn Kula, Stephanie Chandler, Suzanne Desjardin, Denis Arsenault, Hanan Abramovici, Bruna Brands  
HECSB comms: Christine Roush, Bronwyn Cline  
HPFB-NHPD: Valerie Hurry, Robin Marles, Maggie Graham, Stephanie Collins  
HPFB-MHPD: Scott Jordan, Robert Leitch, Mano Murty, Shahid Perwaiz  
HPFBI : Collin Pinto  
HPFB comms: Elizabeth Keeping, Blossom Leung



**Re: Salvia Noi docket??**   
Denis Arsenault to: Carmen Berube  
Cc: Arafo Talane, Stephanie Chandler

2011-01-28 09:55 AM

O.K. Thanks!!! :-)

Denis

---

Denis Arsenault, A/Manager / Gestionnaire p.i.  
Regulatory Policy Division /  
Division des politiques réglementaires,  
Office of Controlled Substances /  
Bureau des substances contrôlées,  
Health Canada / Santé Canada  
Tel/Tél: (613) 957-6828  
Fax / Télécopieur : (613) 946-4224  
E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca

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Carmen Berube FYI - Yesterday, Jocelyn told Arafo this could w... 2011-01-28 09:44:16 AM

---

From: Carmen Berube/HC-SC/GC/CA  
To: Stephanie Chandler/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC  
Cc: Arafo Talane/HC-SC/GC/CA@HWC  
Date: 2011-01-28 09:44 AM  
Subject: Salvia Noi docket??

---

FYI - Yesterday, Jocelyn told Arafo this could wait until today.  
Besides, the doors were locked upstairs as it was after 6 PM.

----- Forwarded by Carmen Berube/HC-SC/GC/CA on 2011-01-28 09:43 AM -----

---

From: Stephanie Chandler/HC-SC/GC/CA  
To: Carmen Berube/HC-SC/GC/CA@HWC  
Cc: Arafo Talane/HC-SC/GC/CA@HWC  
Date: 2011-01-28 09:33 AM  
Subject: Fw: Salvia Noi docket??

---

FYI The docket is with DGO now.

Thanks for your help,

Stephanie

----- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2011-01-28 09:31 AM -----

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From: Stephanie Chandler/HC-SC/GC/CA  
To: Stephanie Szick/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2011-01-28 09:30 AM  
Subject: Re: Salvia Noi docket??

---

Sorry Stephanie. It appears it got left behind in DO yesterday... I just brought it up now.

Stephanie

---


Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

---

Stephanie Szick      hi again both, I've asked here - this hasn't lande...

2011-01-28 09:24:11 AM



**Re: Salvia Noi docket??**   
Stephanie Szick to: Stephanie Chandler  
Cc: Denis Arsenault

2011-01-28 10:00 AM

Thanks Stephanie

Cathy has it - will let you know once she has signed all four copies.

So you know, she has asked that I touch base with ADMO to ensure this is moving ahead - as she is the signatory on the NOI, from there it would go to CG folks -- she wants confirmation this is going ahead for the Feb. 12 date, with the news release on Feb. 10

Will keep you posted.

Stephanie Szick

Director General's Office / Bureau du directeur général  
Controlled Substances & Tobacco Directorate (CSTD) /  
Direction des substances contrôlées et de la lutte au tabagisme (DSCLT)  
Health Canada / Santé Canada  
Tel / Tél: (613) 948-8651

Stephanie Chandler Sorry Stephanie. It appears it got left behind in...

2011-01-28 09:30:22 AM

From: Stephanie Chandler/HC-SC/GC/CA  
To: Stephanie Szick/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2011-01-28 09:30 AM  
Subject: Re: Salvia Noi docket??

Sorry Stephanie. It appears it got left behind in DO yesterday... I just brought it up now.

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
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Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

Stephanie Szick hi again both, I've asked here - this hasn't lande...

2011-01-28 09:24:11 AM



**Re: FYI: Salvia docs**   
Stephanie Szick to: Stephanie Chandler, Jocelyn Kula  
Cc: Denis Arsenault

2011-01-28 10:58 AM

Thanks Stephanie.  
Fingers crossed no changes!  
Stephanie Chandler

----- Original Message -----

**From:** Stephanie Chandler  
**Sent:** 2011-01-28 10:51 AM EST  
**To:** Jocelyn Kula  
**Cc:** Stephanie Szick; Denis Arsenault  
**Subject:** FYI: Salvia docs

FYI

I just spoke with Christine Roush regarding the Salvia comms products and she indicated that she was going to send the MLs back to HPFB for Director approvals before they would go to Cathy for her approval. So its likely DGO won't seem them again until early next week.

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

----- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2011-01-28 10:46 AM -----

**From:** Christine Roush/HC-SC/GC/CA  
**To:** Stephanie Chandler/HC-SC/GC/CA@HWC  
**Date:** 2011-01-28 09:55 AM  
**Subject:** Re: Salvia docs

Thanks Stephanie - I will be putting the products into approval today, and will keep you copied on their progress.

Christine Roush  
Senior Communications Advisor/

Stephanie Chandler	Hi Christine, Here is the revised version of the...	2011-01-28 09:11:30 AM
Jocelyn Kula	Hi Christine Please find attached the latest versi...	2011-01-27 05:48:46 PM

Needs to be updated to reflect tracked changes in English version

## MINISTÈRE DE LA SANTÉ

### LOI RÉGLEMENTANT CERTAINES DROGUES ET AUTRES SUBSTANCES

*Avis aux parties intéressées - Proposition concernant l'ajout de Salvia divinorum et de salvinorine A à l'annexe III de la Loi réglementant certaines drogues et autres substances*

Cet avis informe les parties intéressées de la possibilité de commenter la proposition de Santé Canada d'ajouter la plante *Salvia divinorum* (*S. divinorum*) et son principal ingrédient actif, la salvinorine A, à l'annexe III de la *Loi réglementant certaines drogues et autres substances* (LRCDAS). Les parties intéressées ont aussi l'occasion d'ajouter leur nom pour toute consultation future.

*S. divinorum* est une espèce de sauge appartenant à la famille des menthes. Généralement, ses feuilles sont mâchées ou fumées pour obtenir des effets psychotropes. Alors qu'une incertitude subsiste quant aux risques pour la santé découlant de la consommation de *S. divinorum*, les effets de cette consommation sont connus pour être brefs et comprennent des hallucinations, une dysphorie, des expériences extra-corporel, l'inconscience et une perte de mémoire à court terme. Les effets, qui varient d'une personne à l'autre, sont également souvent décrits comme déplaisants. Ni la *S. divinorum* ni la salvinorine A ne sont actuellement incluses dans les annexes de la LRCDAS.

Des rapports ont récemment été publiés, indiquant que des adolescents et des jeunes adultes canadiens consomment de la *S. divinorum* pour sa capacité à produire des hallucinations. *S. divinorum* est largement vantée comme un hallucinogène "légal" sur Internet et a aussi été signalée comme l'un des produits à base d'herbes médicinales les plus courants utilisés comme option alternative aux drogues illicites.<sup>1</sup> Les conclusions tirées de l'*Enquête de surveillance canadienne de la consommation d'alcool et de drogues* (ESCCAD) révèlent que, en 2009, 1,6 % des Canadiens âgés de 15 ans ou plus ont déclaré avoir consommé de la *S. divinorum* au moins une fois dans leur vie, et que les jeunes âgés de 15 à 24 ans étaient beaucoup plus nombreux à en avoir consommé que les adultes âgés de 25 ans ou plus. Les résultats de l'*Enquête sur le*

---

*la consommation de drogues et la santé des élèves de l'Ontario* (SCDSEO) de 2009 indique que 5,4 % des élèves de l'Ontario des classes scolaires 7 à 12 ont déclaré avoir déjà consommé de la *S. divinorum* et que 4,4 % de ces élèves ont indiqué avoir consommé cette substance au cours de la dernière année. Étant donné ses effets inconnus, ainsi que sa similarité pharmacologique avec d'autres substances comprises dans l'annexe III de la LRCDAS, comme l'acide lysergique diéthylamide (LSD) et la psilocybine, Santé Canada craint que la disponibilité immédiate et la consommation de *S. divinorum* ne posent un risque pour la santé et la sécurité des Canadiens, en particulier pour celles des jeunes.

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<sup>1</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. Oct 2005, vol. 39, no<sup>o</sup>10, pp. 1634-1639.

Alors que la *S. divinorum* et la salvinorine A ne sont actuellement comprises dans aucune des Conventions de l'ONU sur le contrôle des drogues, de nombreux pays ont choisi de réglementer une de ces substances, ou les deux, comme substance désignée. L'Australie, la Belgique, le Danemark, la Finlande, l'Allemagne, l'Italie, le Japon, la Corée du Sud, l'Espagne et la Suède ont tous établi des contrôles sur les importations ou la vente, ou les deux, de *S. divinorum* et/ou de salvinorine A. Certains États américains ont aussi mis en oeuvre des lois restreignant son utilisation, sa vente et/ou sa distribution.

Le fait d'ajouter ces substances à l'annexe III de la LRCDas en interdirait la possession, le commerce, la possession aux fins de commerce, l'importation, l'exportation, la possession aux fins d'exportation et la production (ou la culture). La réglementation de la *S. divinorum* et de la salvinorine A conformément à la LRCDas permettrait également aux organismes d'application de la loi de prendre des mesures contre les activités illicites présumées liées à ces substances.

Étant donné que cette mesure ne vise pas à interférer avec l'utilisation et la disponibilité de la *S. divinorum* et/ou de la salvinorine A à des fins médicales, scientifiques ou industrielles légitimes, Santé Canada sollicite de l'information aux parties intéressées sur les possibilités de ces types d'utilisation au Canada. L'information reçue en réponse à cet avis sera déterminante dans la rédaction d'un règlement approprié conformément à la LRCDas.

La publication de cet avis entame une période de commentaires de 30 jours. Il y aura des occasions supplémentaires de fournir des commentaires au fur et à mesure que progresse le processus de réglementation fédéral.

Si vous êtes intéressé par ce processus ou que vous avez des commentaires sur cette proposition, veuillez communiquer avec Stephanie Chandler de la Division de la politique réglementaire, du Bureau des substances contrôlées, situé au : 3503D, 123, rue Slater, Ottawa (Ontario), Canada, K1A 1B9, par télécopieur au (613) 946-4224 ou par courriel au [OCS\\_Policy\\_and\\_Regulatory\\_Affairs@hc-sc.gc.ca](mailto:OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca).

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Cathy A. Sabiston  
Directrice générale  
Direction des substances contrôlées et de la lutte au  
tabagisme

Date \_\_\_\_\_



## DEPARTMENT OF HEALTH

### CONTROLLED DRUGS AND SUBSTANCES ACT

#### *Notice to interested parties - Proposal regarding the addition of Salvia divinorum and salvinorin A to Schedule III to the Controlled Drugs and Substances Act*

This notice provides interested stakeholders with the opportunity to provide comments on Health Canada's proposal to add the plant *Salvia divinorum* (*S. divinorum*) and its main active ingredient salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA). Stakeholders may also identify themselves for inclusion in any future consultation.

*S. divinorum* is a species of sage belonging to the mint family. Its leaves are generally chewed or smoked to obtain psychotropic effects. While uncertainty remains surrounding the health risks of *S. divinorum*, known effects are reported to be short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant. Neither *S. divinorum* nor salvinorin A are currently included in any of the Schedules to the CDSA.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. *S. divinorum* is widely touted as a "legal" hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs.<sup>1</sup> Results from the *Canadian Alcohol and Drug Use Monitoring Survey* (CADUMS) reveal that, in 2009, 1.6% of Canadians aged 15 years and older reported having used *S. divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24 years. ~~and that youth aged 15-24 were much more likely to have used it than adults aged 25 years and older.~~ The results from the Canadian 2008-2009 *Youth Smoking Survey* also show that 5% of 15 year olds have used *S. divinorum* in the past year. Moreover, the 2009 *Ontario Student Drug Use and Health Survey* (OSDUHS) indicated that 5.4% of Ontario students in grades 7-12 reported ever using *S. divinorum* and 4.4% of these students reported using this substance in the past year. ~~Given its unknown effects and pharmacological similarity to~~ Because its psychoactive effects resemble those of other substances included in Schedule III to the CDSA such as lysergic acid diethylamide (LSD) and psilocybin, Health Canada is concerned that the ready availability and use of *S. divinorum* poses a risk to the health and safety of Canadians, particularly youth.

While *S. divinorum* and salvinorin A are not currently included in any of the United Nations Drug Control Conventions, a number of countries have chosen to regulate one or both as controlled substances. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden have all placed controls on the import and/or sale of *S. divinorum*

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<sup>1</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.

and/or salvinorin A. Some American states have also implemented laws restricting their use, sale and/or distribution.

Including these substances within Schedule III to the CDSA would prohibit: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation). The regulation of *S. divinorum* and salvinorin A under the CDSA will also enable law enforcement agencies to take action against suspected illegal activities involving these substances.

As this action is not intended to interfere with the use and availability of *S. divinorum* and/or salvinorin A for legitimate medical, scientific or industrial purposes, Health Canada is seeking information from stakeholders on whether there are any such uses in Canada. Information received in response to this notice will be instrumental in determining appropriate regulation under the CDSA.

The publication of this notice begins a 30-day comment period. There will be additional opportunities to provide comments as the federal regulatory process progresses.

If you are interested in this process or have comments on this proposal, please contact Stephanie Chandler, Regulatory Policy Division, Office of Controlled Substances, Address Locator: 3503D, 123 Slater St., Ottawa, Ontario, Canada, K1A 1B9, by fax at (613) 946-4224 or by email at [OCS\\_Policy\\_and\\_Regulatory\\_Affairs@hc-sc.gc.ca](mailto:OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca).

Cathy A. Sabiston  
Director General  
Controlled Substances and Tobacco Directorate

Date \_\_\_\_\_

## MINISTÈRE DE LA SANTÉ

### LOI RÉGLEMENTANT CERTAINES DROGUES ET AUTRES SUBSTANCES

*Avis aux parties intéressées - Proposition concernant l'ajout de Salvia divinorum et de la salvinorine A à l'annexe III de la Loi réglementant certaines drogues et autres substances*

Cet avis informe les parties intéressées de la possibilité de commenter la proposition de Santé Canada d'ajouter la plante *Salvia divinorum* (*S. divinorum*) et son principal ingrédient actif, la salvinorine A, à l'annexe III de la *Loi réglementant certaines drogues et autres substances* (LRCDas). Les parties intéressées ont aussi l'occasion d'ajouter leur nom pour toute consultation future.

*S. divinorum* est une espèce de sauge appartenant à la famille des menthes. Généralement, ses feuilles sont mâchées ou fumées pour obtenir des effets psychotropes. Alors qu'une incertitude subsiste quant aux risques pour la santé découlant de la consommation de *S. divinorum*, les effets de cette consommation sont connus pour être brefs et comprennent des hallucinations, une dysphorie, des expériences extra-corporel, l'inconscience et une perte de mémoire à court terme. Les effets, qui varient d'une personne à l'autre, sont également souvent décrits comme déplaisants. Ni la *S. divinorum* ni la salvinorine A ne sont actuellement incluses dans les annexes de la LRCDas.

Des rapports ont récemment été publiés indiquant que des adolescents et des jeunes adultes canadiens consomment de la *S. divinorum* pour sa capacité à produire des hallucinations. *S. divinorum* est largement vantée comme un hallucinogène "légal" sur Internet et a aussi été signalée comme l'un des produits à base d'herbes médicinales les plus courants utilisés comme option alternative aux drogues illicites.<sup>1</sup> Les conclusions tirées de l'*Enquête de surveillance canadienne de la consommation d'alcool et de drogues* (ESCCAD) révèlent que, en 2009, 1,6 % des Canadiens âgés de 15 ans ou plus ont déclaré avoir consommé de la *S. divinorum* au moins une fois dans leur vie, avec un taux de consommation plus important (7,3%) parmi les jeunes âgés de 15 à 24 ans. Les résultats de l'*Enquête sur le tabagisme chez les jeunes* de 2008-2009 au

élèves de l'Ontario (SCDSEO) de 2009 indique que 5,4 % des élèves de l'Ontario des classes scolaires 7 à 12 ont déclaré avoir déjà consommé de la *S. divinorum* et que 4,4 % de ces élèves ont indiqué avoir consommé cette substance au cours de la dernière année. Puisque ses effets psychoactifs ressemblent à ceux ~~avec~~ d'autres substances comprises dans l'annexe III de la LRCDas, comme l'acide lysergique diéthylamide (LSD) et la psilocybine, Santé Canada craint que la disponibilité immédiate et la consommation de *S. divinorum* ne posent un risque pour la santé et la sécurité des Canadiens, en particulier pour celles des jeunes.

<sup>1</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. Oct 2005, vol. 39, no<sup>o</sup> 10, pp. 1634-1639.

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Le fait d'ajouter ces substances à l'annexe III de la LRCDas en interdirait la possession, le commerce, la possession aux fins de commerce, l'importation, l'exportation, la possession aux fins d'exportation et la production (ou la culture). La réglementation de la *S. divinorum* et de la salvinorine A conformément à la LRCDas permettrait également aux organismes d'application de la loi de prendre des mesures contre les activités illicites présumées liées à ces substances.

Étant donné que cette mesure ne vise pas à interférer avec l'utilisation et la disponibilité de la *S. divinorum* et/ou de la salvinorine A à des fins médicales, scientifiques ou industrielles légitimes, Santé Canada sollicite de l'information aux parties intéressées sur les possibilités de ces types d'utilisation au Canada. L'information reçue en réponse à cet avis sera déterminante dans la rédaction d'un règlement approprié conformément à la LRCDas.

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Directrice générale  
Direction des substances contrôlées et de la lutte au  
tabagisme

Date \_\_\_\_\_

MINISTÈRE DE LA SANTÉ

LOI RÉGLEMENTANT CERTAINES DROGUES ET AUTRES SUBSTANCES

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Des rapports ont récemment été publiés/ indiquant que des adolescents et des jeunes adultes canadiens consomment de la *S. divinorum* pour sa capacité à produire des hallucinations. *S. divinorum* est largement vantée comme un hallucinogène "légal" sur Internet et a aussi été signalée comme l'un des produits à base d'herbes médicinales les plus courants utilisés comme option alternative aux drogues illicites.<sup>1</sup> Les conclusions tirées de l'*Enquête de surveillance canadienne de la consommation d'alcool et de drogues* (ESCCAD) révèlent que, en 2009, 1,6 % des Canadiens âgés de 15 ans ou plus ont déclaré avoir consommé de la *S. divinorum* au moins une fois dans leur vie, ~~et que les jeunes âgés de 15 à 24 ans, étaient beaucoup plus nombreux à en avoir consommé que les adultes âgés de 25 ans ou plus.~~ Les résultats de l'*Enquête sur le*

~~la consommation de drogues et la santé des élèves de l'Ontario (SCDSEO) de 2009 indique que~~ la consommation de drogues et la santé des élèves de l'Ontario (SCDSEO) de 2009 indique que 5,4 % des élèves de l'Ontario des classes scolaires 7 à 12 ont déclaré avoir déjà consommé de la *S. divinorum* et que 4,4 % de ces élèves ont indiqué avoir consommé cette substance au cours de la dernière année. ~~Étant donné ses effets inconnus, ainsi que sa similarité pharmacologique avec~~ d'autres substances comprises dans l'annexe III de la LRCIDAS, comme l'acide lysergique diéthylamide (LSD) et la psilocybine, Santé Canada craint que la disponibilité immédiate et la consommation de *S. divinorum* ne posent un risque pour la santé et la sécurité des Canadiens, en particulier pour celles des jeunes.

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avec un taux de consommation important (7,3%)

Puisque ses effets psychotrope sont

l'Organisation des Nations Unies

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Cathy A. Sabiston  
Directrice générale  
Direction des substances contrôlées et de la lutte au tabagisme

Date \_\_\_\_\_

## DEPARTMENT OF HEALTH

### CONTROLLED DRUGS AND SUBSTANCES ACT

#### *Notice to interested parties - Proposal regarding the addition of Salvia divinorum and salvinorin A to Schedule III to the Controlled Drugs and Substances Act*

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Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. *S. divinorum* is widely touted as a "legal" hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs.<sup>1</sup> Results from the *Canadian Alcohol and Drug Use Monitoring Survey* (CADUMS) reveal that, in 2009, 1.6% of Canadians aged 15 years and older reported having used *S. divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24 years. The results from the Canadian 2008-2009 *Youth Smoking Survey* also show that 5% of 15 year olds have used *S. divinorum* in the past year. Moreover, the 2009 *Ontario Student Drug Use and Health Survey* (OSDUHS) indicated that 5.4% of Ontario students in grades 7-12 reported ever using *S. divinorum* and 4.4% of these students reported using this substance in the past year. Because its psychoactive effects resemble those of other substances included in Schedule III to the CDSA such as lysergic acid diethylamide (LSD) and

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<sup>1</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.

Including these substances within Schedule III to the CDSA would prohibit: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation). The regulation of *S. divinorum* and salvinorin A under the CDSA will also enable law enforcement agencies to take action against suspected illegal activities involving these substances.

As this action is not intended to interfere with the use and availability of *S. divinorum* and/or salvinorin A for legitimate medical, scientific or industrial purposes, Health Canada is seeking information from stakeholders on whether there are any such uses in Canada. Information received in response to this notice will be instrumental in determining appropriate regulation under the CDSA.

The publication of this notice begins a 30-day comment period. There will be additional opportunities to provide comments as the federal regulatory process progresses.

If you are interested in this process or have comments on this proposal, please contact Stephanie Chandler, Regulatory Policy Division, Office of Controlled Substances, Address Locator: 3503D, 123 Slater St., Ottawa, Ontario, Canada, K1A 1B9, by fax at (613) 946-4224 or by email at [OCS\\_Policy\\_and\\_Regulatory\\_Affairs@hc-sc.gc.ca](mailto:OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca).

Cathy A. Sabiston  
Director General  
Controlled Substances and Tobacco Directorate

Date \_\_\_\_\_



Madame, Monsieur,

Le présent courriel a pour but de vous informer qu'un *Avis d'intention aux parties intéressées* concernant les substances ci-dessous a été publié dans la Partie I de la *Gazette du Canada*, le 29 janvier 2011:

- *Salvia divinorum* (sauge des devins)
- Salvinorine A

La version électronique de l'Avis d'intention est disponible à l'adresse Internet [www.gazette.gc.ca](http://www.gazette.gc.ca), pages xx-xx, en format PDF (pages xxxx-xxxx dans la Partie I de la *Gazette du Canada*).

Cet avis d'intention décrit la proposition de Santé Canada qui consiste à inclure la *Salvia divinorum* (sauge des devins) et la salvinorine A dans l'annexe III de la *Loi réglementant certaines drogues et autres substances*. Santé Canada cherche précisément à obtenir plus d'information de la part des intervenants afin de déterminer si ces substances ont une utilité légitime sur les plans industriel, scientifique ou médical au Canada. Les renseignements qui seront obtenus permettront de prendre des mesures réglementaires appropriées.

Si vous désirez participer à ce processus ou tout simplement nous fournir de l'information, veuillez communiquer avec nous d'ici le 28 février 2011. Vous pouvez envoyer vos commentaires par la poste à Stephanie Chandler, Division de la politique réglementaire, Bureau des substances contrôlées, indice de l'adresse : 3503D, 123 rue Slater, Ottawa, Ontario, Canada K1A 1B9, par télécopieur, au 613-946-4224, ou par courriel à [OCS\\_Policy\\_and\\_Regulatory\\_Affairs@hc-sc.gc.ca](mailto:OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca).

**VEUILLEZ TRANSFÉRER LE PRÉSENT COURRIEL AUX PERSONNES QUI POURRAIENT ÊTRE INTÉRESSÉES.**

Si vous avez reçu cet avis par erreur, nous vous saurions gré de le transférer à la personne concernée de votre organisation et de lui demander de nous en informer par courriel à : [OCS\\_Policy\\_and\\_Regulatory\\_Affairs@hc-sc.gc.ca](mailto:OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca).

Division de la politique réglementaire  
Bureau des substances contrôlées  
Direction de la stratégie antidrogue et des substances contrôlées  
Direction générale de la santé environnementale et de la sécurité des consommateurs

Dear Sir/Madam:

The purpose of this email is to advise you that a *Notice of Intent to Interested Parties* (NOI) regarding the following substances was published in the *Canada Gazette*, Part I (CGI) on January 29, 2011:

- *Salvia divinorum*
- Salvinorin A

The electronic version of the NOI is available at the following website:

<http://canadagazette.gc.ca/> pages xx-xx in PDF format (pages xxxx-xxxx in *Canada Gazette*, Part I). CGI

This NOI outlines Health Canada's proposal to include *Salvia divinorum* and salvinorin A in Schedule III to the *Controlled Drugs and Substances Act* (CDSA). In particular, Health Canada is seeking further information from stakeholders as to whether these substances have any legitimate industrial, scientific or medical uses in Canada. Information received in response to this notice will be instrumental in determining appropriate regulatory controls.

If you are interested in this process or wish to provide us with information for our consideration please do so by February 28, 2011. You may send your comments to Stephanie Chandler, Regulatory Policy Division, Office of Controlled Substances, Address Locator: 3503D, 123 Slater St., Ottawa, Ontario, Canada K1A 1B9, by fax at (613) 946-4224 or by email to [OCS\\_Policy\\_and\\_Regulatory\\_Affairs@hc-sc.gc.ca](mailto:OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca).

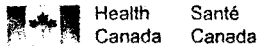
PLEASE FORWARD THIS EMAIL TO OTHERS WHO MAY BE INTERESTED.

Should this notification have reached you in error, it would be appreciated if you could please forward it to the appropriate person in your organization and ask that person to inform us of this by sending an e-mail to: [OCS\\_Policy\\_and\\_Regulatory\\_Affairs@hc-sc.gc.ca](mailto:OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca).

Thank you,

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Office of Controlled Substances  
Drug Strategy and Controlled Substances Directorate  
Healthy Environments and Consumer Safety Branch



HECS, CSTD Office of Controlled Substances

DGSESC, DSCLT, Bureau des substances co

Jocelyn Kula

Acting Director, Office of Controlled Substances  
Directrice intérimaire, Bureau des substances contrôlées

3rd Floor, Room D387  
123 Slater Street  
Address Locator: 3503D

3e étage, bureau D387  
123 rue Slater  
Indice de l'adresse: 3503D

Telephone: (613) 952-2177  
Facsimile: (613) 946-4224

Téléphone: (613) 952-2177  
Télécopieur: (613) 946-4224

FOR SIGNATURE

Name / Nom	Date	Initials
Cathy A. Sabiston, CSTD DGO	Jan 27/11	

Remarks / Remarques

Cathy,

Suzanne has reviewed carefully and suggested a few changes.

We have amended accordingly.

Other common products (media lines, 17H etc) to come via Comms.

DEPARTMENT OF HEALTH

CONTROLLED DRUGS AND SUBSTANCES ACT

*Notice to interested parties - Proposal regarding the addition of Salvia divinorum and salvinorin A to Schedule III to the Controlled Drugs and Substances Act*

This notice provides interested stakeholders with the opportunity to provide comments on Health Canada's proposal to add the plant *Salvia divinorum* (*S. divinorum*) and its main active ingredient salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA). Stakeholders may also identify themselves for inclusion in any future consultation.

*S. divinorum* is a species of sage belonging to the mint family. Its leaves are generally chewed or smoked to obtain psychotropic effects. While uncertainty remains surrounding the health risks of *S. divinorum*, known effects are reported to be short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant. Neither *S. divinorum* nor salvinorin A are currently included in any of the Schedules to the CDSA.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. *S. divinorum* is widely touted as a "legal" hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs.<sup>1</sup> Results from the *Canadian Alcohol and Drug Use Monitoring Survey* (CADUMS) reveal that, in 2009, 1.6% of Canadians aged 15 years and older reported having used *S. divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24 years. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *S. divinorum* in the past year. Moreover, the *2009 Ontario Student Drug Use and Health Survey* (OSDUHS) indicated that 5.4% of Ontario students in grades 7-12 reported ever using *S. divinorum* and 4.4% of these students reported using this substance in the past year. Because its psychoactive effects resemble those of other substances included in Schedule III to the CDSA such as lysergic acid diethylamide (LSD) and

While *S. divinorum* and salvinorin A are not currently included in any of the United Nations Drug Control Conventions, a number of countries have chosen to regulate one or both as controlled substances. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden have all placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. Some American states have also implemented laws restricting their use, sale and/or distribution.

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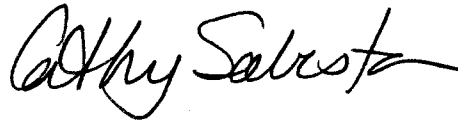
<sup>1</sup>Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.

Including these substances within Schedule III to the CDSA would prohibit: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation). The regulation of *S. divinorum* and salvinorin A under the CDSA will also enable law enforcement agencies to take action against suspected illegal activities involving these substances.

As this action is not intended to interfere with the use and availability of *S. divinorum* and/or salvinorin A for legitimate medical, scientific or industrial purposes, Health Canada is seeking information from stakeholders on whether there are any such uses in Canada. Information received in response to this notice will be instrumental in determining appropriate regulation under the CDSA.

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Cathy A. Sabiston  
Director General  
Controlled Substances and Tobacco Directorate

Date Jan 28/11

## MINISTÈRE DE LA SANTÉ

### LOI RÉGLEMENTANT CERTAINES DROGUES ET AUTRES SUBSTANCES

#### *Avis aux parties intéressées - Proposition concernant l'ajout de Salvia divinorum et de la salvinorine A à l'annexe III de la Loi réglementant certaines drogues et autres substances*

Cet avis informe les parties intéressées de la possibilité de commenter la proposition de Santé Canada d'ajouter la plante *Salvia divinorum* (*S. divinorum*) et son principal ingrédient actif, la salvinorine A, à l'annexe III de la *Loi réglementant certaines drogues et autres substances* (LRCDas). Les parties intéressées ont aussi l'occasion d'ajouter leur nom pour toute consultation future.

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élèves de l'Ontario (SCDSEO) de 2009 indique que 5,4 % des élèves de l'Ontario des classes scolaires 7 à 12 ont déclaré avoir déjà consommé de la *S. divinorum* et que 4,4 % de ces élèves ont indiqué avoir consommé cette substance au cours de la dernière année. Puisque ses effets psychoactifs ressemblent à ceux d'autres substances comprises dans l'annexe III de la LRCDas, comme l'acide lysergique diéthylamide (LSD) et la psilocybine, Santé Canada craint que la disponibilité immédiate et la consommation de *S. divinorum* ne posent un risque pour la santé et la sécurité des Canadiens, en particulier pour celles des jeunes.

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Le fait d'ajouter ces substances à l'annexe III de la LRCDas en interdirait la possession, le commerce, la possession aux fins de commerce, l'importation, l'exportation, la possession aux fins d'exportation et la production (ou la culture). La réglementation de la *S. divinorum* et de la salvinorine A conformément à la LRCDas permettrait également aux organismes d'application de la loi de prendre des mesures contre les activités illicites présumées liées à ces substances.

Étant donné que cette mesure ne vise pas à interférer avec l'utilisation et la disponibilité de la *S. divinorum* et/ou de la salvinorine A à des fins médicales, scientifiques ou industrielles légitimes, Santé Canada sollicite de l'information aux parties intéressées sur les possibilités de ces types d'utilisation au Canada. L'information reçue en réponse à cet avis sera déterminante dans la rédaction d'un règlement approprié conformément à la LRCDas.

La publication de cet avis entame une période de commentaires de 30 jours. Il y aura des occasions supplémentaires de fournir des commentaires au fur et à mesure que progresse le processus de réglementation fédéral.

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Directrice générale  
Direction des substances contrôlées et de la lutte au  
tabagisme

Date Jan 28/11

DEPARTMENT OF HEALTH

CONTROLLED DRUGS AND SUBSTANCES ACT

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a risk to the health and safety of Canadians, particularly youth.

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Cathy A. Sabiston  
Director General  
Controlled Substances and Tobacco Directorate

Date

Jan 28/11

## MINISTÈRE DE LA SANTÉ

### LOI RÉGLEMENTANT CERTAINES DROGUES ET AUTRES SUBSTANCES

*Avis aux parties intéressées - Proposition concernant l'ajout de Salvia divinorum et de la salvinorine A à l'annexe III de la Loi réglementant certaines drogues et autres substances*

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Cathy A. Sabiston  
Directrice générale  
Direction des substances contrôlées et de la lutte au  
tabagisme

Date, 11/11/2000

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#### *Avis aux parties intéressées - Proposition concernant l'ajout de Salvia divinorum et de la salvinorine A à l'annexe III de la Loi réglementant certaines drogues et autres substances*

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L'ajout  
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Date \_\_\_\_\_

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<sup>1</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.

Including these substances within Schedule III to the CDSA would prohibit: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the pose of exportation, and production (or cultivation). The scheduling of *S. divinorum* and vinorin A under the CDSA will also enable law enforcement agencies to take action against suspected illegal activities involving these substances.

As this action is not intended to interfere with the use and availability of *S. divinorum* and/or salvinorin A for legitimate medical, scientific or industrial purposes, Health Canada is seeking information from stakeholders on whether there are any such uses in Canada. Information received in response to this notice will be instrumental in determining appropriate regulation under the CDSA.


The publication of this notice begins a 30-day comment period. There will be additional opportunities to provide comments as the federal regulatory process progresses.

If you are interested in this process or have comments on this proposal, please contact Stephanie Chandler, Regulatory Policy Division, Office of Controlled Substances, Address Locator: 3503D, 123 Slater St., Ottawa, Ontario, Canada, K1A 1B9, by fax at (613) 946-4224 or by email at [OCS.Policy.and.Regulatory.Affairs@hc-sc.gc.ca](mailto:OCS.Policy.and.Regulatory.Affairs@hc-sc.gc.ca).

Cathy A. Sabiston  
Director General  
Controlled Substances and Tobacco Directorate

Date \_\_\_\_\_



**Re: Salvia NOI tracked changes**   
Stephanie Szick to: Stephanie Chandler

2011-01-28 11:28 AM

Thank you. Will bring to her attention.

Stephanie Chandler Hi Stephanie, As requested, these are all of th...

2011-01-28 11:17:19 AM

From: Stephanie Chandler/HC-SC/GC/CA  
To: Stephanie Szick/HC-SC/GC/CA@HWC  
Date: 2011-01-28 11:17 AM  
Subject: Salvia NOI tracked changes

Hi Stephanie,

As requested, these are all of the changes that were suggested by Suzanne.

[attachment "DRAFT Salvia NOI\_Jan 21 (tracked).wpd" deleted by Stephanie Szick/HC-SC/GC/CA]

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca





**Salvia**

Stephanie Szick to: Denis Arsenault, Stephanie Chandler  
Cc: Paula Robert

2011-01-28 01:02 PM

hello both,

Good news - Cathy has signed all four copies of the NOI.

Paula will be audit trailing the docket back to OCS.

I will send to Jesse in ADMO, a PDF of the signed NOI and the routing slip - will keep you posted on any feedback she gets from snr. management on this - i.e. proceeding with the NOI for Feb. 12.

Thanks again for all your quick work on this yesterday and today.

Stephanie Szick  
Director General's Office / Bureau du directeur général  
Controlled Substances & Tobacco Directorate (CSTD) /  
Direction des substances contrôlées et de la lutte au tabagisme (DSCLT)  
Health Canada / Santé Canada  
Tel / Tél: (613) 948-8651



**Fw: Salvia news release - new date**

Jocelyn Kula to: Denis Arsenault, Stephanie Chandler

2011-01-30 09:50 PM

FYI, and for adjustments to reg prioritization plan, 3 month table, etc.

JK

---

Jocelyn Kula

Acting Director/ Directrice par intérim

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs

Health Canada/ Santé Canada

Tel: (613) 952-2177 Fax: (613) 946-4224

---- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2011-01-30 09:49 PM ----

From: Cathy A Sabiston/HC-SC/GC/CA  
To: Dave Stephens/HC-SC/GC/CA@HWC, Jesse Arnup-Blondin/HC-SC/GC/CA@HWC, Jocelyn  
Kula/HC-SC/GC/CA@HWC, Stephanie Szick/HC-SC/GC/CA@HWC  
Cc: Christine Roush/HC-SC/GC/CA@HWC, Brenda Paine/HC-SC/GC/CA@HWC  
Date: 2011-01-28 06:09 PM  
Subject: Re: Salvia news release - new date

---

Jocelyne. We shld adjust noi accrdly svp  
Dave Stephens

----- Original Message -----

**From:** Dave Stephens  
**Sent:** 2011-01-28 05:54 PM EST  
**To:** Cathy A Sabiston; Jesse Arnup-Blondin  
**Cc:** Christine Roush; Nicole Prentice; Joyce Bradley  
**Subject:** Fw: Salvia news release - new date

Fyi.

Comms calendar should be updated accordingly.

Alexis M Tervo

----- Original Message -----

**From:** Alexis M Tervo  
**Sent:** 2011-01-28 05:17 PM EST  
**To:** Dave Stephens; Ken Polk; Charles Mojsej  
**Subject:** Salvia news release - new date

FYI - MO just requested that we push the TBD date for the Salvia news release to February 17th please.  
This date is still tentative



**Re: Fw: Salvia news release - new date**

Jocelyn Kula to: Dave Stephens

2011-01-31 01:35 PM

Cc: "Cathy Sabiston", "Christine Roush", Jesse Arnup-Blondin, "Nicole Prentice", Denis Arsenault, stephanie.chandler

Thanks Dave,

Denis/ Stephanie C- pls note

Jocelyn

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

---

Dave Stephens      Confirmed now.      ----- Original Message -----      2011-01-31 01:10:32 PM

From: Dave Stephens/HC-SC/GC/CA  
To: "Jocelyn Kula" <jocelyn.kula@hc-sc.gc.ca>, "Cathy Sabiston" <cathy.a.sabiston@hc-sc.gc.ca>, Jesse Arnup-Blondin/HC-SC/GC/CA@HWC  
Cc: "Christine Roush" <christine.roush@hc-sc.gc.ca>, "Nicole Prentice" <nicole.prentice@hc-sc.gc.ca>  
Date: 2011-01-31 01:10 PM  
Subject: Fw: Salvia news release - new date

---

Confirmed now.  
Alexis M Tervo

----- Original Message -----

**From:** Alexis M Tervo  
**Sent:** 2011-01-31 01:08 PM EST  
**To:** Dave Stephens  
**Cc:** Ken Polk  
**Subject:** Re: Salvia news release - new date

Hi Dave, MO just confirmed Feb. 17th as the date for the news release and Feb. 19th in the Gazette.  
Thanks!

Alexis Tervo  
Communications Advisor  
Public Affairs, Communications and Consultation  
Health Canada  
Ph: (613) 286-5487

---

Dave Stephens      that would be the plan.      Program would need to...      2011-01-31 12:32:49 PM

**Re: Salvia news release - new date**

Dave Stephens to: Alexis M Tervo

2011-01-31 12:32 PM

Cc: "Ken Polk"

that would be the plan. Program would need to know on Feb 11 to submit it for publication the following week. (electronic on the 18th, hard copy the 19th)

Dave Stephens  
Senior Communications Executive-Gestionnaire Principal des Communications HECSB/DGSCSE  
6th Floor, Room 6-033, 269 Laurier Ave. W., Ottawa, ON  
Tel: (613) 946-8107  
Cell: (613) 859-3581

---

Alexis M Tervo      Hi Dave, if we issued a news release on Feb 17t...      2011-01-31 12:31:03 PM

From:            Alexis M Tervo/HC-SC/GC/CA  
To:                "Dave Stephens" <dave.stephens@hc-sc.gc.ca>  
Cc:                "Ken Polk" <ken.polk@hc-sc.gc.ca>  
Date:             2011-01-31 12:31 PM  
Subject:          Re: Salvia news release - new date

---

Hi Dave, if we issued a news release on Feb 17th, would it be possible to have it in the gazette for Feb 19th?

Alexis Tervo  
Communications Advisor  
Public Affairs, Communications and Consultation  
Health Canada  
Ph: (613) 286-5487

---

Alexis M Tervo      FYI - MO just requested that we push the TBD d...      2011-01-28 05:17:34 PM

**Salvia news release - new date**

Alexis M Tervo to: Dave Stephens, Ken Polk, Charles Mojsej      2011-01-28 05:17 PM

---

FYI - MO just requested that we push the TBD date for the Salvia news release to February 17th please.  
This date is still tentative



**For approval: Salvia Announcement** 

Christine Roush to: Cathy A Sabiston

2011-02-02 01:11 PM

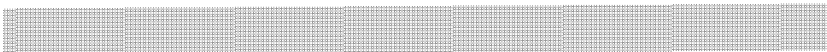
Cc: Stephanie Chandler, Denis Arsenault, Jocelyn Kula, Suzanne Desjardins, CSTD-DGO

History: This message has been forwarded.

Hi Cathy,

It's been a long (and windy) road, but finally we have the salvia products below for your approval. They have been signed off at the DG level in HPFB by the NHPD, the Inspectorate and Marketed Health Products. MO would like the NR issued on February 18th, so hopefully you'll be able to review and approve before your upcoming leave.

**s.19(1)**



Salvia NR MHPD Revisions 2011 02.02.doc



Salvia MLs\_Feb2\_(clean2) NHPD edit.doc



IYH Salvia divinatorum\_v23 Feb2(clean2).doc



DRAFT Salvia NOI\_Feb 2 EN.doc

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
Health Canada/Santé Canada  
Tel/Tél : (613) 954-0712/Cell: (613) 219-7194  
Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca

Jocelyn Kula

well phew re. the event! yes, I am looking at doc...

2011-01-27 10:31:21 AM

From: Jocelyn Kula/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Cc: Stephanie Chandler/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2011-01-27 10:31 AM  
Subject: Re: Salvia Announcement

well phew re. the event!  
yes, I am looking at docs right now

Jocelyn Kula

Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

Health Canada

2011-XX

# News Release

## **The Government of Canada Proposes to Regulate *Salvia Divinorum* and Salvinorin A as Controlled Substances**

**February 18, 2011**  
**For immediate release**

**OTTAWA** – Today, the Honourable Leona Aglukkaq, Minister of Health announced that the Government of Canada intends to regulate *Salvia divinorum* and salvinorin A, also known as Salvia, as controlled substances. A Notice to Interested Parties outlining Health Canada's proposal will be published in *Canada Gazette*, Part I, on February 19, 2011

“After reviewing Canadian surveillance data and scientific reports that suggest this substance has the potential for abuse, especially among young people, we are taking these steps to protect the health and safety of Canadians from the potentially harmful effects of this substance,” said Minister Aglukkaq. “The use of this substance is of concern to Health Canada as very little is known about its long-term effects on the brain and body,” added Aglukkaq.

The Notice to Interested Parties will propose that *Salvia divinorum* and salvinorin A be added to Schedule III to the *Controlled Drugs and Substances Act*. This means that activities such as possession, trafficking, importation, exportation, and production (or cultivation) will be illegal unless authorized by regulation. Regulating *Salvia divinorum* and salvinorin A as a controlled substance will also enable law enforcement agencies to take action against suspected illegal activities involving this substance.

Interested parties are encouraged to submit any comments regarding the Notice to Interested Parties by March 14, 2011.

-30-

**Media Enquiries:**  
Health Canada  
(613) 957-2983

*Également disponible en français*

Jenny Van Alstyne  
Office of the Honourable Leona Aglukkaq  
Federal Minister of Health  
(613) 957-0200

**Public Enquiries:**  
(613) 957-2991  
1-866 225-0709

Health Canada news releases are available on the Internet at  
[www.healthcanada.gc.ca/media](http://www.healthcanada.gc.ca/media)



**DRAFT**  
01/02/2011

**Media Lines**  
***Salvia divinorum***

**Issue**

There is ongoing media interest regarding the availability of *Salvia divinorum* in Canada as well as Canadian surveillance data suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has concluded that *Salvia divinorum* and its main active ingredient salvinorin A should be regulated under the *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth. A Notice to Interested Parties outlining Health Canada's proposal to regulate this substance will be published in *Canada Gazette*, Part I, on February 19, 2011

**Key Messages:**

- After reviewing available information and reports that suggest this substance has the potential for abuse, especially among young people, Health Canada is proposing to regulate both *Salvia divinorum* and its main active ingredient salvinorin A as controlled substances.
- The Government of Canada is taking these steps in order to protect the health and safety of Canadians, particularly youth, from their potentially harmful effects.
- Canadians should not use products containing *Salvia divinorum* and/or salvinorin A because they are hallucinogenic and little is known about the long-term effects of these substances on the brain and body.
- The inclusion of *Salvia divinorum* and salvinorin A in Schedule III to the CDSA will make possession, trafficking, importation, exportation, and production (or cultivation) illegal unless authorized by regulation.

**Supplementary Messages:**

- Though it is a hallucinogen, the plant *Salvia divinorum* is not currently regulated under the CDSA. At the present time, products containing *Salvia divinorum* that indicate its hallucinogenic properties would meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations*.
- To date, Health Canada has not authorized for sale any natural health products which contain *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products containing *Salvia divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act and its associated regulations*.



**DRAFT**  
01/02/2011

## **Questions and Answers:**

### **Q1 – What is involved in regulating *Salvia divinorum* as a controlled substance and what stage is it at?**

A1 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada recently concluded its assessment of *Salvia divinorum* and salvinorin A against the aforementioned factors and proposes to include both substances in Schedule III to the CDSA. The first step in the process of regulating a substance under the CDSA is the publication of a *Notice to Interested Parties* (NOI) in *Canada Gazette*, Part I. Any comments received will be considered during the preparation of a regulatory proposal. There will be additional opportunities for comment as the federal regulatory process progresses.

The regulation of these products will reduce the potential risks to the health and safety of Canadians associated with their ready availability, with their increased use and their unknown effects. The scheduling of *Salvia divinorum* and salvinorin A will also eliminate the current misconception that these substances are a safe alternative to other illegal drugs.

### **Q2 – Are *Salvia divinorum* and/or salvinorin A controlled internationally? How are these substances regulated in other countries?**

A2 - Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions; as a result, there is no requirement for them to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

The move to include *Salvia divinorum* and salvinorin A in Schedule III to the CDSA is consistent with actions taken by several countries (e.g., Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden) that have also

**DRAFT**  
01/02/2011

placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Some individual U.S. states have implemented laws restricting their use, sale and/or distribution.

**Q3 – Is there any research on the use of *Salvia divinorum* in Canada?**

A3 - Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *Salvia divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *Salvia divinorum* in the past year. The 2009 *Ontario Student Drug Use and Health Survey (OSDUHS)* indicated that 5.4% of Ontario students in grades 7-12 reported ever using *Salvia divinorum* and 4.4% of these students reported using this substance in the past year.

**Q4 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why is it not controlled under the Controlled Drugs and Substances Act?**

A4 – The move to regulate *Salvia divinorum* and salvinorin A as controlled substances is based on surveillance data from surveys such as the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)*, *Youth Smoking Survey (YSS)* and the *Ontario Student Drug Use and Health Survey (OSDUHS)*, some of which only became available in 2010.

In the interim, as *Salvia divinorum* is a plant with hallucinogenic properties, it currently meets the definition of a natural health product under the *Natural Health Products Regulations (NHPR)* when marketed as a hallucinogen. The sale of unauthorized natural health products may be subject to compliance and enforcement action in accordance with the *Food and Drugs Act* and its associated regulations.

**Q5 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A5 – Once *Salvia divinorum* and salvinorin A are included in Schedule III to the CDSA, law enforcement will be able to take appropriate action in response to suspected illegal activities with these substances.

Currently, however, *Salvia divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. For more information on how to submit a consumer complaint about the unauthorized sale of drugs containing *Salvia divinorum* and/or salvinorin A, visit: [www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_44\\_consumer\\_consommateur\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_44_consumer_consommateur_cp-pc-eng.php).

**DRAFT**

01/02/2011

**Q6 - Has Health Canada issued any kind of warning to Canadians about *Salvia divinorum*?**

A6 - Health Canada has developed an *It's Your Health* article about *Salvia divinorum* to help inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at: (link to come)

**Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

Data from the 2008-2009 Youth Smoking Survey indicates that:

- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;
- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year; and
- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using *Salvia* in their lifetime (0.2% in the past year); and
- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that:

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;
- 5.4% of students (grades 7-12) ever used *Salvia divinorum*; and
- use of *Salvia divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

**DRAFT**  
01/02/2011

**Prepared by:** Stephanie Chandler and Denis Arsenault, OCS, CSTD  
Reviewed and revised by: Christine Roush, Senior Communications  
Advisor, HECS, Communications

**Input by:** Lisa Mackay IYH/PACCB,  
Suzanne Desjardins HECSB/ODARS,  
Hanan Abramovici HECSB/ODARS,  
Bruna Brands HECSB/ODARS,  
Jocelyn Kula, HECSB/OCS,  
Robin Marles HPFB/NHPD,  
Maggie Graham HPFB/NHPD,  
Stephanie Collins HPFB/NHPD,  
Mano Murty HPFB/MHPD,  
Robert Leitch HPFB/MHPD,  
Shahid Perwaiz HPFB/MHPD,  
Collin Pinto, HPFB/HPFBI

**Approved by:**  
Robin Marles, Director, Bureau of Clinical Trials, NHPD (2011-01-20 and 2011-01-28)  
Jocelyn Kula, A/Director, OCS, CSTD, HECS (Jan 19, 2011 and Jan 27, 2011)  
Suzanne Desjardins, Director, ODARS, CSTD, HECS (Approved Jan 20, 2011)  
Cathy Sabiston, DG, CSTD, HECS (pending)  
Chris Turner, DG, MHPD (pending)  
Scott Sawler, DG, NHPD  
Diana Dowthwaite, DG, HPFBI  
Sharon Mullin, Director, Compliance and Enforcement Coordination, HPFB  
David Gotlieb, A/Communications Executive, HPFB (pending)  
Ken Polk, A/Director, Public Affairs, PACCB (pending)  
Charles Mojsej, DG, PACCB (pending)  
HECS Legal (pending)  
HPFB Legal (pending)  
Dave Stephens, Communications Executive, HECS (pending)  
Paul Glover, ADM, HECSB (pending)  
Meena Ballantyne, ADM, HPFB (pending)  
Anne Lamar, ADM, PACCB (pending)  
DMO (pending)  
MO (pending)  
PCO (pending)

## **Salvia divinorum**

### **Issue**

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff, incense special, and salvia.

Certain websites promote the use of *S. divinorum* as a "legal" alternative to street drugs. Recent Canadian surveillance data indicates that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. Scientific reports also suggest that it has the potential for abuse.

Canadians should not use products containing *S. divinorum* and/or salvinorin A because they are hallucinogenic and little is known about the long-term effects of these substances on the brain and body. There is also no way to predict how it will affect you with each use.

In light of this information, Health Canada is proposing to regulate both *S. divinorum* and its main active ingredient salvinorin A under Schedule III to the *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth.

### **Risks Associated with the Use of *Salvia divinorum***

*S. divinorum* is known to have both physical and mental effects. The effects of *S. divinorum*, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product
- how much is used
- the purity of the product (products that contain *S. divinorum* may be mixed with other substances)

- how it is taken, for example, whether the product is chewed, swallowed or smoked
- the user's mood and expectations

While scientists know which brain receptors are targeted by the active ingredient, salvinorin A, very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or if it can cause permanent damage
- how it interacts with other substances, including other drugs, natural health products and alcohol
- the potential of *S. divinorum* to produce physical dependence and/or addiction

### **Minimizing Your Risk**

Hallucinogens like *S. divinorum* work by modifying functions in the brain. Health Canada recommends that you avoid using *S. divinorum* because very little is known about the effects it may have on your body and/or brain functions. There is also no way to predict how it will affect you with each use. Just because a drug is plant-based or "natural", does not mean that it is safe.

Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs, such as marijuana, cocaine, ecstasy, LSD and other substances that distort reality. See the "***Need More Info?***" section below for links to resources that can help you with this.

### **Legal Status of *Salvia divinorum***

#### In Canada

As *S. divinorum* is a plant with hallucinogenic properties when consumed by humans, it currently meets the definition of a natural health product (NHP) under the *Natural Health Products Regulations* when marketed as a hallucinogen. As of February 2011, Health Canada has not authorized for sale any natural health products which contain *S. divinorum* as an ingredient. The sale of unauthorized natural health products containing *S. divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

While *S. divinorum* and salvinorin A are not currently regulated under the *Controlled Drugs and Substances Act* (CDSA), Health Canada is now developing a regulatory proposal that would add *S. divinorum* and salvinorin A to Schedule III to the CDSA.

#### In Other Countries

Several countries including but not limited to Australia, Belgium, Germany, Italy and Japan, have placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A.

In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on their sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution. In some states, for example, it is illegal for *S. divinorum* to be sold to anyone under the age of 18.

## Background

The leaves of this plant have been used traditionally by the Mazatec people for medicinal and mystical purposes.

Products that claim to contain *S. divinorum* or its main active ingredient, salvinorin A are widely available on the Internet and are sold in various "head shops" and natural food stores. The products are sold in a number of forms, including fresh or dried leaves, liquids or seeds and plant cuttings for growing purposes.

Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *S. divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *S. divinorum* in the past year. The 2009 *Ontario Student Drug Use and Health Survey (OSDUHS)* indicated that 5.4% of Ontario students in grades 7-12 reported ever using *S. divinorum* and 4.4% of these students reported using this substance in the past year. For more information on these surveys, see the *Need More Info* section below.

## Health Canada's Role

In light of the health and safety risks associated with the use of *S. divinorum* and particularly the risks to youth, Health Canada is taking steps to regulate *S. divinorum* and salvinorin A as controlled substances. As a first step in this process, Health Canada issued a *Notice to Interested Parties (NOI)* on February 19, 2011. In the interim, Health Canada will continue to monitor the sale of unauthorized health products that contain *S. divinorum* or its main active ingredient salvinorin A. It will take appropriate action should it become aware of any unauthorized health products that may pose a risk to Canadians.

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## Need More Info?

- For information on how to submit a consumer or trade complaint about the unauthorized sale of health products containing *S. divinorum* please consult the following documents:

Consumers: [http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_44\\_consumer\\_consommateur\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_44_consumer_consommateur_cp-pc-eng.php)

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Field Code Changed

Trade: [http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_38\\_trade-industrie\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_38_trade-industrie_cp-pc-eng.php) Or contact the **Health Products and Food Branch Inspectorate** directly call toll-free 1-800-267-9675.

- You can report any adverse reactions to the Canada Vigilance Program by one of the following three ways:

Report online at the **MedEffect™** Canada website at: <http://www.hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>

Call toll-free at 1-866-234-2345

Complete a **Canada Vigilance Reporting Form** and either:

Fax toll-free to 1-866-678-6789

Mail to: Canada Vigilance Program

Health Canada

AL 0701C

Ottawa, ON K1A 0K9

To have postage pre-paid, download the postage paid label from the **MedEffect™ Canada website**. The **Canada Vigilance Reporting Form** and the adverse reaction reporting guidelines may also be obtained via this website at : [http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei\\_form-eng.php](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei_form-eng.php)

- For information about the Government of Canada's **National Anti-Drug Strategy**, go to: [www.nationalantidrugstrategy.gc.ca/](http://www.nationalantidrugstrategy.gc.ca/)

The Prevention section on this site has a number of helpful resources for parents, including:

- **Tips on Talking to Your Teenager**, at: [www.hc-sc.gc.ca/hc-ps/pubs/adp-adp/talk-aborder/index-eng.php](http://www.hc-sc.gc.ca/hc-ps/pubs/adp-adp/talk-aborder/index-eng.php)
- **What to Do if Your Teen is Using Drugs**, at: [www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html](http://www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html)
- Health Canada's **Not4Me** youth drug prevention section at: <http://www.hc-sc.gc.ca/hc-ps/drugs-drogues/youth-jeunes/facts-faits/index-eng.php>

- Information on natural health products and the **Natural Health Products Regulations** can be found at: [www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php)

For more on the surveys that have collected information about *Salvia divinorum* use in Canada, see:

- **The 2008-2009 Youth Smoking Survey**, at: <http://www.yss.uwaterloo.ca/index.cfm?section=5&page=288>
- **The 2009 Canadian Alcohol and Drug Use Monitoring Survey**, at: <http://www.hc-sc.gc.ca/hc-ps/drugs-drogues/stat/index-eng.php>
- **The 2009 Ontario Student Drug Use and Health Survey**, at: [http://www.camh.net/News\\_events/News\\_releases\\_and\\_media\\_advisories\\_and\\_b\\_ackgrounders/osduhs2009\\_advisory.html](http://www.camh.net/News_events/News_releases_and_media_advisories_and_b_ackgrounders/osduhs2009_advisory.html)

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<#>Complaints about the unauthorized sale of drugs containing *S. divinorum* can be made to the **Health Products and Food Branch Inspectorate** at: [http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_44\\_consumer\\_consommateur\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_44_consumer_consommateur_cp-pc-eng.php) ¶  
<#> Tel: 1-800-267-9675. ¶  
<#>¶



Additional Resources:

- U.S. Drug Enforcement Administration: **Drugs and Chemicals of Concern: *Salvia divinorum* and Salvinorin A** at:  
[www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)
- U.S. Department of Health & Human Services, **National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006** at:  
[www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf](http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf)
- For additional articles on health and safety issues go to the ***It's Your Health*** web section at: [www.healthcanada.gc.ca/iyh](http://www.healthcanada.gc.ca/iyh)

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

Original:

©Her Majesty the Queen in Right of Canada, represented by the Minister of Health, 2010

Catalogue#

ISBN#

Version/date: Draft 17. September 8, 2010.

PACCB IYH - Lisa Mackay: 613-954-0105 – [Lisa.Mackay@hc-sc.gc.ca](mailto:Lisa.Mackay@hc-sc.gc.ca)

Comments from: HECSB - CSTD (OCS&ODARS) & HPFB – NHPD, MHPD & HPFBI

Contacts: HECSB: Jocelyn Kula, Stephanie Chandler, Suzanne Desjardin, Denis Arsenault, Hanan Abramovici, Bruna Brands  
HECSB comms: Christine Roush, Bronwyn Cline  
HPFB-NHPD: Valerie Hurry, Robin Marles, Maggie Graham, Stephanie Collins  
HPFB-MHPD: Scott Jordan, Robert Leitch, Mano Murty, Shahid Perwaiz  
HPFBI : Collin Pinto  
HPFB comms: Elizabeth Keeping, Blossom Leung

DEPARTMENT OF HEALTH

CONTROLLED DRUGS AND SUBSTANCES ACT

*Notice to interested parties - Proposal regarding the addition of Salvia divinorum and salvinorin A to Schedule III to the Controlled Drugs and Substances Act*

This notice provides interested stakeholders with the opportunity to provide comments on Health Canada's proposal to add the plant *Salvia divinorum* (*S. divinorum*) and its main active ingredient salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA). Stakeholders may also identify themselves for inclusion in any future consultation.

*S. divinorum* is a species of sage belonging to the mint family. Its leaves are generally chewed or smoked to obtain psychotropic effects. While uncertainty remains surrounding the health risks of *S. divinorum*, known effects are reported to be short and long-term in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant. Neither *S. divinorum* nor salvinorin A are currently included in any of the Schedules to the CDSA.

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Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. *S. divinorum* is widely touted as a "legal" hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs.<sup>1</sup> Results from the *Canadian Alcohol and Drug Use Monitoring Survey* (CADUMS) reveal that, in 2009, 1.6% of Canadians aged 15 years and older reported having used *S. divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24 years. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *S. divinorum* in the past year. Moreover, the 2009 *Ontario Student Drug Use and Health Survey* (OSDUHS) indicated that 5.4% of Ontario students in grades 7-12 reported ever using *S. divinorum* and 4.4% of these students reported using this substance in the past year. Because its psychoactive effects resemble those of other substances included in Schedule III to the CDSA such as lysergic acid diethylamide (LSD) and psilocybin, Health Canada is concerned that the ready availability and use of *S. divinorum* poses a risk to the health and safety of Canadians, particularly youth.

While *S. divinorum* and salvinorin A are not currently included in any of the United Nations Drug Control Conventions, a number of countries have chosen to regulate one or both as controlled substances. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden have all placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. Some American states have also implemented laws restricting their use, sale and/or distribution.

<sup>1</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.

Including these substances within Schedule III to the CDSA would prohibit: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation). The regulation of *S. divinorum* and salvinorin A under the CDSA will also enable law enforcement agencies to take action against suspected illegal activities involving these substances.

As this action is not intended to interfere with the use and availability of *S. divinorum* and/or salvinorin A for legitimate medical, scientific or industrial purposes, Health Canada is seeking information from stakeholders on whether there are any such uses in Canada. Information received in response to this notice will be instrumental in determining appropriate regulation under the CDSA.


The publication of this notice begins a 30-day comment period. There will be additional opportunities to provide comments as the federal regulatory process progresses.

If you are interested in this process or have comments on this proposal, please contact Stephanie Chandler, Regulatory Policy Division, Office of Controlled Substances, Address Locator: 3503D, 123 Slater St., Ottawa, Ontario, Canada, K1A 1B9, by fax at (613) 946-4224 or by email at [OCS\\_Policy\\_and\\_Regulatory\\_Affairs@hc-sc.gc.ca](mailto:OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca).

Cathy A. Sabiston  
Director General  
Controlled Substances and Tobacco Directorate

Date \_\_\_\_\_



**Re: Fw: Update - Events in February**   
Denis Arsenault to: Jocelyn Kula  
Bcc: Stephanie Chandler

2011-02-02 10:48 AM

---

History: This message has been replied to.

---

Hi Jocelyn,

For the PRAD email account, while the old format with the underscores still seems to function, the address also functions with the underscores replaced by periods. For the sake of consistency, we will use the period format.

We will explore asap whether there are any associations for natural food stores or alternative lifestyle shops that could be added to the list of stakeholders.

Denis

---

Denis Arsenault, A/Manager / Gestionnaire p.i.  
Regulatory Policy Division /  
Division des politiques réglementaires,  
Office of Controlled Substances /  
Bureau des substances contrôlées,  
Health Canada / Santé Canada  
Tel/Tél: (613) 957-6828  
Fax / Télécopieur : (613) 946-4224  
E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca

---

Jocelyn Kula two comments: do we not need to update the P... 2011-02-02 10:19:51 AM

From: Jocelyn Kula/HC-SC/GC/CA  
To: Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2011-02-02 10:19 AM  
Subject: Re: Fw: Update - Events in February

---

two comments:

do we not need to update the PRAD email address to have "."s in it rather than "\_"s in it?

for the list of stakeholders, what about looking for an association of natural health food stores (I doubt there is an association for head shops), or an association for alternative life style stores.....just that retailers are who are most likely to be impacted....

JK

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

---

Denis Arsenault Hi Jocelyn, As requested. 2011-02-01 02:49:54 PM

From: Denis Arsenault/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Date: 2011-02-01 02:49 PM  
Subject: Re: Fw: Update - Events in February

---

Hi Jocelyn,

As requested.

[attachment "Stakeholder notification of NOI Jan 28 2011 EN.wpd" deleted by Denis Arsenault/HC-SC/GC/CA] [attachment "List of Salvia Stakeholders v.2.doc" deleted by Denis Arsenault/HC-SC/GC/CA]

Denis

---

Denis Arsenault, A/Manager / Gestionnaire p.i.  
Regulatory Policy Division /  
Division des politiques réglementaires,  
Office of Controlled Substances /  
Bureau des substances contrôlées,  
Health Canada / Santé Canada  
Tel/Tél: (613) 957-6828  
Fax / Télécopieur : (613) 946-4224  
E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca

---

Jocelyn Kula                      great. can I please see email text and list of stak...                      2011-02-01 02:20:33 PM

From: Jocelyn Kula/HC-SC/GC/CA  
To: Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2011-02-01 02:20 PM  
Subject: Re: Fw: Update - Events in February

---

great. can I please see email text and list of stakeholders it is going to....

JK

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

---

Denis Arsenault                      Hi Jocelyn, For publication on February 19, we...                      2011-02-01 02:11:13 PM

From: Denis Arsenault/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2011-02-01 02:11 PM  
Subject: Re: Fw: Update - Events in February

---

Hi Jocelyn,

For publication on February 19, we need to have the package delivered to *Canada Gazette* by noon on

Friday, February 11. While the copies of the NOI that Cathy signed are dated January 28, these probably don't need to be re-signed (to be confirmed with Stephanie) as it is the covering letter to *Canada Gazette* that indicates the date on which we want the NOI published.

Unlike the NOI, the covering letter would be signed by yourself and can thus be easily amended here in OCS to reflect the new target date of February 19.

As for the list of stakeholders, Stephanie submitted to me a final list of stakeholders which I approved with a few minor modifications. The actual message we would send up is approved and ready to go.

I will work with Carmen to set-up a bilat.

Denis

Denis Arsenault, A/Manager / Gestionnaire p.i.  
Regulatory Policy Division /  
Division des politiques réglementaires,  
Office of Controlled Substances /  
Bureau des substances contrôlées,  
Health Canada / Santé Canada  
Tel/Tél: (613) 957-6828  
Fax / Télécopieur : (613) 946-4224  
E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca

Jocelyn Kula                      so when do we have to have our package with t...                      2011-02-01 10:07:43 AM

From:                      Jocelyn Kula/HC-SC/GC/CA  
To:                          Denis Arsenault/HC-SC/GC/CA@HWC  
Date:                        2011-02-01 10:07 AM  
Subject:                    Fw: Update - Events in February

so when do we have to have our package with the CG office by for publication on Feb 19.  
also: 1) do we need to get Cathy to resign the hard copies (I didn't think they were dated but pls advise)  
2) how are things going with list of stakeholders to send message out to re NOI?

It seems that we have not had a bilat in ages so perhaps you should check with Carmen re arranging one?

JK

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224  
----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2011-02-01 10:05 AM -----

From:                      Stephanie Szick/HC-SC/GC/CA  
To:                          Jocelyn Kula/HC-SC/GC/CA@HWC  
Date:                        2011-02-01 10:03 AM  
Subject:                    Fw: Update - Events in February

fyi Jocelyn

note re: Salvia, Feb. 17 for news release  
date for mm still TBC

----- Forwarded by Stephanie Szick/HC-SC/GC/CA on 2011-02-01 10:02 AM -----

From: Dave Stephens/HC-SC/GC/CA  
To: paul.spendlove@hc-sc.gc.ca, christine.roush@hc-sc.gc.ca, Jesse  
Arnup-Blondin/HC-SC/GC/CA@HWC, Cathy A Sabiston/HC-SC/GC/CA@HWC, Louis  
Proulx/HC-SC/GC/CA@HWC, Jeannine Ritchot/HC-SC/GC/CA@HWC, Louise  
Bertrand/HC-SC/GC/CA@HWC, Stephanie Szick/HC-SC/GC/CA@HWC,  
heidi.jackson@hc-sc.gc.ca  
Date: 2011-02-01 10:01 AM  
Subject: Fw: Update - Events in February

---

Announcements of HWM's (CG1) and Medical Marihuana are still in the TBC category.

Dave Stephens  
Senior Communications Executive-Gestionnaire Principal des Communications HECSB/DGSCSE  
6th Floor, Room 6-033, 269 Laurier Ave. W., Ottawa, ON  
Tel: (613) 946-8107  
Cell: (613) 859-3581

----- Forwarded by Dave Stephens/HC-SC/GC/CA on 2011-02-01 10:00 AM -----

From: Alexis M Tervo/HC-SC/GC/CA  
To: Charles Mojsej/HC-SC/GC/CA@HWC, Warren Braun/HC-SC/GC/CA@HWC, Tom  
Kelly/HC-SC/GC/CA@HWC, Rick Mofina/HC-SC/GC/CA@HWC, Ken Polk/HC-SC/GC/CA@HWC,  
David Gottlieb/HC-SC/GC/CA@HWC, Jennifer Peddle/HC-SC/GC/CA@HWC, Rob  
Furlong/HC-SC/GC/CA@HWC, Debbie Paine/HC-SC/GC/CA@HWC, Dave  
Stephens/HC-SC/GC/CA@HWC, Alastair Sinclair/HC-SC/GC/CA@HWC, Adam  
Blondin/HC-SC/GC/CA@HWC  
Cc: Olivia Caron/HC-SC/GC/CA@HWC, Blossom Leung/HC-SC/GC/CA@HWC, Joyce  
Bradley/HC-SC/GC/CA@HWC  
Date: 2011-02-01 09:59 AM  
Subject: Update - Events in February

---

Salvia - Thursday, Feb. 17 (news release)  
National residencies - Feb 8 or 10 (in Ottawa or Toronto)  
Arctic Minister's Meeting in Nuuk on Feb 16 - Minister is not attending (we may issue an HC release...MO  
would like to see a draft)

TBC  
Allergens - in February (but no date yet)  
Medical Marihuana  
Tobacco labelling

PHAC  
\$2.4 Million for the Qaujigiartitt Health Research Centre - Friday, Feb 4th in Iqaluit.  
Multiple Sclerosis - Monday, Feb 7th (news release only)  
Feb 15 - Childhood obesity

Alexis Tervo  
Communications Advisor  
Public Affairs, Communications and Consultation  
Health Canada  
Ph: (613) 286-5487



**Re: For approval: Salvia Announcement**

Christine Roush to: Cathy A Sabiston

2011-02-03 11:53 AM

Cc: CSTD-DGO, Denis Arsenault, Jocelyn Kula, Stephanie Chandler, Stephanie Szick, Suzanne Desjardins

Cathy - I will check with my colleague in Ministerial Services who is responsible for these articles and let you know.

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
Health Canada/Santé Canada  
Tel/Tél : (613) 954-0712/Cell: (613) 219-7194  
Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca

Cathy A Sabiston      Agree to 3 of 4 pts. Still wondering how this iyh...      2011-02-03 11:49:45 AM

From: Cathy A Sabiston/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC, Stephanie Szick/HC-SC/GC/CA@HWC  
Cc: Christine Roush/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC, CSTD-DGO  
Date: 2011-02-03 11:49 AM  
Subject: Re: For approval: Salvia Announcement

Agree to 3 of 4 pts. Still wondering how this iyh compares to other iyh on citing where these illicit substances are available.

Jocelyn Kula

----- Original Message -----

**From:** Jocelyn Kula  
**Sent:** 2011-02-03 11:13 AM EST  
**To:** Stephanie Szick  
**Cc:** Christine Roush; Cathy A Sabiston; Stephanie Chandler; Denis Arsenault; Suzanne Desjardins; CSTD-DGO  
**Subject:** Re: For approval: Salvia Announcement

Re, use vs consume. This wording is consistent with other drug-related IYHs and the fact that generally speaking, people talk about using (or taking) a drug (medicinal or illicit), not consuming it. Allowing for the fact that language is supposed to be Grade 8, I vote for sticking with "use".

Re. citing where substances are sold, we are not providing any more information than what is already splashed all over the internet, and I don't see this as causing any more of a risk than doing a NR to say that we are moving to schedule but this will take time, i.e, it is still legal for a bit.....

Re. the weblink to the NOI, sending people to [www.canadagazette.gc.ca](http://www.canadagazette.gc.ca) is a minefield as the search engine on the site is very hard to use.....generally speaking, once we have the official link to the specific page from the Gazette office, we provide to comms for reference in their lines.

In the NR, not sure why we are now removing the reference to "also known as Salvia" when in fact, that is how 99% of the media reports and internet sites refer to it?



JK

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

---

Stephanie Szick      hi Christine, Please see attached -- some v. mi...      2011-02-03 11:02:02 AM

---

From:            Stephanie Szick/HC-SC/GC/CA  
To:              Christine Roush/HC-SC/GC/CA@HWC  
Cc:              Cathy A Sabiston/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC, CSTD-DGO  
Date:            2011-02-03 11:02 AM  
Subject:        Re: For approval: Salvia Announcement

---

hi Christine,

Please see attached -- some v. minor edits overall, with some questions on the media lines and the IYH article.

Please have a look and get back to us with revised/clean docs addressing these questions -- will review quickly on this end!

Please give me a call if any questions.

Thanks,

Stephanie Szick  
Director General's Office / Bureau du directeur général  
Controlled Substances & Tobacco Directorate (CSTD) /  
Direction des substances contrôlées et de la lutte au tabagisme (DSCLT)  
Health Canada / Santé Canada  
Tel / Tél: (613) 948-8651

[attachment "IYH Salvia divinorum\_v24\_CSTD-DG\_03-02-11.doc" deleted by Cathy A Sabiston/HC-SC/GC/CA]

[attachment "Salvia MLs\_CSTD-DG\_03-02-11.doc" deleted by Cathy A Sabiston/HC-SC/GC/CA]

[attachment "Salvia NR\_CSTD-DG\_03-02-11.doc" deleted by Cathy A Sabiston/HC-SC/GC/CA]

---

Christine Roush      Hi Cathy, It's been a long (and windy) road, but f...      2011-02-02 01:11:34 PM

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From:            Christine Roush/HC-SC/GC/CA  
To:              Cathy A Sabiston/HC-SC/GC/CA@HWC  
Cc:              Stephanie Chandler/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC, CSTD-DGO  
Date:            2011-02-02 01:11 PM  
Subject:        For approval: Salvia Announcement

---

Hi Cathy,

**Re: For approval: Salvia Announcement** 

Christine Roush to: Jocelyn Kula

2011-02-03 01:54 PM

Cc: Cathy A Sabiston, CSTD-DGO, Denis Arsenault, Stephanie Chandler, Stephanie Szick, Suzanne Desjardins

Hi Jocelyn - yes, I realize this is the case but was trying to keep my msg brief. Thanks for clarifying though - it does bear repeating a number of times for people to get their head around this. I trust you are oK with the rewrite of the sentence I provided below?

Jocelyn Kula

----- Original Message -----

**From:** Jocelyn Kula

**Sent:** 2011-02-03 01:26 PM EST

**To:** Christine Roush

**Cc:** Cathy A Sabiston; CSTD-DGO; Denis Arsenault; Stephanie Chandler; Stephanie Szick; Suzanne Desjardins

**Subject:** Re: For approval: Salvia Announcement

Christine,

Only to clarify that your statement about where salvia can be sold is not quite right. It is not illegal under the FDA to sell salvia in head shops or natural health stores because there are no approved products, it is illegal to sell in those establishments when it is specifically sold as a hallucinogen, which is when the definition of an NHP comes into play, and the requirement for authorization under the FDA kicks in. Technically, someone selling salvia as a herbal incense product in a natural health store would not be doing anything illegal.

It has taken us all a long time to get our heads around this I know.....

JK

---

Jocelyn Kula

Acting Director/ Directrice par intérim

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs

Health Canada/ Santé Canada

Tel: (613) 952-2177 Fax: (613) 946-4224

---

Christine Roush

Cathy, IYH doesn't have a lot of articles on cont...

2011-02-03 12:47:21 PM

**From:** Christine Roush/HC-SC/GC/CA

**To:** Cathy A Sabiston/HC-SC/GC/CA@HWC

**Cc:** CSTD-DGO, Denis Arsenault/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC, Stephanie Szick/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC

**Date:** 2011-02-03 12:47 PM

**Subject:** Re: For approval: Salvia Announcement

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Cathy,

IYH doesn't have a lot of articles on controlled substances but the article on Opioids does state:

"Opioid medications come in many forms, including tablets, capsules, syrups, solutions, nasal sprays, skin patches and suppositories. The strength of the opioid in these medications varies greatly, and most

are available in Canada by prescription only. However, some products containing very low doses of the opioid codeine, combined with at least two other medicinal ingredients, can be purchased directly from a pharmacist."

I think there are good points to leaving it in and taking it out. Originally I think it was included to warn parents that it was available (and where) - as most people who would use it already know where to get it. However, I would probably change the wording as I don't think we want to admit it is widely available, and under the FDA it is illegal to sell in head shops and Natural Health stores, as it hasn't been approved as a Natural Health Product.

Let me know if you are OK with saying:

Products that claim to contain *S. divinorum* or its main active ingredient, salvinin A are widely available on the Internet and may be sold ~~are sold~~ in various "head shops" and natural food stores. The products are sold in a number of forms, including fresh or dried leaves, liquids or seeds and plant cuttings for growing purposes.

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
Health Canada/Santé Canada  
Tel/Tél : (613) 954-0712/Cell: (613) 219-7194  
Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca

---

Cathy A Sabiston      Agree to 3 of 4 pts. Still wondering how this iyh...      2011-02-03 11:49:45 AM  
Jocelyn Kula

----- Original Message -----

**From:** Jocelyn Kula  
**Sent:** 2011-02-03 11:13 AM EST  
**To:** Stephanie Szick  
**Cc:** Christine Roush; Cathy A Sabiston; Stephanie Chandler; Denis  
Arsenault; Suzanne Desjardins; CSTD-DGO  
**Subject:** Re: For approval: Salvia Announcement

Re, use vs consume. This wording is consistent with other drug-related IYHs and the fact that generally speaking, people talk about using (or taking) a drug (medicinal or illicit), not consuming it. Allowing for the fact that language is supposed to be Grade 8, I vote for sticking with "use".

Re. citing where substances are sold, we are not providing any more information than what is already splashed all over the internet, and I don't see this as causing any more of a risk than doing a NR to say that we are moving to schedule but this will take time, i.e, it is still legal for a bit....

Re. the weblink to the NOI, sending people to [www.canadagazette.gc.ca](http://www.canadagazette.gc.ca) is a minefield as the search engine on the site is very hard to use.....generally speaking, once we have the official link to the specific page from the Gazette office, we provide to comms for reference in their lines.

In the NR, not sure why we are now removing the reference to "also known as Salvia" when in fact, that is how 99% of the media reports and internet sites refer to it?

JK



**Re: For approval: Salvia Announcement** 

Stephanie Szick to: Christine Roush

2011-02-03 11:02 AM

Cc: Cathy A Sabiston, Stephanie Chandler, Denis Arsenault, Jocelyn  
Kula, Suzanne Desjardins, CSTD-DGO

hi Christine,

Please see attached -- some v. minor edits overall, with some questions on the media lines and the IYH article.

Please have a look and get back to us with revised/clean docs addressing these questions -- will review quickly on this end!

Please give me a call if any questions.

Thanks,

Stephanie Szick  
Director General's Office / Bureau du directeur général  
Controlled Substances & Tobacco Directorate (CSTD) /  
Direction des substances contrôlées et de la lutte au tabagisme (DSCLT)  
Health Canada / Santé Canada  
Tel / Tél: (613) 948-8651



IYH Salvia divinorum\_v24\_CSTD-DG\_03-02-11.doc



Salvia MLs\_CSTD-DG\_03-02-11.doc



Salvia NR\_CSTD-DG\_03-02-11.doc

Christine Roush

Hi Cathy, It's been a long (and windy) road, but f...

2011-02-02 01:11:34 PM

From: Christine Roush/HC-SC/GC/CA  
To: Cathy A Sabiston/HC-SC/GC/CA@HWC  
Cc: Stephanie Chandler/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, Jocelyn  
Kula/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC, CSTD-DGO  
Date: 2011-02-02 01:11 PM  
Subject: For approval: Salvia Announcement

Hi Cathy,

It's been a long (and windy) road, but finally we have the salvia products below for your approval. They have been signed off at the DG level in HPFB by the NHPD, the Inspectorate and Marketed Health Products. MO would like the NR issued on February 18th, so hopefully you'll be able to review and approve before your upcoming leave.

**s.19(1)**

[attachment "Salvia NR MHPD Revisions 2011 02.02.doc" deleted by Stephanie Szick/HC-SC/GC/CA]  
[attachment "Salvia MLs\_Feb2\_(clean2) NHPD edit.doc" deleted by Stephanie Szick/HC-SC/GC/CA]  
[attachment "IYH Salvia divinorum\_v23 Feb2(clean2).doc" deleted by Stephanie Szick/HC-SC/GC/CA]  
[attachment "DRAFT Salvia NOI\_Feb 2 EN.doc" deleted by Stephanie Szick/HC-SC/GC/CA]

Christine Roush

002605

## Salvia divinorum

### Issue

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff, incense special, and salvia.

**Comment [S1]:** Q From Cathy - Should this info. be in the media lines - as a Q&A? Stephanie - have added this line to the Media lines background

Certain websites promote the use of *S. divinorum* as a "legal" alternative to street drugs. Recent Canadian surveillance data indicates that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. Scientific reports also suggest that it has the potential for abuse.

Canadians should not use products containing *S. divinorum* and/or salvinorin A because they are hallucinogenic and little is known about the long-term effects of these substances on the brain and body. There is also no way to predict how it will affect you with each use.

In light of this information, Health Canada is proposing to regulate both *S. divinorum* and its main active ingredient salvinorin A under Schedule III to the *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth.

### Risks Associated with the Use of *Salvia divinorum*

*S. divinorum* is known to have both physical and mental effects. The effects of *S. divinorum*, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product
- how much is used
- the purity of the product (products that contain *S. divinorum* may be mixed with other substances)

- how it is taken, for example, whether the product is chewed, swallowed or smoked
- the user's mood and expectations

While scientists know which brain receptors are targeted by the main active ingredient, salvinorin A, very little is known about the following:

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- how it affects the brain overall, including whether there are any long-term effects or if it can cause permanent damage
- how it interacts with other substances, including other drugs, natural health products and alcohol
- the potential of *S. divinorum* to produce physical dependence and/or addiction

### Minimizing Your Risk

Hallucinogens like *S. divinorum* work by modifying functions in the brain. Health Canada recommends that you should not use *S. divinorum* because very little is known about the effects it may have on your body and/or brain functions. There is also no way to predict how it will affect you with each use. Just because a drug is plant-based or "natural", does not mean that it is safe.

**Comment [S2]:** Our media lines are more definitive - i.e. Canadians SHOULD NOT USE salvia - plse. continue this strong messaging in the IYH.  
NOTE from Cathy - "Shouldn't we say 'do not consume'?" is the best way to reduce risk?

Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs, such as marijuana, cocaine, ecstasy, LSD and other substances that distort reality. See the "**Need More Info?**" section below for links to resources that can help you with this.

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### Legal Status of *Salvia divinorum*

#### In Canada

As *S. divinorum* is a plant with hallucinogenic properties when consumed by humans, it currently meets the definition of a natural health product (NHP) under the *Natural Health Products Regulations* when marketed as a hallucinogen. As of February 2011, Health Canada has not authorized for sale any natural health products which contain *S. divinorum* as an ingredient. The sale of unauthorized natural health products containing *S. divinorum* or its main active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

While *S. divinorum* and salvinorin A are not currently regulated under the *Controlled Drugs and Substances Act* (CDSA), Health Canada is now developing a regulatory proposal that would add *S. divinorum* and salvinorin A to Schedule III to the CDSA.

#### In Other Countries

Several countries including but not limited to Australia, Belgium, Germany, Italy and Japan, have placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A.

In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on their sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution. In some states, for example, it is illegal for *S. divinorum* to be sold to anyone under the age of 18.

## Background

The leaves of this plant have been used traditionally by the Mazatec people for medicinal and mystical purposes.

Products that claim to contain *S. divinorum* or its main active ingredient, salvinorin A are widely available on the Internet and are sold in various "head shops" and natural food stores. The products are sold in a number of forms, including fresh or dried leaves, liquids or seeds and plant cuttings for growing purposes.

**Comment [S3]:** Is it typical in IYH articles to provide information on where substances are available, where they can be bought? Could providing this information prompt some to go looking?  
NOTE from Cathy: "do we say this in IYHs?"

Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *S. divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *S. divinorum* in the past year. The 2009 *Ontario Student Drug Use and Health Survey (OSDUHS)* indicated that 5.4% of Ontario students in grades 7-12 reported ever using *S. divinorum* and 4.4% of these students reported using this substance in the past year. For more information on these surveys, see the *Need More Info* section below.

## Health Canada's Role

In light of the health and safety risks associated with the use of *S. divinorum* and particularly the risks to youth, Health Canada is taking steps to regulate *S. divinorum* and salvinorin A as controlled substances. As a first step in this process, Health Canada published a *Notice to Interested Parties (NOI)* in *Canada Gazette, Part I*, on February 19, 2011. In the interim, Health Canada will continue to monitor the sale of unauthorized health products that contain *S. divinorum* or its main active ingredient salvinorin A. It will take appropriate action should it become aware of any unauthorized health products that may pose a risk to Canadians.

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## Need More Info?

- For information on how to submit a consumer or trade complaint about the unauthorized sale of health products containing *S. divinorum* please consult the following documents:  
Consumers: [http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_44\\_consumer\\_consommateur\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_44_consumer_consommateur_cp-pc-eng.php)

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Trade: [http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_38\\_trade-industrie\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_38_trade-industrie_cp-pc-eng.php) Or contact the **Health Products and Food Branch Inspectorate** directly call toll-free 1-800-267-9675.

- You can report any adverse reactions to the Canada Vigilance Program by one of the following three ways:

Report online at the **MedEffect™** Canada website at: <http://www.hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>

Call toll-free at 1-866-234-2345

Complete a **Canada Vigilance Reporting Form** and either:

Fax toll-free to 1-866-678-6789

Mail to: Canada Vigilance Program

Health Canada

AL 0701C

Ottawa, ON K1A 0K9

To have postage pre-paid, download the **postage paid label** from the **MedEffect™ Canada website**. The **Canada Vigilance Reporting Form** and the adverse reaction reporting guidelines may also be obtained via this website at : [http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei\\_form-eng.php](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei_form-eng.php)

- For information about the Government of Canada's **National Anti-Drug Strategy**, go to: [www.nationalantidrugstrategy.gc.ca/](http://www.nationalantidrugstrategy.gc.ca/)  
The Prevention section on this site has a number of helpful resources for parents, including:

- **Tips on Talking to Your Teenager**, at: [www.hc-sc.gc.ca/hc-ps/pubs/adp-adp/talk-aborder/index-eng.php](http://www.hc-sc.gc.ca/hc-ps/pubs/adp-adp/talk-aborder/index-eng.php)
- **What to Do if Your Teen is Using Drugs**, at: [www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html](http://www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html)
- Health Canada's **Not4Me** youth drug prevention section at: <http://www.hc-sc.gc.ca/hc-ps/drugs-drogues/youth-jeunes/facts-faits/index-eng.php>

- Information on natural health products and the **Natural Health Products Regulations** can be found at: [www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php)

For more on the surveys that have collected information about *Salvia divinorum* use in Canada, see:

- **The 2008-2009 Youth Smoking Survey**, at: <http://www.yss.uwaterloo.ca/index.cfm?section=5&page=288>
- **The 2009 Canadian Alcohol and Drug Use Monitoring Survey**, at: <http://www.hc-sc.gc.ca/hc-ps/drugs-drogues/stat/index-eng.php>
- **The 2009 Ontario Student Drug Use and Health Survey**, at: [http://www.camh.net/News\\_events/News\\_releases\\_and\\_media\\_advisories\\_and\\_backgrounders/osduhs2009\\_advisory.html](http://www.camh.net/News_events/News_releases_and_media_advisories_and_backgrounders/osduhs2009_advisory.html)

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<#>Complaints about the unauthorized sale of drugs containing *S. divinorum* can be made to the **Health Products and Food Branch Inspectorate** at: [http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_44\\_consumer\\_consommateur\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_44_consumer_consommateur_cp-pc-eng.php)¶  
<#> . Tel: 1-800-267-9675.¶  
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Additional Resources:

- U.S. Drug Enforcement Administration: **Drugs and Chemicals of Concern: *Salvia divinorum* and Salvinorin A** at:  
[www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)
- U.S. Department of Health & Human Services, **National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006** at:  
[www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf](http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf)
- For additional articles on health and safety issues go to the ***It's Your Health*** web section at: [www.healthcanada.gc.ca/iyh](http://www.healthcanada.gc.ca/iyh)

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

Original:

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Catalogue#

ISBN#

Version/date: Draft 17. September 8, 2010.

PACCB IYH - Lisa Mackay: 613-954-0105 – [Lisa.Mackay@hc-sc.gc.ca](mailto:Lisa.Mackay@hc-sc.gc.ca)

Comments from: HECSB - CSTD (OCS&ODARS) & HPFB – NHPD, MHPD & HPFBI

Contacts: HECSB: Jocelyn Kula, Stephanie Chandler, Suzanne Desjardin, Denis  
Arsenault, Hanan Abramovici, Bruna Brands  
HECSB comms: Christine Roush, Bronwyn Cline  
HPFB-NHPD: Valerie Hurry, Robin Marles, Maggie Graham, Stephanie  
Collins  
HPFB-MHPD: Scott Jordan, Robert Leitch, Mano Murty, Shahid Perwaiz  
HPFBI : Collin Pinto  
HPFB comms: Elizabeth Keeping, Blossom Leung

**DRAFT**  
01/02/2011

**Media Lines**  
***Salvia divinorum***

**Issue**

There is ongoing media interest regarding the availability of *Salvia divinorum* in Canada as well as Canadian surveillance data suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has concluded that *Salvia divinorum* and its main active ingredient salvinorin A should be regulated under the *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth. A Notice to Interested Parties outlining Health Canada's proposal to regulate this substance will be published in *Canada Gazette*, Part I, on February 19, 2011. ([www.gazette.gc.ca](http://www.gazette.gc.ca))

**Key Messages:**

- After reviewing available information and reports that suggest this substance has the potential for abuse, especially among young people, Health Canada is proposing to regulate both *Salvia divinorum* and its main active ingredient salvinorin A as controlled substances.
- The Government of Canada is taking these steps in order to protect the health and safety of Canadians, particularly youth, from the potentially harmful effects of these substances.
- Canadians should not use products containing *Salvia divinorum* and/or salvinorin A because they are hallucinogenic and little is known about the long-term effects of these substances on the brain and body.
- The inclusion of *Salvia divinorum* and salvinorin A in Schedule III to the Controlled Drugs and Substances Act will make possession, trafficking, importation, exportation, and production (or cultivation) illegal unless authorized by regulation.

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**Supplementary Messages:**

- Though it is a hallucinogen, the plant *Salvia divinorum* is not currently regulated under the CDSA. At the present time, products containing *Salvia divinorum* that indicate its hallucinogenic properties would meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations*.
- To date, Health Canada has not authorized for sale any natural health products which contain *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products containing *Salvia divinorum* or its active ingredient

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Last saved by Christine Roush

Created by Christine Roush  
2011-02-09

**DRAFT**  
01/02/2011

salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act and its associated regulations*.

### Questions and Answers:

#### **Q1 – What is involved in regulating *Salvia divinorum* as a controlled substance and what stage is it at?**

A1 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act (CDSA)* is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada recently concluded its assessment of *Salvia divinorum* and salvinorin A against the aforementioned factors and proposes to include both substances in Schedule III to the CDSA. The first step in the process of regulating a substance under the CDSA is the publication of a *Notice to Interested Parties (NOI)* in *Canada Gazette, Part I*. Any comments received will be considered during the preparation of a regulatory proposal. There will be additional opportunities for comment as the federal regulatory process progresses.

The regulation of these products will reduce the potential risks to the health and safety of Canadians associated with their ready availability, with their increased use and their unknown effects. The scheduling of *Salvia divinorum* and salvinorin A will also eliminate the current misconception that these substances are a safe alternative to other illegal drugs. Furthermore, the scheduling will also enable law enforcement agencies to take action against suspected illegal activities involving these substances.

#### **Q2 – Are *Salvia divinorum* and/or salvinorin A controlled internationally? How are these substances regulated in other countries?**

A2 - Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions; as a result, there is no requirement for them to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

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The move to include *Salvia divinorum* and salvinorin A in Schedule III to the CDSA is consistent with actions taken by several countries (e.g., Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Some individual U.S. states have implemented laws restricting their use, sale and/or distribution.

**Q3 – Is there any research on the use of *Salvia divinorum* in Canada?**

A3 - Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *Salvia divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *Salvia divinorum* in the past year. The 2009 *Ontario Student Drug Use and Health Survey (OSDUHS)* indicated that 5.4% of Ontario students in grades 7-12 reported ever using *Salvia divinorum* and 4.4% of these students reported using this substance in the past year.

**Q4 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why is it not controlled under the Controlled Drugs and Substances Act?**

A4 – The move to regulate *Salvia divinorum* and salvinorin A as controlled substances is based on surveillance data from surveys such as the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)*, *Youth Smoking Survey (YSS)* and the *Ontario Student Drug Use and Health Survey (OSDUHS)*, some of which only became available in 2010.

In the interim, as *Salvia divinorum* is a plant with hallucinogenic properties, it currently meets the definition of a natural health product under the *Natural Health Products Regulations (NHPR)* when marketed as a hallucinogen. The sale of unauthorized natural health products may be subject to compliance and enforcement action in accordance with the *Food and Drugs Act* and its associated regulations.

**Q5 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A5 – Once *Salvia divinorum* and salvinorin A are included in Schedule III to the CDSA, law enforcement will be able to take appropriate action in response to suspected illegal activities with these substances.

Currently, however, *Salvia divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. For more information on how to submit a consumer complaint about the unauthorized sale of drugs containing *Salvia divinorum* and/or salvinorin A,

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2011-02-09

**DRAFT**  
01/02/2011

visit: [www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_44\\_consumer\\_consommateur\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_44_consumer_consommateur_cp-pc-eng.php).

**Please confirm -- Has HPFB approved this reply and this link -- is it correct? The Approved By: listing on page 5 indicates HPFB approvals are pending, with the exception of Robin Marles in NHPD.**

**Q6 - Has Health Canada issued any kind of warning to Canadians about *Salvia divinorum*?**

A6 - Health Canada has developed an *It's Your Health* article about *Salvia divinorum* to help inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at: (link to come)

### **Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff, incense special, and salvia. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

**Comment [S1]:** Copied and pasted this line from the IYH article. Please see notes in the article about this.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. *Salvia divinorum* is widely advertised and promoted on the Internet and sold in various alternative lifestyle stores as a "legal" alternative to street drugs.

Data from the 2008-2009 Youth Smoking Survey indicates that:

- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;
- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year; and
- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using Salvia in their lifetime (0.2% in the past year); and

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2011-02-09

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01/02/2011

- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that:

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;
- 5.4% of students (grades 7-12) ever used *Salvia divinorum*; and
- use of *Salvia divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

**Prepared by:** Stephanie Chandler and Denis Arsenault, OCS, CSTD  
Reviewed and revised by: Christine Roush, Senior Communications Advisor, HECS, Communications

**Input by:** Lisa Mackay IYH/PACCB,  
Suzanne Desjardins HECSB/ODARS,  
Hanan Abramovici HECSB/ODARS,  
Bruna Brands HECSB/ODARS,  
Jocelyn Kula, HECSB/OCS,  
Robin Marles HPFB/NHPD,  
Maggie Graham HPFB/NHPD,  
Stephanie Collins HPFB/NHPD,  
Mano Murty HPFB/MHPD,  
Robert Leitch HPFB/MHPD,  
Shahid Perwaiz HPFB/MHPD,  
Collin Pinto, HPFB/HPFBI

**Approved by:**  
Robin Marles, Director, Bureau of Clinical Trials, NHPD (2011-01-20 and 2011-01-28)  
Jocelyn Kula, A/Director, OCS, CSTD, HECS (Jan 19, 2011 and Jan 27, 2011)  
Suzanne Desjardins, Director, ODARS, CSTD, HECS (Approved Jan 20, 2011)  
Cathy Sabiston, DG, CSTD, HECS (pending)  
Chris Turner, DG, MHPD (pending) ?  
Scott Sawler, DG, NHPD ?  
Diana Dowthwaite, DG, HPFB, ?  
Sharon Mullin, Director, Compliance and Enforcement Coordination, HPFB ?  
David Gotlieb, A/Communications Executive, HPFB (pending) ?  
Ken Polk, A/Director, Public Affairs, PACCB (pending)  
Charles Mojsej, DG, PACCB (pending)  
HECS Legal (pending)  
HPFB Legal (pending)  
Dave Stephens, Communications Executive, HECS (pending)  
Paul Glover, ADM, HECSB (pending)  
Meena Ballantyne, ADM, HPFB (pending)

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01/02/2011

Anne Lamar, ADM, PACCB (pending)  
DMO (pending)  
MO (pending)  
PCO (pending)

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Health Canada

2011-XX

# News Release

## The Government of Canada Proposes to Regulate *Salvia Divinorum* and Salvinorin A as Controlled Substances

February 17, 2011

For immediate release

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OTTAWA – Today, the Honourable Leona Aglukkaq, Minister of Health announced that the Government of Canada intends to regulate *Salvia divinorum* and salvinorin A, as controlled substances. A Notice to Interested Parties outlining Health Canada's proposal will be published in *Canada Gazette*, Part I, on February 19, 2011

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"After reviewing Canadian surveillance data and scientific reports that suggest this substance has the potential for abuse, especially among young people, we are taking these steps to protect the health and safety of Canadians from the potentially harmful effects of this substance," said Minister Aglukkaq. "The use of this substance is of concern to Health Canada as very little is known about its long-term effects on the brain and body," added Aglukkaq.

The Notice to Interested Parties will propose that *Salvia divinorum* and its main active ingredient salvinorin A be added to Schedule III to the *Controlled Drugs and Substances Act*. This means that activities such as possession, trafficking, importation, exportation, and production (or cultivation) will be illegal unless authorized by regulation. Regulating *Salvia divinorum* and salvinorin A as a controlled substance will also enable law enforcement agencies to take action against suspected illegal activities involving these substances.

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Interested parties are encouraged to submit any comments regarding the Notice to Interested Parties by March 14, 2011. ([www.gazette.gc.ca](http://www.gazette.gc.ca))

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Media Enquiries:  
Health Canada

Également disponible en français



(613) 957-2983

Jenny Van Alstyne  
Office of the Honourable Leona Aglukkaq  
Federal Minister of Health  
(613) 957-0200

**Public Enquiries:**

(613) 957-2991  
1-866 225-0709

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[www.healthcanada.gc.ca/media](http://www.healthcanada.gc.ca/media)



Government  
of Canada

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du Canada

Canada



**Re: For approval: Salvia Announcement** 

Christine Roush to: Cathy A Sabiston

2011-02-03 02:38 PM

Cc: CSTD-DGO, Denis Arsenault, Jocelyn Kula, Stephanie Chandler,  
Stephanie Szick, Suzanne Desjardins

OK - one more time, for your approval....



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Salvia MLs\_CSTD-DG\_03-02-11.doc



IYH Salvia divinorum\_v24\_CSTD-DG\_03-02-11.doc



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Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
Health Canada/Santé Canada  
Tel/Tél : (613) 954-0712/Cell: (613) 219-7194  
Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca

Cathy A Sabiston Ok. Going back to my original view. Remove th...

2011-02-03 01:52:33 PM

From: Cathy A Sabiston/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC, Christine Roush/HC-SC/GC/CA@HWC  
Cc: CSTD-DGO, Denis Arsenault/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC,  
Stephanie Szick/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC  
Date: 2011-02-03 01:52 PM  
Subject: Re: For approval: Salvia Announcement

Ok. Going back to my original view. Remove this section svp.

Jocelyn Kula

----- Original Message -----

**From:** Jocelyn Kula  
**Sent:** 2011-02-03 01:26 PM EST  
**To:** Christine Roush  
**Cc:** Cathy A Sabiston; CSTD-DGO; Denis Arsenault; Stephanie Chandler;  
Stephanie Szick; Suzanne Desjardins  
**Subject:** Re: For approval: Salvia Announcement  
Christine,

Only to clarify that your statement about where salvia can be sold is not quite right. It is not illegal under the FDA to sell salvia in head shops or natural health stores because there are no approved products, it is illegal to sell in those establishments when it is specifically sold as a hallucinogen, which is when the definition of an NHP comes into play, and the requirement for authorization under the FDA kicks in. Technically, someone selling salvia as a herbal incense product in a natural health store would not be doing anything illegal.

Health Canada

2011-XX

# News Release

## The Government of Canada Proposes to Regulate *Salvia Divinorum* and Salvinorin A as Controlled Substances

February 17, 2011  
For immediate release

OTTAWA – Today, the Honourable Leona Aglukkaq, Minister of Health announced that the Government of Canada intends to regulate *Salvia divinorum* and salvinorin A, also known as Salvia, as controlled substances. A Notice to Interested Parties outlining Health Canada's proposal will be published in *Canada Gazette*, Part I, on February 19, 2011

“After reviewing Canadian surveillance data and scientific reports that suggest this substance has the potential for abuse, especially among young people, we are taking these steps to protect the health and safety of Canadians from the potentially harmful effects of this substance,” said Minister Aglukkaq. “The use of this substance is of concern to Health Canada as very little is known about its long-term effects on the brain and body,” added Aglukkaq.

The Notice to Interested Parties will propose that *Salvia divinorum* and its main active ingredient salvinorin A be added to Schedule III to the *Controlled Drugs and Substances Act*. This means that activities such as possession, trafficking, importation, exportation, and production (or cultivation) will be illegal unless authorized by regulation. Regulating *Salvia divinorum* and salvinorin A as a controlled substance will also enable law enforcement agencies to take action against suspected illegal activities involving these substances.

Interested parties are encouraged to submit any comments regarding the Notice to Interested Parties by March 14, 2011.

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Insert link to the *It's Your Health* article

**Media Enquiries:**  
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01/02/2011

## Media Lines *Salvia divinorum*

### Issue

There is ongoing media interest regarding the availability of *Salvia divinorum* in Canada as well as Canadian surveillance data suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has concluded that *Salvia divinorum* and its main active ingredient salvinorin A should be regulated under the *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth. A Notice to Interested Parties outlining Health Canada's proposal to regulate this substance will be published in *Canada Gazette*, Part I, on February 19, 2011.

### Key Messages:

- After reviewing available information and reports that suggest this substance has the potential for abuse, especially among young people, Health Canada is proposing to regulate both *Salvia divinorum* and its main active ingredient salvinorin A as controlled substances.
- The Government of Canada is taking these steps in order to protect the health and safety of Canadians, particularly youth, from the potentially harmful effects of these substances.
- Canadians should not use products containing *Salvia divinorum* and/or salvinorin A because they are hallucinogenic and little is known about the long-term effects of these substances on the brain and body.
- The inclusion of *Salvia divinorum* and salvinorin A in Schedule III to the *Controlled Drugs and Substances Act* will make possession, trafficking, importation, exportation, and production (or cultivation) illegal unless authorized by regulation.

### Supplementary Messages:

- Though it is a hallucinogen, the plant *Salvia divinorum* is not currently regulated under the CDSA. At the present time, products containing *Salvia divinorum* that indicate its hallucinogenic properties would meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations*.
- To date, Health Canada has not authorized for sale any natural health products which contain *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products containing *Salvia divinorum* or its active ingredient

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salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act and its associated regulations*.

**Questions and Answers:**

**Q1 – What is involved in regulating *Salvia divinorum* as a controlled substance and what stage is it at?**

A1 - Health Canada considers several factors in determining whether regulation of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada recently concluded its assessment of *Salvia divinorum* and salvinorin A against the aforementioned factors and proposes to include both substances in Schedule III to the CDSA. The first step in the process of regulating a substance under the CDSA is the publication of a *Notice to Interested Parties* (NOI) in *Canada Gazette*, Part I. Any comments received will be considered during the preparation of a regulatory proposal. There will be additional opportunities for comment as the federal regulatory process progresses.

The regulation of these products will reduce the potential risks to the health and safety of Canadians associated with their ready availability, with their increased use and their unknown effects. The scheduling of *Salvia divinorum* and salvinorin A will also eliminate the current misconception that these substances are a safe alternative to other illegal drugs. Furthermore, the scheduling will also enable law enforcement agencies to take action against suspected illegal activities involving these substances.

**Q2 – Are *Salvia divinorum* and/or salvinorin A controlled internationally? How are these substances regulated in other countries?**

A2 - Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions; as a result, there is no requirement for them to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

The move to include *Salvia divinorum* and salvinorin A in Schedule III to the CDSA is consistent with actions taken by several countries (e.g., Australia, Belgium, Denmark,

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Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Some individual U.S. states have implemented laws restricting their use, sale and/or distribution.

**Q3 – Is there any research on the use of *Salvia divinorum* in Canada?**

A3 - Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *Salvia divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *Salvia divinorum* in the past year. The 2009 *Ontario Student Drug Use and Health Survey (OSDUHS)* indicated that 5.4% of Ontario students in grades 7-12 reported ever using *Salvia divinorum* and 4.4% of these students reported using this substance in the past year.

**Q4 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why is it not controlled under the Controlled Drugs and Substances Act?**

A4 – The move to regulate *Salvia divinorum* and salvinorin A as controlled substances is based on surveillance data from surveys such as the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)*, *Youth Smoking Survey (YSS)* and the *Ontario Student Drug Use and Health Survey (OSDUHS)*, some of which only became available in 2010.

In the interim, as *Salvia divinorum* is a plant with hallucinogenic properties, it currently meets the definition of a natural health product under the *Natural Health Products Regulations (NHPR)* when marketed as a hallucinogen. The sale of unauthorized natural health products may be subject to compliance and enforcement action in accordance with the *Food and Drugs Act* and its associated regulations.

**Q5 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A5 – Once *Salvia divinorum* and salvinorin A are included in Schedule III to the CDSA, law enforcement will be able to take appropriate action in response to suspected illegal activities with these substances.

Currently, however, *Salvia divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. For more information on how to submit a consumer complaint about the unauthorized sale of drugs containing *Salvia divinorum* and/or salvinorin A, visit: [www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_44\\_consumer\\_consommateur\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_44_consumer_consommateur_cp-pc-eng.php).

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**Please confirm -- Has HPFB approved this reply and this link -- is it correct? The Approved By: listing on page 5 indicates HPFB approvals are pending, with the exception of Robin Marles in NHPD. All three DGs in HPFB have signed off: Diana Dowthwaite, DG, HPFB, Sharon Mullin, Director, Compliance and Enforcement Coordination, HPFB, Robin Marles, Director, Bureau of Clinical Trials, NHPD**

**Q6 - Has Health Canada issued any kind of warning to Canadians about *Salvia divinorum*?**

A6 - Health Canada has developed an *It's Your Health* article about *Salvia divinorum* to help inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at: (link to come)

**Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff, incense special, and salvia. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago.

Data from the 2008-2009 Youth Smoking Survey indicates that:

- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;
- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year; and
- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using Salvia in their lifetime (0.2% in the past year); and
- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

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Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that:

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- 5.4% of students (grades 7-12) ever used *Salvia divinorum*; and
- use of *Salvia divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

**Prepared by:** Stephanie Chandler and Denis Arsenault, OCS, CSTD

Reviewed and revised by: Christine Roush, Senior Communications Advisor, HECS, Communications

**Approved by:**

Jocelyn Kula, A/Director, OCS, CSTD, HECS (Jan 19, 2011 and Jan 27, 2011)

Suzanne Desjardins, Director, ODARS, CSTD, HECS (Approved Jan 20, 2011)

Cathy Sabiston, DG, CSTD, HECS (pending)

Chris Turner, DG, MHPD

Scott Sawler, DG, NHPD

Diana Dowthwaite, DG, HPFB

Sharon Mullin, Director, Compliance and Enforcement Coordination, HPFB

Robin Marles, Director, Bureau of Clinical Trials, NHPD

David Gotlieb, A/Communications Executive, HPFB (pending)

Ken Polk, A/Director, Public Affairs, PACCB (pending)

Charles Mojsej, DG, PACCB (pending)

HECS Legal (pending)

HPFB Legal (pending)

Dave Stephens, Communications Executive, HECS (pending)

Paul Glover, ADM, HECSB (pending)

Meena Ballantyne, ADM, HPFB (pending)

Anne Lamar, ADM, PACCB (pending)

DMO (pending)

MO (pending)

PCO (pending)

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## Salvia divinorum

### Issue

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff, incense special, and salvia.

**Comment [S1]:** Q From Cathy - Should this info. be in the media lines - as a Q&A? Stephanie - have added this line to the Media lines background

Certain websites promote the use of *S. divinorum* as a "legal" alternative to street drugs. Recent Canadian surveillance data indicates that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. Scientific reports also suggest that it has the potential for abuse.

**Comment [CR2]:** Not necessary - we will be providing a link to the FYH article from the media lines and NR.

Canadians should not use products containing *S. divinorum* and/or salvinorin A because they are hallucinogenic and little is known about the long-term effects of these substances on the brain and body. There is also no way to predict how it will affect you with each use.

In light of this information, Health Canada is proposing to regulate both *S. divinorum* and its main active ingredient salvinorin A under Schedule III to the *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth.

### Risks Associated with the Use of *Salvia divinorum*

*S. divinorum* is known to have both physical and mental effects. The effects of *S. divinorum*, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product
- how much is used
- the purity of the product (products that contain *S. divinorum* may be mixed with other substances)

- how it is taken, for example, whether the product is chewed, swallowed or smoked
- the user's mood and expectations

While scientists know which brain receptors are targeted by the main active ingredient, salvinorin A, very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or if it can cause permanent damage
- how it interacts with other substances, including other drugs, natural health products and alcohol
- the potential of *S. divinorum* to produce physical dependence and/or addiction

### **Minimizing Your Risk**

Hallucinogens like *S. divinorum* work by modifying functions in the brain. Health Canada recommends that you should not use *S. divinorum* because very little is known about the effects it may have on your body and/or brain functions. There is also no way to predict how it will affect you with each use. Just because a drug is plant-based or "natural", does not mean that it is safe.

Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs, such as marijuana, cocaine, ecstasy, LSD and other substances that distort reality. See the "*Need More Info?*" section below for links to resources that can help you with this.

### **Legal Status of *Salvia divinorum***

#### In Canada

As *S. divinorum* is a plant with hallucinogenic properties when consumed by humans, it currently meets the definition of a natural health product (NHP) under the *Natural Health Products Regulations* when marketed as a hallucinogen. As of February 2011, Health Canada has not authorized for sale any natural health products which contain *S. divinorum* as an ingredient. The sale of unauthorized natural health products containing *S. divinorum* or its main active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

While *S. divinorum* and salvinorin A are not currently regulated under the *Controlled Drugs and Substances Act* (CDSA), Health Canada is now developing a regulatory proposal that would add *S. divinorum* and salvinorin A to Schedule III to the CDSA.

#### In Other Countries

Several countries including but not limited to Australia, Belgium, Germany, Italy and Japan, have placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A.

In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on their sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution. In some states, for example, it is illegal for *S. divinorum* to be sold to anyone under the age of 18.

## Background

The leaves of this plant have been used traditionally by the Mazatec people for medicinal and mystical purposes.

The products are sold in a number of forms, including fresh or dried leaves, liquids or seeds and plant cuttings for growing purposes.

Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *S. divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *S. divinorum* in the past year. The 2009 *Ontario Student Drug Use and Health Survey (OSDUHS)* indicated that 5.4% of Ontario students in grades 7-12 reported ever using *S. divinorum* and 4.4% of these students reported using this substance in the past year. For more information on these surveys, see the *Need More Info* section below.

## Health Canada's Role

In light of the health and safety risks associated with the use of *S. divinorum* and particularly the risks to youth, Health Canada is taking steps to regulate *S. divinorum* and salvinorin A as controlled substances. As a first step in this process, Health Canada published a *Notice to Interested Parties (NOI)* in *Canada Gazette, Part I*, on February 19, 2011. In the interim, Health Canada will continue to monitor the sale of unauthorized health products that contain *S. divinorum* or its main active ingredient salvinorin A. It will take appropriate action should it become aware of any unauthorized health products that may pose a risk to Canadians.

## Need More Info?

- For information on how to submit a consumer or trade complaint about the unauthorized sale of health products containing *S. divinorum* please consult the following documents:  
Consumers: [http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_44\\_consumer\\_consommateur\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_44_consumer_consommateur_cp-pc-eng.php)  
Trade: [http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_38\\_trade-industrie\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_38_trade-industrie_cp-pc-eng.php). Or contact the **Health Products and Food Branch Inspectorate** directly by calling toll-free 1-800-267-9675.

- You can report any adverse reactions to the Canada Vigilance Program by one of the following three ways:  
Report online at the MedEffect™ Canada website at: <http://www.hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>  
Call toll-free at 1-866-234-2345  
Complete a Canada Vigilance Reporting Form and either:  
Fax toll-free to 1-866-678-6789  
Mail to: Canada Vigilance Program  
Health Canada  
AL 0701C  
Ottawa, ON K1A 0K9  
To have postage pre-paid, download the postage paid label from the MedEffect™ Canada website. The Canada Vigilance Reporting Form and the adverse reaction reporting guidelines may also be obtained via this website at: [http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei\\_form-eng.php](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei_form-eng.php)
- For information about the Government of Canada's National Anti-Drug Strategy, go to: [www.nationalantidrugstrategy.gc.ca/](http://www.nationalantidrugstrategy.gc.ca/)  
The Prevention section on this site has a number of helpful resources for parents, including:
  - **Tips on Talking to Your Teenager**, at: [www.hc-sc.gc.ca/hc-ps/pubs/adp-apd/talk-aborder/index-eng.php](http://www.hc-sc.gc.ca/hc-ps/pubs/adp-apd/talk-aborder/index-eng.php)
  - **What to Do if Your Teen is Using Drugs**, at: [www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html](http://www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html)
  - Health Canada's **Not4Me** youth drug prevention section at: <http://www.hc-sc.gc.ca/hc-ps/drugs-drogues/youth-jeunes/facts-faits/index-eng.php>
- Information on natural health products and the Natural Health Products Regulations can be found at: [www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php)

For more on the surveys that have collected information about *Salvia divinorum* use in Canada, see:

- **The 2008-2009 Youth Smoking Survey**, at: <http://www.yss.uwaterloo.ca/index.cfm?section=5&page=288>
- **The 2009 Canadian Alcohol and Drug Use Monitoring Survey**, at: <http://www.hc-sc.gc.ca/hc-ps/drugs-drogues/stat/index-eng.php>
- **The 2009 Ontario Student Drug Use and Health Survey**, at: [http://www.camh.net/News\\_events/News\\_releases\\_and\\_media\\_advisories\\_and\\_backgrounders/osduhs2009\\_advisory.html](http://www.camh.net/News_events/News_releases_and_media_advisories_and_backgrounders/osduhs2009_advisory.html)

Additional Resources:

- U.S. Drug Enforcement Administration: **Drugs and Chemicals of Concern: *Salvia divinorum* and *Salvinorin A*** at:  
[www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)
- U.S. Department of Health & Human Services, **National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006** at:  
[www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf](http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf)
- For additional articles on health and safety issues go to the ***It's Your Health*** web section at: [www.healthcanada.gc.ca/iyh](http://www.healthcanada.gc.ca/iyh)

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

Original:

©Her Majesty the Queen in Right of Canada, represented by the Minister of Health, 2010

Catalogue#

ISBN#

Version/date: Draft 17. September 8, 2010.

PACCB IYH - Lisa Mackay: 613-954-0105 – [Lisa.Mackay@hc-sc.gc.ca](mailto:Lisa.Mackay@hc-sc.gc.ca)

Comments from: HECSB - CSTD (OCS&ODARS) & HPFB – NHPD, MHPD & HPFBI

Approved by:

**Approved by:**

Jocelyn Kula, A/Director, OCS, CSTD, HECS (Jan 19, 2011 and Jan 27, 2011)  
Suzanne Desjardins, Director, ODARS, CSTD, HECS (Approved Jan 20, 2011)  
Cathy Sabiston, DG, CSTD, HECS (pending)  
Chris Turner, DG, MHPD  
Scott Sawler, DG, NHPD  
Diana Dowthwaite, DG, HPFB  
Sharon Mullin, Director, Compliance and Enforcement Coordination, HPFB  
Robin Marles, Director, Bureau of Clinical Trials, NHPD  
David Gotlieb, A/Communications Executive, HPFB (pending)  
Ken Polk, A/Director, Public Affairs, PACCB (pending)  
Charles Mojsej, DG, PACCB (pending)  
HECS Legal (pending)  
HPFB Legal (pending)  
Dave Stephens, Communications Executive, HECS (pending)  
Paul Glover, ADM, HECSB (pending)  
Meena Ballantyne, ADM, HPFB (pending)  
Anne Lamar, ADM, PACCB (pending)  
DMO (pending)  
MO (pending)  
PCO (pending)

DEPARTMENT OF HEALTH

CONTROLLED DRUGS AND SUBSTANCES ACT

*Notice to interested parties - Proposal regarding the addition of Salvia divinorum and salvinorin A to Schedule III to the Controlled Drugs and Substances Act*

This notice provides interested stakeholders with the opportunity to provide comments on Health Canada's proposal to add the plant *Salvia divinorum* (*S. divinorum*) and its main active ingredient salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA). Stakeholders may also identify themselves for inclusion in any future consultation.

*S. divinorum* is a species of sage belonging to the mint family. Its leaves are generally chewed or smoked to obtain psychotropic effects. While uncertainty remains surrounding the health risks of *S. divinorum*, known effects are reported to be short and long-term in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant. Neither *S. divinorum* nor salvinorin A are currently included in any of the Schedules to the CDSA.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. *S. divinorum* is widely touted as a "legal" hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs.<sup>1</sup> Results from the *Canadian Alcohol and Drug Use Monitoring Survey* (CADUMS) reveal that, in 2009, 1.6% of Canadians aged 15 years and older reported having used *S. divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24 years. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *S. divinorum* in the past year. Moreover, the 2009 *Ontario Student Drug Use and Health Survey* (OSDUHS) indicated that 5.4% of Ontario students in grades 7-12 reported ever using *S. divinorum* and 4.4% of these students reported using this substance in the past year. Because its psychoactive effects resemble those of other substances included in Schedule III to the CDSA such as lysergic acid diethylamide (LSD) and psilocybin, Health Canada is concerned that the ready availability and use of *S. divinorum* poses a risk to the health and safety of Canadians, particularly youth.

While *S. divinorum* and salvinorin A are not currently included in any of the United Nations Drug Control Conventions, a number of countries have chosen to regulate one or both as controlled substances. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden have all placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. Some American states have also implemented laws restricting their use, sale and/or distribution.

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<sup>1</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.

Including these substances within Schedule III to the CDSA would prohibit: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation). The regulation of *S. divinorum* and salvinorin A under the CDSA will also enable law enforcement agencies to take action against suspected illegal activities involving these substances.

As this action is not intended to interfere with the use and availability of *S. divinorum* and/or salvinorin A for legitimate medical, scientific or industrial purposes, Health Canada is seeking information from stakeholders on whether there are any such uses in Canada. Information received in response to this notice will be instrumental in determining appropriate regulation under the CDSA.

The publication of this notice begins a 30-day comment period. There will be additional opportunities to provide comments as the federal regulatory process progresses.

If you are interested in this process or have comments on this proposal, please contact Stephanie Chandler, Regulatory Policy Division, Office of Controlled Substances, Address Locator: 3503D, 123 Slater St., Ottawa, Ontario, Canada, K1A 1B9, by fax at (613) 946-4224 or by email at [OCS\\_Policy\\_and\\_Regulatory\\_Affairs@hc-sc.gc.ca](mailto:OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca).

Cathy A. Sabiston  
Director General  
Controlled Substances and Tobacco Directorate

Date \_\_\_\_\_





**Re: For approval: Salvia Announcement** 

Cathy A Sabiston to: Christine Roush

2011-02-03 02:39 PM

Cc: CSTD-DGO, Denis Arsenault, Jocelyn Kula, Stephanie Chandler,  
Stephanie Szick, Suzanne Desjardins

This message is digitally signed.

approved thank you

Cathy Sabiston  
Director General / Directrice générale  
Controlled Substances & Tobacco Directorate (CSTD)  
Direction des substances contrôlées et de la lutte au tabagisme (DSCLT)  
Health Canada / Santé Canada  
Tel: (613) 941-1977 Fax: (613) 954-2288  
E-mail/courriel: cathy.a.sabiston@hc-sc.gc.ca  
Website/Site web: www.hc-sc.gc.ca

Christine Roush OK - one more time, for your approval.... Christi...

2011-02-03 02:38:17 PM

From: Christine Roush/HC-SC/GC/CA  
To: Cathy A Sabiston/HC-SC/GC/CA@HWC  
Cc: CSTD-DGO, Denis Arsenault/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC,  
Stephanie Chandler/HC-SC/GC/CA@HWC, Stephanie Szick/HC-SC/GC/CA@HWC, Suzanne  
Desjardins/HC-SC/GC/CA@HWC  
Date: 2011-02-03 02:38 PM  
Subject: Re: For approval: Salvia Announcement

OK - one more time, for your approval....

[attachment "Salvia NR\_CSTD-DG\_03-02-11.doc" deleted by Cathy A Sabiston/HC-SC/GC/CA]  
[attachment "Salvia MLs\_CSTD-DG\_03-02-11.doc" deleted by Cathy A Sabiston/HC-SC/GC/CA]  
[attachment "IYH Salvia divinorum\_v24\_CSTD-DG\_03-02-11.doc" deleted by Cathy A  
Sabiston/HC-SC/GC/CA] [attachment "DRAFT Salvia NOI\_Feb 3 EN.doc" deleted by Cathy A  
Sabiston/HC-SC/GC/CA]

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
Health Canada/Santé Canada  
Tel/Tél : (613) 954-0712/Cell: (613) 219-7194  
Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca

Cathy A Sabiston Ok. Going back to my original view. Remove th...  
Jocelyn Kula

2011-02-03 01:52:33 PM

----- Original Message -----

From: Jocelyn Kula  
Sent: 2011-02-03 01:26 PM EST  
To: Christine Roush  
Cc: Cathy A Sabiston; CSTD-DGO; Denis Arsenault; Stephanie Chandler;



**Re: Salvia Retailers**   
Lisa Marie NG to: Stephanie Chandler

2011-02-03 03:42 PM

Ok, so more like this:

Canadian Health Food Association  
Toronto, ON  
[www.chfa.ca](http://www.chfa.ca)

Canadian Natural Health Association  
North York, ON

Natural Health Practitioners of Canada Association  
Edmonton, AB  
[www.nhpcanada.org](http://www.nhpcanada.org)

Stephanie Chandler    Hi Lisa Marie, Yes these are the sort of stores...    2011-02-03 03:29:22 PM

From:            Stephanie Chandler/HC-SC/GC/CA  
To:                Lisa Marie NG/HC-SC/GC/CA@HWC  
Date:             2011-02-03 03:29 PM  
Subject:          Re: Salvia Retailers

Hi Lisa Marie,

Yes these are the sort of stores we are interested in, but because it would be impossible to find the names of all the stores in Canada (and it might be perceived as unfair to contact some and not others), we were hoping to find a central association or group which many would belong to. But I have a feeling such an association doesn't exist... If you can't find any, I'll talk to Denis and see what he thinks about targeting specific shops like the ones you listed below.

Stephanie

Lisa Marie NG    Hi Stephanie, Is this what you had in mind? If s...    2011-02-03 03:23:05 PM



**Re: Fw: For approval: Salvia Announcement**   
Denis Arsenault to: Stephanie Chandler

2011-02-03 05:11 PM

Can we talk about this tomorrow morning?

Denis

---

Denis Arsenault, A/Manager / Gestionnaire p.i.  
Regulatory Policy Division /  
Division des politiques réglementaires,  
Office of Controlled Substances /  
Bureau des substances contrôlées,  
Health Canada / Santé Canada  
Tel/Tél: (613) 957-6828  
Fax / Télécopieur : (613) 946-4224  
E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca

---

Stephanie Chandler Hi Denis, I have one comment with regards to t...

2011-02-02 01:44:03 PM

---

From: Stephanie Chandler/HC-SC/GC/CA  
To: Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2011-02-02 01:44 PM  
Subject: Fw: For approval: Salvia Announcement

---

Hi Denis,

I have one comment with regards to the NOI. It has been revised to state that "effects are reported to be short and **long-term** in nature". According to the IAS (which both ODARS and HPFB have reviewed), there has only been one reported case of *deja-vu* after using Salvia which could possibly be considered a long-term effect. Besides that we have no other info about long-term effects, so I don't think its strictly true to suggests that there are long-term effects given the available scientific info. We also state in the MLs and IYH that very little is known about its long-term effects. It was also never our intention to have HPFB review the NOI, so I suggest we leave the NOI as is.

Besides that, the NR, MLs and IYH look fine to me.

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

----- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2011-02-02 01:31 PM -----

---

From: Christine Roush/HC-SC/GC/CA  
To: Cathy A Sabiston/HC-SC/GC/CA@HWC  
Cc: Stephanie Chandler/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, Jocelyn



**Fw: Update - Events in February**  
Denis Arsenault to: Jocelyn Kula  
Cc: Stephanie Chandler

2011-02-03 05:16 PM

Hi Jocelyn,

Further to my previous email, Stephanie has pointed out to me that the signed version of the NOI contains the version of the PRAD email account address with the underscores. Given that both versions of the PRAD address function, I suggest we stick with the underscore version for the purposes of the NOI.

Also, for the list of stakeholders, Stephanie clarified for me that we never did receive any names/suggestions from HPFB. Apparently, they are unable to extract info their database(s) in manner where they could simply give us contacts interested in salvia! As a result, once the NOI goes out, they will send a message to this effect themselves through their database.

Denis

---

Denis Arsenault, A/Manager / Gestionnaire p.i.  
Regulatory Policy Division /  
Division des politiques réglementaires,  
Office of Controlled Substances /  
Bureau des substances contrôlées,  
Health Canada / Santé Canada  
Tel/Tél: (613) 957-6828  
Fax / Télécopieur : (613) 946-4224  
E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca  
----- Forwarded by Denis Arsenault/HC-SC/GC/CA on 2011-02-03 05:06 PM -----

From: Denis Arsenault/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Date: 2011-02-02 10:48 AM  
Subject: Re: Fw: Update - Events in February

Hi Jocelyn,

For the PRAD email account, while the old format with the underscores still seems to function, the address also functions with the underscores replaced by periods. For the sake of consistency, we will use the period format.

We will explore asap whether there are any associations for natural food stores or alternative lifestyle shops that could be added to the list of stakeholders.

Denis

---

Denis Arsenault, A/Manager / Gestionnaire p.i.  
Regulatory Policy Division /  
Division des politiques réglementaires,  
Office of Controlled Substances /  
Bureau des substances contrôlées,  
Health Canada / Santé Canada  
Tel/Tél: (613) 957-6828  
Fax / Télécopieur : (613) 946-4224  
E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca

Jocelyn Kula      two comments: do we not need to update the P...      2011-02-02 10:19:51 AM

From:            Jocelyn Kula/HC-SC/GC/CA  
To:              Denis Arsenault/HC-SC/GC/CA@HWC  
Date:            2011-02-02 10:19 AM  
Subject:        Re: Fw: Update - Events in February

---

two comments:

do we not need to update the PRAD email address to have ".s in it rather than "\_s in it?

for the list of stakeholders, what about looking for an association of natural health food stores (I doubt there is an association for head shops), or an association for alternative life style stores.....just that retailers are who are most likely to be impacted....

JK

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

Denis Arsenault      Hi Jocelyn, As requested.      2011-02-01 02:49:54 PM

From:            Denis Arsenault/HC-SC/GC/CA  
To:              Jocelyn Kula/HC-SC/GC/CA@HWC  
Date:            2011-02-01 02:49 PM  
Subject:        Re: Fw: Update - Events in February

---

Hi Jocelyn,

As requested.

[attachment "Stakeholder notification of NOI Jan 28 2011 EN.wpd" deleted by Denis  
Arsenault/HC-SC/GC/CA] [attachment "List of Salvia Stakeholders v.2.doc" deleted by Denis  
Arsenault/HC-SC/GC/CA]

Denis

---

Denis Arsenault, A/Manager / Gestionnaire p.i.  
Regulatory Policy Division /  
Division des politiques réglementaires,  
Office of Controlled Substances /  
Bureau des substances contrôlées,  
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Tel/Tél: (613) 957-6828  
Fax / Télécopieur : (613) 946-4224  
E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca

Jocelyn Kula      great. can I please see email text and list of stak...      2011-02-01 02:20:33 PM

From: Jocelyn Kula/HC-SC/GC/CA  
To: Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2011-02-01 02:20 PM  
Subject: Re: Fw: Update - Events in February

---

great. can I please see email text and list of stakeholders it is going to....

JK

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

Denis Arsenault      Hi Jocelyn, For publication on February 19, we...      2011-02-01 02:11:13 PM

From: Denis Arsenault/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2011-02-01 02:11 PM  
Subject: Re: Fw: Update - Events in February

---

Hi Jocelyn,

For publication on February 19, we need to have the package delivered to *Canada Gazette* by noon on Friday, February 11. While the copies of the NOI that Cathy signed are dated January 28, these probably don't need to be re-signed (to be confirmed with Stephanie) as it is the covering letter to *Canada Gazette* that indicates the date on which we want the NOI published.

Unlike the NOI, the covering letter would be signed by yourself and can thus be easily amended here in OCS to reflect the new target date of February 19.

As for the list of stakeholders, Stephanie submitted to me a final list of stakeholders which I approved with a few minor modifications. The actual message we would send up is approved and ready to go.

I will work with Carmen to set-up a bilat.

Denis

---

Denis Arsenault, A/Manager / Gestionnaire p.i.  
Regulatory Policy Division /  
Division des politiques réglementaires,  
Office of Controlled Substances /  
Bureau des substances contrôlées,  
Health Canada / Santé Canada  
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Fax / Télécopieur : (613) 946-4224  
E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca

Jocelyn Kula      so when do we have to have our package with t...      2011-02-01 10:07:43 AM

From: Jocelyn Kula/HC-SC/GC/CA  
To: Denis Arsenault/HC-SC/GC/CA@HWC

**Re: Salvia NR, MLs, NOI and IYH article - DLSU input** 

Christine Roush to: Jocelyn Kula

2011-02-03 07:09 PM

Cc: Denis Arsenault, Stephanie Chandler

Jocelyn - I read through the comments and don't think Cathy needs to approve again - 

Once HPFB sorts through this seemingly unanswerable question, then we can provide Cathy with a copy of the revised docs as an fyi only. I don't see that Chantale's suggested changes are controversial and if you agree with them pls let me know if you want me to make the changes or Stephanie C. I will send the comments below to my comms colleague in HPFB and ask her to follow up with her client.

I hope the end is in sight on this soon. I feel we have been going in circles on the NHP issue too long.

Christine

Jocelyn Kula

----- Original Message -----

**From:** Jocelyn Kula

**Sent:** 2011-02-03 05:37 PM EST

**To:** Christine Roush

**Cc:** Denis Arsenault; Stephanie Chandler

**Subject:** Fw: 

Just got this. I see that some changes are required, but am not sure at this point if they have to go back through Cathy or not. Perhaps you can read through and let me know what you think....

JK

---

Jocelyn Kula

Acting Director/ Directrice par intérim

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs

Health Canada/ Santé Canada

Tel: (613) 952-2177 Fax: (613) 946-4224

----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2011-02-03 05:31 PM -----

**From:** Sherrey Collier/HC-SC/GC/CA

**To:** Elizabeth Keeping/HC-SC/GC/CA@HWC

**Cc:** Jocelyn Kula/HC-SC/GC/CA@HWC, Diane Labelle/HC-SC/GC/CA@HWC, Chantal Trepanier/HC-SC/GC/CA@HWC, Nancy Othmer/HC-SC/GC/CA@HWC

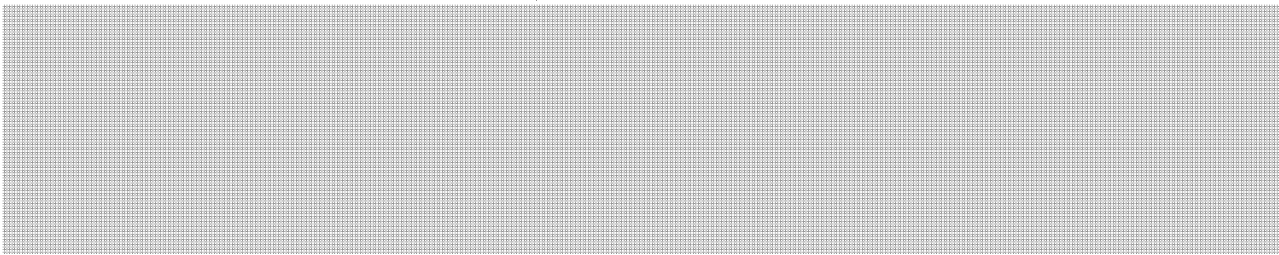
**Date:** 2011-02-03 05:05 PM

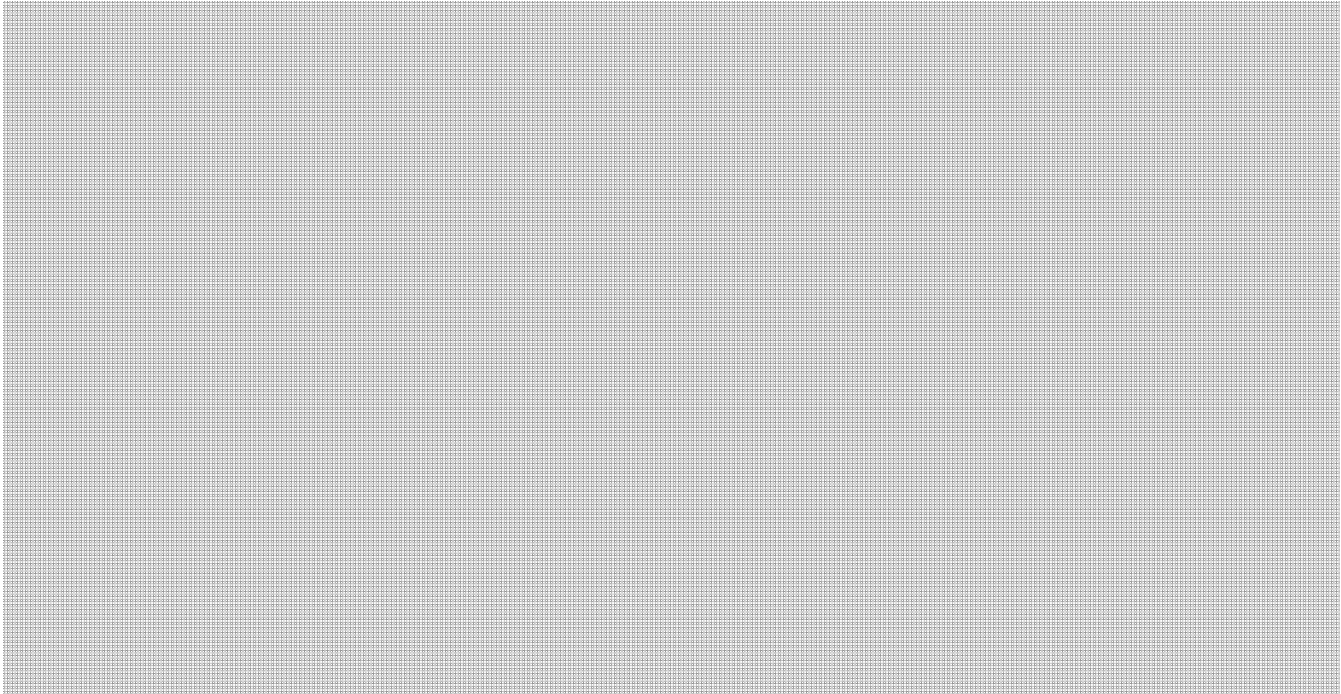
**Subject:** 

---

**Solicitor-Client Privilege/Protected  
Secret professionnel de l'avocat/Protégé**

Hi Beth,



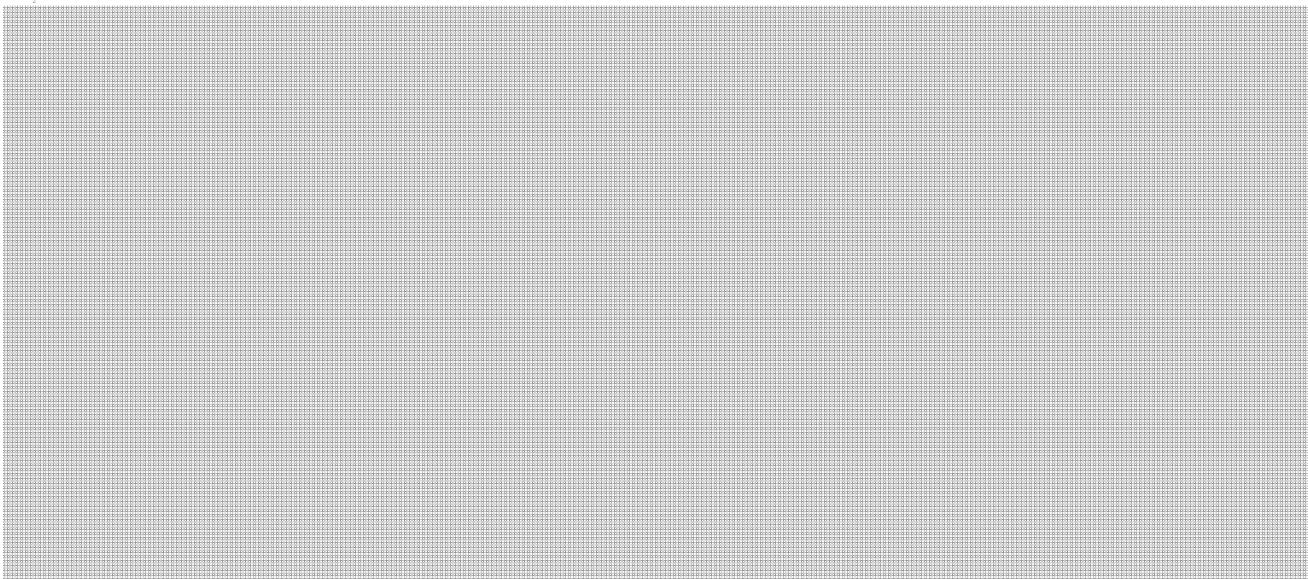


Pls call if you'd like to discuss, thanks.

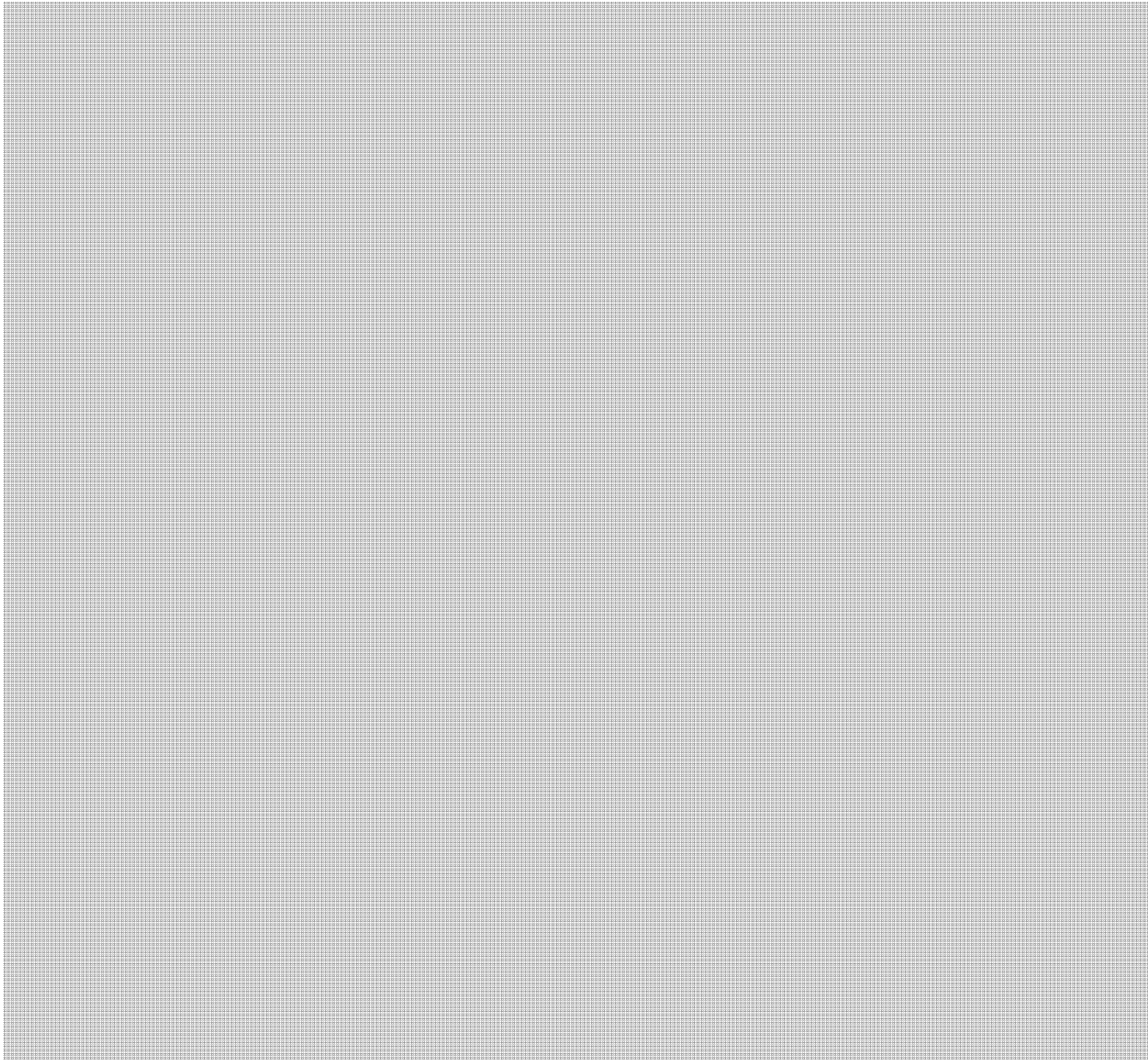
Sherrey Collier

Legal Counsel / Conseillère juridique  
Department of Justice / Ministère de la Justice  
Health Canada Legal Services / Services juridiques - Santé Canada  
tel: 613-941-8053  
fax: 613-954-9485  
e-mail: [sherrey.collier@hc-sc.gc.ca](mailto:sherrey.collier@hc-sc.gc.ca)

Solicitor-Client Privilege/Protected  
Secret professionnel de l'avocat/Protégé







**Chantal**  
Tél/Tel: 613 946-5682  
Télec/Fax: 613 954-9485

**Solicitor-Client Privilege/Protected**

This message is intended for the use of the individual or entity to which it is addressed and may contain information that is privileged or confidential and exempt from disclosure under applicable law. Unauthorized disclosure, copying or re-transmission is prohibited. Modification of the transmission is prohibited. If you have received this transmission in error, please notify me immediately by sending me a return e-mail copy. Then, delete the original message. Thank you.

**Secret professionnel de l'avocat/Protégé**

Cette communication est exclusivement destinée à l'individu ou l'entité à qui elle est adressée. Elle peut contenir de l'information privilégiée, confidentielle et ne pouvant être divulguée selon la loi applicable à l'espèce. Toute divulgation non-autorisée est défendue. Toute copie non-autorisée ou re-transmission non-autorisée de ce message sont défendues. Si vous avez reçu cette communication par erreur, veuillez m'en aviser immédiatement par retour de courriel. Puis, supprimez le courriel reçu. Merci

----- Forwarded by Sherrey Collier/HC-SC/GC/CA on 03/02/2011 12:39 PM -----

**Sherrey  
Collier/HC-SC/GC/CA**  
03/02/2011 10:45 AM

To Barbara Ursel/HC-SC/GC/CA@HWC  
cc "Barbara Ursel" <Barbara\_Ursel@hc-sc.gc.ca>, Diane  
Labelle/HC-SC/GC/CA@HWC, "Jana Dinelle"  
<Jana\_Dinelle@hc-sc.gc.ca>, Nancy  
Othmer/HC-SC/GC/CA@HWC, Paula  
Fewer/HC-SC/GC/CA@HWC  
Subject Re: Fw: FOR APPROVAL: Salvia NR, MLs, NOI and IYH  
article

Barbara Ursel/HC-SC/GC/CA

Nancy Othmer/HC-SC/GC/CA

**Nancy  
Othmer/HC-SC/GC/CA**  
03/02/2011 10:20 AM

To "Barbara Ursel" <Barbara\_Ursel@hc-sc.gc.ca>  
cc "Jana Dinelle" <Jana\_Dinelle@hc-sc.gc.ca>  
Subject Fw: FOR APPROVAL: Salvia NR, MLs, NOI and IYH article

Elizabeth Keeping

----- Original Message -----

**From:** Elizabeth Keeping  
**Sent:** 2011-02-03 10:13 AM EST  
**To:** Nancy Othmer  
**Cc:** David Gotlieb  
**Subject:** Fw: FOR APPROVAL: Salvia NR, MLs, NOI and IYH article

Hi Nancy,

The attached documents require legal review/approval as soon as possible.

I'm not sure if you're the correct person - if not, would you be able to pass along and let me know?

Thanks much,  
Beth

----- Forwarded by Elizabeth Keeping/HC-SC/GC/CA on 2011-02-03 10:11 AM -----

**From:** Christine Roush/HC-SC/GC/CA  
**To:** Elizabeth Keeping/HC-SC/GC/CA@HWC  
**Date:** 2011-02-02 12:02 PM  
**Subject:** Re: Fw: FOR APPROVAL: Salvia NR, MLs, NOI and IYH article

---

[attachment "DRAFT Salvia NOI\_Feb 2 EN.doc" deleted by Christine Roush/HC-SC/GC/CA]  
[attachment "Salvia NR MHPD Revisions 2011 02.02.doc" deleted by Christine Roush/HC-SC/GC/CA]  
[attachment "Salvia MLs\_Feb2\_(clean) NHPD edit.doc" deleted by Christine Roush/HC-SC/GC/CA]  
[attachment "IYH Salvia divinatorum\_v23 Feb2(clean).doc" deleted by Christine Roush/HC-SC/GC/CA]

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
Health Canada/Santé Canada  
Tel/Tél : (613) 954-0712/Cell: (613) 219-7194  
Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca

Elizabeth Keeping Here's the approvals (and comments, if any) fro... 2011-02-02 11:18:23 AM

From: Elizabeth Keeping/HC-SC/GC/CA  
To: "Senior Communications Advisor Christine Roush" <christine.roush@hc-sc.gc.ca>  
Date: 2011-02-02 11:18 AM  
Subject: Fw: FOR APPROVAL: Salvia NR, MLs, NOI and IYH article

Here's the approvals (and comments, if any) from Inspectorate.  
I'm just on BB today, so can't review them.

B

Diane Marcheterre

----- Original Message -----

**From:** Diane Marcheterre  
**Sent:** 2011-02-02 11:15 AM EST  
**To:** Elizabeth Keeping  
**Cc:** Aldege Bellefeuille; Laura Francis-Lamb; Ian Grimwood; Chantal Ricard-Lacroix; Brenda Lajeunesse; Sharon Mullin; Diana Dowthwaite  
**Subject:** Fw: FOR APPROVAL: Salvia NR, MLs, NOI and IYH article  
Director Sharon Mullin and DG Diana Dowthwaith **Approved**

Diane Marcheterre  
Executive Assistant  
Compliance and Enforcement Coordination Division  
Tel: 613-952-5756  
Fax: 613-952-9805

----- Forwarded by Diane Marcheterre/HC-SC/GC/CA on 2011-02-02 11:11 AM -----

From: Ian Grimwood/HC-SC/GC/CA  
To: Sharon Mullin/HC-SC/GC/CA@HWC  
Cc: Diane Marcheterre/HC-SC/GC/CA@HWC  
Date: 2011-02-01 12:22 PM  
Subject: Fw: FOR APPROVAL: Salvia NR, MLs, NOI and IYH article

As requested incorporated the specific changes..

Here are the general comments:

- Dates of posting NOI need to be confirmed and made consistent through out all documents.

[attachment "DRAFT Salvia NOI\_Jan 25 EN (DCVI comments).wpd" deleted by Christine Roush/HC-SC/GC/CA] [attachment "IYH Salvia divinorum\_v19 Jan 27 (DCVIU Comments).doc" deleted by Christine Roush/HC-SC/GC/CA] [attachment "Salvia NR\_Jan 27\_OCS (clean) (DCVI comments).doc" deleted by Christine Roush/HC-SC/GC/CA] [attachment "Salvia MLs\_Jan27\_OCS(clean) (DCVI Comments).doc" deleted by Christine Roush/HC-SC/GC/CA]

Ian Grimwood

a/Manager / i/Gestionnaire

Drug Compliance Verification & Investigation Unit/ Enquête et vérification de conformité des drogues

Inspectorate / Inspectorat

Health Products and Food Branch / Direction générale des produits de santé et des aliments

Tel:(613)952-9906

Fax:(613)946-5636

----- Forwarded by Ian Grimwood/HC-SC/GC/CA on 2011-02-01 11:43 AM -----

From: Ian Grimwood/HC-SC/GC/CA  
To: Sharon Mullin/HC-SC/GC/CA@HWC  
Cc: Diane Marcheterre/HC-SC/GC/CA@HWC  
Date: 2011-01-30 06:14 PM  
Subject: Fw: FOR APPROVAL: Salvia NR, MLs, NOI and IYH article

---

For DIR approval,

I have review the documents and Collin's comments and approve.

General Comment

- Dates to posting NOI need to be confirmed and made consistent through out all documents.

IYH Article

- Statement under "Minimizing your Risk"of "Just because a drug is plant-based or "natural", does not mean that it is safe." needs to be run by NHPD as not sure this is consistent with they wording.."
- Statement of Legal Status need to confirm date with NHPD.
- Under the sentence about compliance actions should mention NHPRs in addition to FDA.
- Under "Need More Info" - complaints about unauthorised sale cannot be "made" to the link. That link goes to consumer complaints doc. Wording should say something like "information on how to submit a complaint about the unauthorized sale of ....can be found at: [link](#)"

NOI Document

- In paragraph 2 may want to explicitly say "short and long term" for the health risks?

ML

- Propose the first Supplemental message be reworded to :  
The plant *Salvia divinorum* is not currently regulated under the CDSA despite being a hallucinogen. Currently products containing *Salvia divinorum* that indicate its halocogenic properties would meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations* .
- I also agree with Collin and Dina that using the word illegal in Q4 is misleading..

NR

- I agree with Collin for consistency sake.

Ian Grimwood  
a/Manager / i/Gestionnaire  
Drug Compliance Verification & Investigation Unit/ Enquête et vérification de conformité des drogues  
Inspectorate / Inspectorat  
Health Products and Food Branch / Direction générale des produits de santé et des aliments  
Tel:(613)952-9906  
Fax:(613)946-5636

----- Forwarded by Ian Grimwood/HC-SC/GC/CA on 2011-01-30 05:35 PM -----

From: Collin Pinto/HC-SC/GC/CA  
To: Ian Grimwood/HC-SC/GC/CA@HWC  
Cc: Diane Marcheterre/HC-SC/GC/CA@HWC  
Date: 2011-01-29 12:25 AM  
Subject: Re: Fw: FOR APPROVAL: Salvia NR, MLs, NOI and IYH article

---

**Draft NOI - looks fine**

**MLs** - agree with suggested wording in first comment under "Key Messages". Maybe it's getting late but the first bullet under "supplementary messages" seems confusing. Also, I do not like the wording at the end of question 4 - "...why isn't it illegal" - this was my comment from last week. Fact is, it is a contravention to sell if unauthorised (i.e. no NPN) and no salvia product has ever been issued an NPN. Not sure why we are saying "why isn't it illegal" in the question when all salvia products essentially are.

**Salvia News Release** - see second last para - minor but may want to include "(or cultivation)" next to production as this is how it is written in the draft NOI. Otherwise looks fine.

**IYH Article** - will need to confirm dates for official NOI align with one another in all of these documents: IYH says Feb 5 and NR says Feb 12. Also, under "Need More Info" - complaints about unauthorized sale cannot be "made" to the link. That link goes to consumer complaints doc. Wording should say something like "information on how to submit a complaint about the unauthorized sale of ....can be found at: [link](#)"

---

Diane Marcheterre Hi just before you go far far away :(

2011-01-28 01:26:01 PM



**Fw: Salvia NR, MLs, NOI and IYH article - DLSU input**  
Christine Roush to: Stephanie Chandler  
Cc: Denis Arsenault

2011-02-04 10:42 AM

FYI

Christine Roush  
Senior Communications Advisor/

From: Christine Roush/HC-SC/GC/CA  
To: Suzanne Desjardins/HC-SC/GC/CA@HWC  
Date: 2011-02-04 10:41 AM  
Subject: Fw: Salvia NR, MLs, NOI and IYH article - DLSU input

Hi Suzanne - can you please see the comments below from Sherrey Collier, Legal Counsel for HPFB on the inconsistency in the way we refer to the effects of Salvia in these documents. Can you please let me know how you would like to revise the documents so we are being consistent in our messaging about the effects of Salvia. The package has already been approved by Cathy, and the three DGs in HPFB, so we will provide a copy to her again as an FYI only. Jocelyn's group is making the required changes to the NOI and will have Cathy re-approve this document. The NHPD has approved the deletion of the hallucinogenic phrase below in Sherrey's email. thx.

Christine Roush  
Senior Communications Advisor/

From: Jocelyn Kula/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC, stephanie.chandler@hc-sc.gc.ca  
Date: 2011-02-03 05:37 PM  
Subject: Fw: Salvia NR, MLs, NOI and IYH article - DLSU input

Just got this. I see that some changes are required, but am not sure at this point if they have to go back through Cathy or not. Perhaps you can read through and let me know what you think....

JK

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224  
----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2011-02-03 05:31 PM -----

From: Sherrey Collier/HC-SC/GC/CA  
To: Elizabeth Keeping/HC-SC/GC/CA@HWC  
Cc: Jocelyn Kula/HC-SC/GC/CA@HWC, Diane Labelle/HC-SC/GC/CA@HWC, Chantal Trepanier/HC-SC/GC/CA@HWC, Nancy Othmer/HC-SC/GC/CA@HWC  
Date: 2011-02-03 05:05 PM  
Subject: Salvia NR, MLs, NOI and IYH article - DLSU input



**Fw: Salvia NR, MLs, NOI and IYH article - DLSU input**  
Denis Arsenault to: Jocelyn Kula  
Cc: Stephanie Chandler

2011-02-04 10:46 AM

We are revising the NOI now - you should get it from Stephanie any minute.

Denis

Denis Arsenault, A/Manager / Gestionnaire p.i.  
Regulatory Policy Division /  
Division des politiques réglementaires,  
Office of Controlled Substances /  
Bureau des substances contrôlées,  
Health Canada / Santé Canada  
Tel/Tél: (613) 957-6828  
Fax / Télécopieur : (613) 946-4224  
E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca

---- Forwarded by Denis Arsenault/HC-SC/GC/CA on 2011-02-04 10:45 AM ----

From: Christine Roush/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: "Denis Arsenault" <denis.arsenault@hc-sc.gc.ca>, "Stephanie Chandler" <stephanie.chandler@hc-sc.gc.ca>  
Date: 2011-02-04 10:33 AM  
Subject: Re: Fw: Fw: Salvia NR, MLs, NOI and IYH article - DLSU input

Hi all - could you please share the updated NOI with me, and I will update the rest of the products.  
Thanks,

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
Health Canada/Santé Canada  
Tel/Tél : (613) 954-0712/Cell: (613) 219-7194  
Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca

Jocelyn Kula

great! Denis/ Stephanie- I think we still have to c...

2011-02-04 10:01:50 AM

From: Jocelyn Kula/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Cc: "Denis Arsenault" <denis.arsenault@hc-sc.gc.ca>, "Stephanie Chandler" <stephanie.chandler@hc-sc.gc.ca>  
Date: 2011-02-04 10:01 AM  
Subject: Re: Fw: Fw: Salvia NR, MLs, NOI and IYH article - DLSU input

great!

Denis/ Stephanie- I think we still have to change the NOI, and I assume that means Cathy will have to resign. That means another docket, which we will need to get Arafo to rush as today is her last day. Please add note to docket explaining why she needs to sign again.

JK

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224


Christine Roush

Jocelyn - NHPD is ok with dropping the hallucin...

2011-02-04 08:55:50 AM





**Re: Revised Salvia NOI**   
Jocelyn Kula to: Stephanie Chandler  
Cc: CSTD-OCS-DO, Denis Arsenault

2011-02-04 11:10 AM

there were no track changes but looks good to me

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

---

Stephanie Chandler Hi Jocelyn, We have revised the Salvia NOI ac... 2011-02-04 10:51:47 AM

From: Stephanie Chandler/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC, CSTD-OCS-DO  
Date: 2011-02-04 10:51 AM  
Subject: Revised Salvia NOI

---

Hi Jocelyn,

We have revised the Salvia NOI according to the recommendations from legal. Denis has requested that I send these tracked versions to you for review prior to us sending it up to DO in a docket.

[attachment "DRAFT Salvia NOI\_Feb 4 FR\_tracked.wpd" deleted by Jocelyn Kula/HC-SC/GC/CA]  
[attachment "DRAFT Salvia NOI\_Feb 4 EN\_tracked.wpd" deleted by Jocelyn Kula/HC-SC/GC/CA]

Thanks,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca



**Re: NOI - signed**  
Stephanie Szick to: Jocelyn Kula  
Cc: Arafo Talane, Stephanie Chandler

2011-02-04 01:13 PM

Great. Perfect. Let me know otherwise.

Jocelyn Kula No need for docs to be re-approved. Comms co... 2011-02-04 01:11:33 PM

From: Jocelyn Kula/HC-SC/GC/CA  
To: Stephanie Szick/HC-SC/GC/CA@HWC  
Cc: Arafo Talane/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2011-02-04 01:11 PM  
Subject: Re: NOI - signed

No need for docs to be re-approved. Comms consultation with OCS and NHPD were that changes did not require re-approval but will go back through as an FYI only. My understanding from Christine is that this means we are still on track for Feb 19, but perhaps Stephanie C can double-check.

JK

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

Stephanie Szick just spoke with Arafo - ready for pick up. Cathy's... 2011-02-04 01:06:41 PM

From: Stephanie Szick/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC  
Cc: Arafo Talane/HC-SC/GC/CA@HWC  
Date: 2011-02-04 01:06 PM  
Subject: NOI - signed

just spoke with Arafo - ready for pick up.

Cathy's asked if everything still in line for a Feb. 19 publishing - all comms products lined up (changes made per legal feedback and the NOI)? Please let me know if the comms products are coming back to DGO, in which case Brenda will sign off as A/DG.

Thanks,

Stephanie Szick  
Director General's Office / Bureau du directeur général  
Controlled Substances & Tobacco Directorate (CSTD) /  
Direction des substances contrôlées et de la lutte au tabagisme (DSCLT)  
Health Canada / Santé Canada  
Tel / Tél: (613) 948-8651



**Re: Revised Salvia NOI** 

Stephanie Chandler to: Christine Roush

2011-02-04 01:18 PM

Cc: Jocelyn Kula, "Denis Arsenault", "Stephanie Chandler", Stephanie Szick

---

1 attachment



DRAFT Salvia NOI\_Feb 4 EN\_clean.wpd

---

Hi Christine,

This is the revised NOI that Cathy has just signed. We have not included the suggested reference by HPFB to include "short and long-term effects" and we have changed "The regulation of Salvia" to "The scheduling of Salvia" in the fifth paragraph. We have also revised the OCS email for consistency, however I don't believe any of the comms products include our email.

DGO would also like to confirm that it is not necessary for Cathy to re-approve any of the comms products and that we are still on track as far as comms is concerned for publication on Feb 19. Could you please confirm?

Thanks,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

From: Christine Roush/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: "Denis Arsenault" <denis.arsenault@hc-sc.gc.ca>, "Stephanie Chandler" <stephanie.chandler@hc-sc.gc.ca>  
Date: 2011-02-04 10:33 AM  
Subject: Re: Fw: Fw: Salvia NR, MLs, NOI and IYH article - DLSU input

Hi all - could you please share the updated NOI with me, and I will update the rest of the products.  
Thanks,

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
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Tel/Tél : (613) 954-0712/Cell: (613) 219-7194  
Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca

From: Jocelyn Kula/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Cc: "Denis Arsenault" <denis.arsenault@hc-sc.gc.ca>, "Stephanie Chandler" <stephanie.chandler@hc-sc.gc.ca>  
Date: 2011-02-04 10:01 AM  
Subject: Re: Fw: Fw: Salvia NR, MLs, NOI and IYH article - DLSU input

great!

Denis/ Stephanie- I think we still have to change the NOI, and I assume that means Cathy will have to resign. That means another docket, which we will need to get Arafo to rush as today is her last day. Please add note to docket explaining why she needs to sign again.

JK

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

From: Christine Roush/HC-SC/GC/CA  
To: "Jocelyn Kula" <jocelyn.kula@hc-sc.gc.ca>  
Cc: "Denis Arsenault" <denis.arsenault@hc-sc.gc.ca>, "Stephanie Chandler" <stephanie.chandler@hc-sc.gc.ca>  
Date: 2011-02-04 08:55 AM  
Subject: Fw: Fw: Salvia NR, MLs, NOI and IYH article - DLSU input

Jocelyn - NHPD is ok with dropping the hallucinogen statement. I'll make the rest of the changes to the docs and keep them moving.  
That was easier than I expected.

C

----- Original Message -----

**From:** Elizabeth Keeping

**Sent:** 2011-02-04 08:46 AM EST

**To:** Christine Roush

**Subject:** Re: Fw: Salvia NR, MLs, NOI and IYH article - DLSU input

Hey Christine,

NHPD says it's okay to drop the hallucinogen statement - per legal advice.

Cheers,  
Beth

From: Christine Roush/HC-SC/GC/CA  
To: "Elizabeth Keeping" <elizabeth.keeping@phac-aspc.gc.ca>  
Date: 2011-02-04 07:40 AM  
Subject: Fw: Salvia NR, MLs, NOI and IYH article - DLSU input

Hi Beth - I will address points 1 and 2 below in Sherrey's email as well as the recommended changes by Chantale Trepanier. Unfortunately that leaves you with the most difficult issue to resolve with your client in point 3 of Sherrey's email. I am home sick today so doubt much will move forward on this til Monday.

Christine

----- Original Message -----

**From:** Jocelyn Kula

**Sent:** 2011-02-03 05:37 PM EST

**To:** Christine Roush

**Cc:** Denis Arsenault; Stephanie Chandler

**Subject:** Fw: Salvia NR, MLs, NOI and IYH article - DLSU input

Just got this. I see that some changes are required, but am not sure at this point if they have to go back through Cathy or not. Perhaps you can read through and let me know what you think....

DEPARTMENT OF HEALTH

CONTROLLED DRUGS AND SUBSTANCES ACT

*Notice to interested parties - Proposal regarding the addition of Salvia divinorum and salvinorin A to Schedule III to the Controlled Drugs and Substances Act*

This notice provides interested stakeholders with the opportunity to provide comments on Health Canada's proposal to add the plant *Salvia divinorum* (*S. divinorum*) and its main active ingredient salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA). Stakeholders may also identify themselves for inclusion in any future consultation.

*S. divinorum* is a species of sage belonging to the mint family. Its leaves are generally chewed or smoked to obtain psychotropic effects. While uncertainty remains surrounding the health risks of *S. divinorum*, known effects are reported to be short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant. Neither *S. divinorum* nor salvinorin A are currently included in any of the Schedules to the CDSA.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. *S. divinorum* is widely touted as a "legal" hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs.<sup>1</sup> Results from the *Canadian Alcohol and Drug Use Monitoring Survey* (CADUMS) reveal that, in 2009, 1.6% of Canadians aged 15 years and older reported having used *S. divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24 years. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *S. divinorum* in the past year. Moreover, the *2009 Ontario Student Drug Use and Health Survey* (OSDUHS) indicated that 5.4% of Ontario students in grades 7-12 reported ever using *S. divinorum* and 4.4% of these students reported using this substance in the past year. Because its psychoactive effects resemble those of other substances included in Schedule III to the CDSA such as lysergic acid diethylamide (LSD) and psilocybin, Health Canada is concerned that the ready availability and use of *S. divinorum* poses a risk to the health and safety of Canadians, particularly youth.

While *S. divinorum* and salvinorin A are not currently included in any of the United Nations Drug Control Conventions, a number of countries have chosen to regulate one or both as controlled substances. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden have all placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. Some American states have also implemented laws restricting their use, sale and/or distribution.

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<sup>1</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.

Including these substances within Schedule III to the CDSA would prohibit: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation). The scheduling of *S. divinorum* and salvinorin A under the CDSA will also enable law enforcement agencies to take action against suspected illegal activities involving these substances.

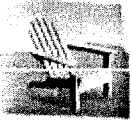
As this action is not intended to interfere with the use and availability of *S. divinorum* and/or salvinorin A for legitimate medical, scientific or industrial purposes, Health Canada is seeking information from stakeholders on whether there are any such uses in Canada. Information received in response to this notice will be instrumental in determining appropriate regulation under the CDSA.


The publication of this notice begins a 30-day comment period. There will be additional opportunities to provide comments as the federal regulatory process progresses.

If you are interested in this process or have comments on this proposal, please contact Stephanie Chandler, Regulatory Policy Division, Office of Controlled Substances, Address Locator: 3503D, 123 Slater St., Ottawa, Ontario, Canada, K1A 1B9, by fax at (613) 946-4224 or by email at [OCS.Policy.and.Regulatory.Affairs@hc-sc.gc.ca](mailto:OCS.Policy.and.Regulatory.Affairs@hc-sc.gc.ca).

Cathy A. Sabiston  
Director General  
Controlled Substances and Tobacco Directorate

Date \_\_\_\_\_



**Re: Fw: Revised Salvia NOI**   
Nicole Prentice to: Stephanie Chandler  
Cc: Christine Roush

2011-02-04 02:10 PM

Sorry Stephanie, I can't help you out on this one. Christine took over on all the salvia items, so I am a bit out of the loop. She has been checking her berry throughout the day, so she may respond shortly.

Have a good day.

**Nicole Prentice**

Junior Communications Officer | Agente junior des Communications  
Regulatory Communications and Media Relations Division | Division des communications  
réglementaires et des relations avec les médias  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires  
publiques, de la consultation et des communications  
Health Canada | Santé Canada  
Tel: 613.941.3107  
Fax: 613.948.8085

Stephanie Chandler Nicole, Just got Christine's out of office messa... 2011-02-04 01:21:49 PM

From: Stephanie Chandler/HC-SC/GC/CA  
To: Nicole Prentice/HC-SC/GC/CA@HWC  
Date: 2011-02-04 01:21 PM  
Subject: Fw: Revised Salvia NOI

Nicole,

Just got Christine's out of office message, so an FYI, and not sure if you can confirm the question from DGO below? If not we will wait for a reply from Christine.

Thanks,

Stephanie

----- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2011-02-04 01:21 PM -----

From: Stephanie Chandler/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Cc: Jocelyn Kula/HC-SC/GC/CA@HWC, "Denis Arsenault" <denis.arsenault@hc-sc.gc.ca>, "Stephanie Chandler" <stephanie.chandler@hc-sc.gc.ca>, Stephanie Szick/HC-SC/GC/CA@HWC  
Date: 2011-02-04 01:18 PM  
Subject: Re: Revised Salvia NOI

Hi Christine,

This is the revised NOI that Cathy has just signed. We have not included the suggested reference by HPFB to include "short and long-term effects" and we have changed "The regulation of Salvia" to "The scheduling of Salvia" in the fifth paragraph. We have also revised the OCS email for consistency, however I don't believe any of the comms products include our email.

[attachment "DRAFT Salvia NOI\_Feb 4 EN\_clean.wpd" deleted by Nicole Prentice/HC-SC/GC/CA]



DGO would also like to confirm that it is not necessary for Cathy to re-approve any of the comms products and that we are still on track as far as comms is concerned for publication on Feb 19. Could you please confirm?

Thanks,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

Christine Roush	Hi all - could you please share the updated NOI...	2011-02-04 10:33:36 AM
Jocelyn Kula	great! Denis/ Stephanie- I think we still have to c...	2011-02-04 10:01:50 AM
Christine Roush	Jocelyn - NHPD is ok with dropping the hallucin...	2011-02-04 08:55:50 AM

DEPARTMENT OF HEALTH

CONTROLLED DRUGS AND SUBSTANCES ACT

*Notice to interested parties - Proposal regarding the addition of Salvia divinorum and salvinorin A to Schedule III to the Controlled Drugs and Substances Act*

This notice provides interested stakeholders with the opportunity to provide comments on Health Canada's proposal to add the plant *Salvia divinorum* (*S. divinorum*) and its main active ingredient salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA). Stakeholders may also identify themselves for inclusion in any future consultation.

*S. divinorum* is a species of sage belonging to the mint family. Its leaves are generally chewed or smoked to obtain psychotropic effects. While uncertainty remains surrounding the health risks of *S. divinorum*, known effects are reported to be short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant. Neither *S. divinorum* nor salvinorin A are currently included in any of the Schedules to the CDSA.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. *S. divinorum* is widely touted as a "legal" hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs.<sup>1</sup> Results from the *Canadian Alcohol and Drug Use Monitoring Survey* (CADUMS) reveal that, in 2009, 1.6% of Canadians aged 15 years and older reported having used *S. divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24 years. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *S. divinorum* in the past year. Moreover, the *2009 Ontario Student Drug Use and Health Survey* (OSDUHS) indicated that 5.4% of Ontario students in grades 7-12 reported ever using *S. divinorum* and 4.4% of these students reported using this substance in the past year. Because its psychoactive effects resemble those of other substances included in Schedule III to the CDSA such as lysergic acid diethylamide (LSD) and psilocybin, Health Canada is concerned that the ready availability and use of *S. divinorum* poses a risk to the health and safety of Canadians, particularly youth.

While *S. divinorum* and salvinorin A are not currently included in any of the United Nations Drug Control Conventions, a number of countries have chosen to regulate one or both as controlled substances. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden have all placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. Some American states have also implemented laws restricting their use, sale and/or distribution.

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<sup>1</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.

Including these substances within Schedule III to the CDSA would prohibit: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation). The scheduling of *S. divinorum* and salvinorin A under the CDSA will also enable law enforcement agencies to take action against suspected illegal activities involving these substances.

As this action is not intended to interfere with the use and availability of *S. divinorum* and/or salvinorin A for legitimate medical, scientific or industrial purposes, Health Canada is seeking information from stakeholders on whether there are any such uses in Canada. Information received in response to this notice will be instrumental in determining appropriate regulation under the CDSA.

The publication of this notice begins a 30-day comment period. There will be additional opportunities to provide comments as the federal regulatory process progresses.

If you are interested in this process or have comments on this proposal, please contact Stephanie Chandler, Regulatory Policy Division, Office of Controlled Substances, Address Locator: 3503D, 123 Slater St., Ottawa, Ontario, Canada, K1A 1B9, by fax at (613) 946-4224 or by email at [OCS.Policy.and.Regulatory.Affairs@hc-sc.gc.ca](mailto:OCS.Policy.and.Regulatory.Affairs@hc-sc.gc.ca).



Cathy A. Sabiston  
Director General  
Controlled Substances and Tobacco Directorate

Date Feb 4 / 11

## MINISTÈRE DE LA SANTÉ

### LOI RÉGLEMENTANT CERTAINES DROGUES ET AUTRES SUBSTANCES

*Avis aux parties intéressées - Proposition concernant l'ajout de Salvia divinorum et de la salvinorine A à l'annexe III de la Loi réglementant certaines drogues et autres substances*

Cet avis informe les parties intéressées de la possibilité de commenter la proposition de Santé Canada d'ajouter la plante *Salvia divinorum* (*S. divinorum*) et son principal ingrédient actif, la salvinorine A, à l'annexe III de la *Loi réglementant certaines drogues et autres substances* (LRCDas). Les parties intéressées ont aussi l'occasion d'ajouter leur nom pour toute consultation future.

*S. divinorum* est une espèce de sauge appartenant à la famille des menthes. Généralement, ses feuilles sont mâchées ou fumées pour obtenir des effets psychotropes. Alors qu'une incertitude subsiste quant aux risques pour la santé découlant de la consommation de *S. divinorum*, les effets de cette consommation sont connus pour être brefs et comprennent des hallucinations, une dysphorie, des expériences extra-corporel, l'inconscience et une perte de mémoire à court terme. Les effets, qui varient d'une personne à l'autre, sont également souvent décrits comme déplaisants. Ni la *S. divinorum* ni la salvinorine A ne sont actuellement incluses dans les annexes de la LRCDas.

Des rapports ont récemment été publiés indiquant que des adolescents et des jeunes adultes canadiens consomment de la *S. divinorum* pour sa capacité à produire des hallucinations. *S. divinorum* est largement vantée comme un hallucinogène "légal" sur Internet et a aussi été signalée comme l'un des produits à base d'herbes médicinales les plus courants utilisés comme option alternative aux drogues illicites.<sup>1</sup> Les conclusions tirées de l'*Enquête de surveillance canadienne de la consommation d'alcool et de drogues* (ESCCAD) révèlent que, en 2009, 1,6 % des Canadiens âgés de 15 ans ou plus ont déclaré avoir consommé de la *S. divinorum* au moins une fois dans leur vie, avec un taux de consommation plus important (7,3%) parmi les jeunes âgés de 15 à 24 ans. Les résultats de l'*Enquête sur le tabagisme chez les jeunes* de 2008-2009 au Canada montrent également que 5 % des jeunes de 15 ans ont consommé de la *S. divinorum* au cours de la dernière année. De plus, le *Sondage sur la consommation de drogues et la santé des élèves de l'Ontario* (SCDSEO) de 2009 indique que 5,4 % des élèves de l'Ontario des classes scolaires 7 à 12 ont déclaré avoir déjà consommé de la *S. divinorum* et que 4,4 % de ces élèves ont indiqué avoir consommé cette substance au cours de la dernière année. Puisque ses effets psychoactifs ressemblent à ceux d'autres substances comprises dans l'annexe III de la LRCDas, comme l'acide lysergique diéthylamide (LSD) et la psilocybine, Santé Canada craint que la disponibilité immédiate et la consommation de *S. divinorum* ne posent un risque pour la santé et la sécurité des Canadiens, en particulier pour celles des jeunes.

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<sup>1</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. Oct 2005, vol. 39, no<sup>o</sup>10, pp. 1634-1639.

Alors que la *S. divinorum* et la salvinorine A ne sont actuellement comprises dans aucune des Conventions de l'Organisation des Nations Unies sur le contrôle des drogues, de nombreux pays ont choisi de réglementer une de ces substances, ou les deux, comme substance désignée. L'Australie, la Belgique, le Danemark, la Finlande, l'Allemagne, l'Italie, le Japon, la Corée du Sud, l'Espagne et la Suède ont tous établi des contrôles sur les importations ou la vente, ou les deux, de *S. divinorum* et/ou de salvinorine A. Certains États américains ont aussi mis en oeuvre des lois restreignant son utilisation, sa vente et/ou sa distribution.

Le fait d'ajouter ces substances à l'annexe III de la LRCDas en interdirait la possession, le commerce, la possession aux fins de commerce, l'importation, l'exportation, la possession aux fins d'exportation et la production (ou la culture). La mise en annexe de la *S. divinorum* et de la salvinorine A sous la LRCDas permettrait également aux organismes d'application de la loi de prendre des mesures contre les activités illicites présumées liées à ces substances.

Étant donné que cette mesure ne vise pas à interférer avec l'utilisation et la disponibilité de la *S. divinorum* et/ou de la salvinorine A à des fins médicales, scientifiques ou industrielles légitimes, Santé Canada sollicite de l'information aux parties intéressées sur les possibilités de ces types d'utilisation au Canada. L'information reçue en réponse à cet avis sera déterminante dans la rédaction d'un règlement approprié conformément à la LRCDas.

La publication de cet avis entame une période de commentaires de 30 jours. Il y aura des occasions supplémentaires de fournir des commentaires au fur et à mesure que progresse le processus de réglementation fédéral.

Si vous êtes intéressé par ce processus ou que vous avez des commentaires sur cette proposition, veuillez communiquer avec Stephanie Chandler de la Division de la politique réglementaire, du Bureau des substances contrôlées, situé au : 3503D, 123, rue Slater, Ottawa (Ontario), Canada, K1A 1B9, par télécopieur au (613) 946-4224 ou par courriel au [OCS.Policy.and.Regulatory.Affairs@hc-sc.gc.ca](mailto:OCS.Policy.and.Regulatory.Affairs@hc-sc.gc.ca).



Cathy A. Sabiston  
Directrice générale  
Direction des substances contrôlées et de la lutte au  
tabagisme

Date

Feb 4/11



**Re: Revised Salvia NOI** 

Suzanne Desjardins to: Jocelyn Kula

2011-02-07 07:56 AM

Cc: stephanie.chandler, Christine Roush, Denis Arsenault, Stephanie Szick

thank you both for the clarification

Suzanne

Jocelyn Kula

Suzanne Only to echo what Stephanie just said,...

2011-02-04 03:14:25 PM

From: Jocelyn Kula/HC-SC/GC/CA  
To: Suzanne Desjardins/HC-SC/GC/CA@HWC  
Cc: stephanie.chandler@hc-sc.gc.ca, Christine Roush/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, Stephanie Szick/HC-SC/GC/CA@HWC  
Date: 2011-02-04 03:14 PM  
Subject: Re: Revised Salvia NOI

Suzanne

Only to echo what Stephanie just said, the NOI below has the wording that you recommended in it, and hence that is why we went ahead and got Cathy to resign. To be clear, the only reason we had to get her to resign was because Legal advised that we should use the word "schedule" or "control" rather than "regulate" because at this point, we are not recommending including Salvia in a schedule to any of the regulations.

JK

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

Stephanie Chandler Hi Suzanne, As far as the NOI is concerned w...

2011-02-04 03:08:42 PM

From: Stephanie Chandler/HC-SC/GC/CA  
To: Suzanne Desjardins/HC-SC/GC/CA@HWC  
Cc: Christine Roush/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Stephanie Szick/HC-SC/GC/CA@HWC  
Date: 2011-02-04 03:08 PM  
Subject: Re: Revised Salvia NOI

Hi Suzanne,

As far as the NOI is concerned we have stuck with the original wording from the version you reviewed and we incorporated the two changes you had suggested. Please note that Cathy has already approved the version attached below for your information.

[attachment "DRAFT Salvia NOI\_Feb 4 EN\_clean.wpd" deleted by Suzanne Desjardins/HC-SC/GC/CA]

I think there may be some confusion regarding a previous version that HPFB commented on, so feel free

to call me if you have any questions/concerns.

Regards,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

---

Suzanne Desjardins Hi All, I wouldn't mind commenting, but the NO... 2011-02-04 02:58:10 PM

From: Suzanne Desjardins/HC-SC/GC/CA  
To: Stephanie Chandler/HC-SC/GC/CA@HWC  
Cc: Christine Roush/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Stephanie Szick/HC-SC/GC/CA@HWC  
Date: 2011-02-04 02:58 PM  
Subject: Re: Revised Salvia NOI

---

Hi All,

I wouldn't mind commenting, but the NOI is no longer attached.

Thanks

Suzanne

---

Stephanie Chandler Hi Christine, Hope you are feeling better soon! 2011-02-04 02:09:37 PM

From: Stephanie Chandler/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Stephanie Szick/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC  
Date: 2011-02-04 02:09 PM  
Subject: Re: Revised Salvia NOI

---

Hi Christine,

**s.19(1)**

The reason we did not include the "long-term effects" statement in the NOI was to keep it consistent with the MLs and IYH as pointed out by Sherrey in Legal:

When talking about the known effects of salvia, the documents are somewhat inconsistent. For example, in the *Notice to Interested Parties*, it says "known effects are reported to be short and long-term in nature"; the Medial Lines under Key Messages, News Release and IYH say "little is known about the long-term effects of these substances on the brain and body"; and finally, in the background: "These effects are short-acting in nature..."

Throughout the analysis of Salvia there has been little information with regard to the long-term effects and I believe that the current IYH and MLs reflect this (as does the final NOI). Suzanne also reviewed the NOI in January when it had the wording "While uncertainty remains surrounding the health risks of *S. divinorum*, known effects are reported to be short-acting in nature..." which is what we have kept for the final version. Therefore I don't believe that the comms products need to be revised in this particular regard.

I have cc'ed Suzanne so that she may provide any comments she might have.

Regards,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

Christine Roush Thanks Stephanie - and w... 2011-02-04 01:44:07 PM  
Stephanie Chandler

s.19(1)

----- Original Message -----

**From:** Stephanie Chandler  
**Sent:** 2011-02-04 01:17 PM EST  
**To:** Christine Roush  
**Cc:** Jocelyn Kula; Denis Arsenault; Stephanie Chandler; Stephanie Szick  
**Subject:** Re: Revised Salvia NOI

Hi Christine,

This is the revised NOI that Cathy has just signed. We have not included the suggested reference by HPFB to include "short and long-term effects" and we have changed "The regulation of Salvia" to "The scheduling of Salvia" in the fifth paragraph. We have also revised the OCS email for consistency, however I don't believe any of the comms products include our email.

[attachment "DRAFT Salvia NOI\_Feb 4 EN\_clean.wpd" deleted by Christine Roush/HC-SC/GC/CA]

DGO would also like to confirm that it is not necessary for Cathy to re-approve any of the comms products and that we are still on track as far as comms is concerned for publication on Feb 19. Could you please confirm?

Thanks,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées





**Re: Revised Salvia NOI**

Christine Roush to: Suzanne Desjardins

2011-02-07 11:20 AM

Cc: Jocelyn Kula, stephanie.chandler, Denis Arsenault, Stephanie Szick

History: This message has been replied to.

Hi All - I revised all the documents based on comments from HPFB & HECS Legal services, and your revised NOI. As a quick signal check to ensure consistency throughout all documents in how we refer to the known effects (short and long-term), I have highlighted in yellow the references to these in all docs. Could you please take a quick look and let me know by 1:00 pm today if all are OK with the revisions, before seeking HECS and HPFB ADMO approvals. thx.



DRAFT Salvia NOI\_Feb 4 EN\_clean.wpd Salvia NR\_CSTD-DG\_07-02-11.doc



Salvia MLs\_CSTD-DG\_07-02-11.doc IYH Salvia divinatorum\_v24\_CSTD-DG\_07-02-11.doc

Christine Roush  
Senior Communications Advisor/

Suzanne Desjardins thank you both for the clarification Suzanne

2011-02-07 07:56:44 AM

From: Suzanne Desjardins/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: stephanie.chandler@hc-sc.gc.ca, Christine Roush/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, Stephanie Szick/HC-SC/GC/CA@HWC  
Date: 2011-02-07 07:56 AM  
Subject: Re: Revised Salvia NOI

thank you both for the clarification

Suzanne

Jocelyn Kula	Suzanne Only to echo what Stephanie just said,...	2011-02-04 03:14:25 PM
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Stephanie Chandler	Hi Christine, Hope you are feeling better soon!	2011-02-04 02:09:37 PM
Christine Roush	Thanks Stephanie - I am home sick today and w...	2011-02-04 01:44:07 PM
Stephanie Chandler		

----- Original Message -----

**From:** Stephanie Chandler  
**Sent:** 2011-02-04 01:17 PM EST  
**To:** Christine Roush  
**Cc:** Jocelyn Kula; Denis Arsenault; Stephanie Chandler; Stephanie Szick  
**Subject:** Re: Revised Salvia NOI

Hi Christine,

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however I don't believe any of the comms products include our email.

[attachment "DRAFT Salvia NOI\_Feb 4 EN\_clean.wpd" deleted by Christine Roush/HC-SC/GC/CA]

DGO would also like to confirm that it is not necessary for Cathy to re-approve any of the comms products and that we are still on track as far as comms is concerned for publication on Feb 19. Could you please confirm?

Thanks,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

Christine Roush	Hi all - could you please share the updated NOI...	2011-02-04 10:33:36 AM
Jocelyn Kula	great! Denis/ Stephanie- I think we still have to c...	2011-02-04 10:01:50 AM
Christine Roush	Jocelyn - NHPD is ok with dropping the hallucin...	2011-02-04 08:55:50 AM

DEPARTMENT OF HEALTH

CONTROLLED DRUGS AND SUBSTANCES ACT

*Notice to interested parties - Proposal regarding the addition of Salvia divinorum and salvinorin A to Schedule III to the Controlled Drugs and Substances Act*

This notice provides interested stakeholders with the opportunity to provide comments on Health Canada's proposal to add the plant *Salvia divinorum* (*S. divinorum*) and its main active ingredient salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA). Stakeholders may also identify themselves for inclusion in any future consultation.

*S. divinorum* is a species of sage belonging to the mint family. Its leaves are generally chewed or smoked to obtain psychotropic effects. While uncertainty remains surrounding the health risks of *S. divinorum*, known effects are reported to be short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant. Neither *S. divinorum* nor salvinorin A are currently included in any of the Schedules to the CDSA.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. *S. divinorum* is widely touted as a "legal" hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs.<sup>1</sup> Results from the *Canadian Alcohol and Drug Use Monitoring Survey* (CADUMS) reveal that, in 2009, 1.6% of Canadians aged 15 years and older reported having used *S. divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24 years. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *S. divinorum* in the past year. Moreover, the *2009 Ontario Student Drug Use and Health Survey* (OSDUHS) indicated that 5.4% of Ontario students in grades 7-12 reported ever using *S. divinorum* and 4.4% of these students reported using this substance in the past year. Because its psychoactive effects resemble those of other substances included in Schedule III to the CDSA such as lysergic acid diethylamide (LSD) and psilocybin, Health Canada is concerned that the ready availability and use of *S. divinorum* poses a risk to the health and safety of Canadians, particularly youth.

While *S. divinorum* and salvinorin A are not currently included in any of the United Nations Drug Control Conventions, a number of countries have chosen to regulate one or both as controlled substances. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden have all placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. Some American states have also implemented laws restricting their use, sale and/or distribution.

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<sup>1</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.

Including these substances within Schedule III to the CDSA would prohibit: possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation). The scheduling of *S. divinorum* and salvinorin A under the CDSA will also enable law enforcement agencies to take action against suspected illegal activities involving these substances.

As this action is not intended to interfere with the use and availability of *S. divinorum* and/or salvinorin A for legitimate medical, scientific or industrial purposes, Health Canada is seeking information from stakeholders on whether there are any such uses in Canada. Information received in response to this notice will be instrumental in determining appropriate regulation under the CDSA.

The publication of this notice begins a 30-day comment period. There will be additional opportunities to provide comments as the federal regulatory process progresses.

If you are interested in this process or have comments on this proposal, please contact Stephanie Chandler, Regulatory Policy Division, Office of Controlled Substances, Address Locator: 3503D, 123 Slater St., Ottawa, Ontario, Canada, K1A 1B9, by fax at (613) 946-4224 or by email at [OCS.Policy.and.Regulatory.Affairs@hc-sc.gc.ca](mailto:OCS.Policy.and.Regulatory.Affairs@hc-sc.gc.ca).

Cathy A. Sabiston  
Director General  
Controlled Substances and Tobacco Directorate

Date \_\_\_\_\_

# News Release

## The Government of Canada Proposes to Schedule *Salvia Divinorum* and Salvinorin A as Controlled Substances

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February 17, 2011  
For immediate release

OTTAWA – Today, the Honourable Leona Aglukkaq, Minister of Health announced the Government of Canada's proposed intention to include *Salvia divinorum* and salvinorin A, also known as Salvia, as controlled substances. A Notice to Interested Parties outlining Health Canada's proposal will be published in *Canada Gazette*, Part I, on February 19, 2011

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"After reviewing Canadian surveillance data and scientific reports that suggest this substance has the potential for abuse, especially among young people, we are taking these steps to protect the health and safety of Canadians from the potentially harmful effects of this substance," said Minister Aglukkaq. "The use of this substance is of concern to Health Canada as very little is known about its long-term effects on the brain and body."

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The Notice to Interested Parties will propose that *Salvia divinorum* and its main active ingredient salvinorin A be added to Schedule III to the *Controlled Drugs and Substances Act*. This means that activities such as possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation) will be illegal unless authorized by regulation. The scheduling of *Salvia divinorum* and salvinorin A as a controlled substance will also enable law enforcement agencies to take action against suspected illegal activities involving these substances.

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Interested parties are encouraged to submit any comments regarding the Notice to Interested Parties by March 14, 2011.

For more information on *Salvia divinorum* and the risks associated with its use, please see *It's Your Health* at: (insert link to the *It's Your Health* article.)

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Your Health* article!

**Media Enquiries:**

Health Canada  
(613) 957-2983

*Également disponible en français*

Jenny Van Alstyne  
Office of the Honourable Leona Aglukkaq  
Federal Minister of Health  
(613) 957-0200

**Public Enquiries:**

(613) 957-2991  
1-866 225-0709

Health Canada news releases are available on the Internet at  
[www.healthcanada.gc.ca/media](http://www.healthcanada.gc.ca/media)



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of Canada

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du Canada

Canada

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**Media Lines**  
***Salvia divinorum***

**Issue**

There is ongoing media interest regarding the availability of *Salvia divinorum* in Canada as well as Canadian surveillance data suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has concluded that *Salvia divinorum* and its main active ingredient salvinorin A should be scheduled under the *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth. A Notice to Interested Parties outlining Health Canada's proposal to regulate this substance will be published in *Canada Gazette*, Part I, on February 19, 2011.

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**Key Messages:**

- After reviewing available information and reports that suggest this substance has the potential for abuse, especially among young people, Health Canada is proposing to schedule both *Salvia divinorum* and its main active ingredient salvinorin A as controlled substances.
- The Government of Canada is taking these steps in order to protect the health and safety of Canadians, particularly youth, from the potentially harmful effects of these substances.
- Canadians should not use products containing *Salvia divinorum* and/or salvinorin A because they are hallucinogenic and little is known about the long-term effects of these substances on the brain and body.
- The proposed inclusion of *Salvia divinorum* and salvinorin A in Schedule III to the *Controlled Drugs and Substances Act* will make possession, trafficking, importation, exportation, production (or cultivation), possession for the purpose of trafficking or possession for the purposes of exporting illegal unless authorized by regulation.

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**Supplementary Messages:**

- Though it is a hallucinogen, the plant *Salvia divinorum* is not currently scheduled under the CDSA. At the present time, products containing *Salvia divinorum* would meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations*.
- To date, Health Canada has not authorized for sale any natural health products which contain *Salvia divinorum* as an ingredient. The sale of unauthorized

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natural health products containing *Salvia divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act and its associated regulations*.

**Questions and Answers:**

**Q1 – What is involved in scheduling *Salvia divinorum* as a controlled substance and what stage is it at?**

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**A1 -** Health Canada considers several factors in determining whether the scheduling of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

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- International requirements and trends in international control;
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- Overall risk to public health and safety posed by the substance.

Health Canada recently concluded its assessment of *Salvia divinorum* and salvinorin A against the aforementioned factors and proposes to include both substances in Schedule III to the CDSA. The first step in the process of scheduling a substance under the CDSA is the publication of a *Notice to Interested Parties* (NOI) in *Canada Gazette*, Part I. Any comments received will be considered during the preparation of a regulatory proposal. There will be additional opportunities for comment as the federal regulatory process progresses.

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Controlling these products will reduce the potential risks to the health and safety of Canadians associated with their ready availability, with their increased use and their unknown effects. The scheduling of *Salvia divinorum* and salvinorin A will also eliminate the current misconception that these substances are a safe alternative to other illegal drugs. Furthermore, the scheduling will also enable law enforcement agencies to take action against suspected illegal activities involving these substances.

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**Q2 – Are *Salvia divinorum* and/or salvinorin A controlled internationally? How are these substances regulated in other countries?**

**A2 -** Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions; as a result, there is no requirement for them to be scheduled as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

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The move to include *Salvia divinorum* and salvinorin A in Schedule III to the CDSA is consistent with actions taken by several countries (e.g., Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Some individual U.S. states have implemented laws restricting their use, sale and/or distribution.

**Q3 – Is there any research on the use of *Salvia divinorum* in Canada?**

A3 - Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *Salvia divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *Salvia divinorum* in the past year. The 2009 *Ontario Student Drug Use and Health Survey (OSDUHS)* indicated that 5.4% of Ontario students in grades 7-12 reported ever using *Salvia divinorum* and 4.4% of these students reported using this substance in the past year.

**Q4 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why is it not controlled under the Controlled Drugs and Substances Act?**

A4 – The move to schedule *Salvia divinorum* and salvinorin A as controlled substances is based on surveillance data from surveys such as the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)*, *Youth Smoking Survey (YSS)* and the *Ontario Student Drug Use and Health Survey (OSDUHS)*, some of which only became available in 2010.

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In the interim, as *Salvia divinorum* is a plant with hallucinogenic properties, it currently meets the definition of a natural health product under the *Natural Health Products Regulations (NHPR)*. The sale of unauthorized natural health products may be subject to compliance and enforcement action in accordance with the *Food and Drugs Act* and its associated regulations.

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**Q5 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A5 – Once *Salvia divinorum* and salvinorin A are included in Schedule III to the CDSA, law enforcement will be able to take appropriate action in response to suspected illegal activities with these substances.

Currently, however, *Salvia divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. For more information on how to submit a consumer complaint about the unauthorized sale of drugs containing *Salvia divinorum* and/or salvinorin A,

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visit: [www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_44\\_consumer\\_consommateur\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_44_consumer_consommateur_cp-pc-eng.php).

**Q6 - Has Health Canada issued any kind of warning to Canadians about *Salvia divinorum*?**

A6 - Health Canada has developed an *It's Your Health* article about *Salvia divinorum* to help inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at: (link to come). Health Canada also issued a news release on February 17<sup>th</sup> announcing the Government of Canada's intention to schedule *Salvia divinorum* and salvinorin A, as controlled substances. A Notice to Interested Parties, outlining Health Canada's proposal, was published in *Canada Gazette*, Part I, on February 19, 2011, giving interested parties a 30-day period to submit their comments.

**Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff, incense special, and salvia. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago.

Data from the 2008-2009 Youth Smoking Survey indicates that:

- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;
- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year; and
- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using Salvia in their lifetime (0.2% in the past year); and

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Diana Dowthwaite, DG, HPFB, Sharon Mullin, Director, Compliance and Enforcement Coordination, HPFB, Robin Marles, Director, Bureau of Clinical Trials, NHPD ¶

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- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that:

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;
- 5.4% of students (grades 7-12) ever used *Salvia divinorum*; and
- use of *Salvia divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

**Prepared by:** Stephanie Chandler and Denis Arsenault, OCS, CSTD  
Reviewed and revised by: Christine Roush, Senior Communications Advisor, HECS, Communications

**Approved by:**

Jocelyn Kula, A/Director, OCS, CSTD, HECS (Jan 19, 2011 and Jan 27, 2011)  
Suzanne Desjardins, Director, ODARS, CSTD, HECS (Approved Jan 20, 2011)  
Cathy Sabiston, DG, CSTD, HECS (pending)  
Chris Turner, DG, MHPD  
Scott Sawler, DG, NHPD  
Diana Dowthwaite, DG, HPFB  
Sharon Mullin, Director, Compliance and Enforcement Coordination, HPFB  
Robin Marles, Director, Bureau of Clinical Trials, NHPD  
David Gottlieb, A/Communications Executive, HPFB (pending)  
Ken Polk, A/Director, Public Affairs, PACCB (pending)  
Charles Mojsej, DG, PACCB (pending)  
HECS Legal (pending)  
HPFB Legal (pending)  
Judith O'Brien, A/Communications Executive, HECS  
Paul Glover, ADM, HECSB (pending)  
Meena Ballantyne, ADM, HPFB (pending)  
Anne Lamar, ADM, PACCB (pending)  
DMO (pending)  
MO (pending)  
PCO (pending)

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## Salvia divinorum

### Issue

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff, incense special, and salvia.

**Comment [S1]:** Q From Cathy - Should this info. be in the media lines – as a Q&A? Stephanie – have added this line to the Media lines background

Certain websites promote the use of *S. divinorum* as a “legal” alternative to street drugs. Recent Canadian surveillance data indicates that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. Scientific reports also suggest that it has the potential for abuse.

**Comment [CR2]:** Not necessary – we will be providing a link to the IYH article from the media lines and NR.

Canadians should not use products containing *S. divinorum* and/or salvinorin A because they are hallucinogenic and little is known about the long-term effects of these substances on the brain and body. There is also no way to predict how it will affect you with each use.

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In light of this information, Health Canada is proposing to schedule both *S. divinorum* and its main active ingredient salvinorin A under Schedule III to the *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth.

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### Risks Associated with the Use of *Salvia divinorum*

*S. divinorum* is known to have both physical and mental effects. The effects of *S. divinorum*, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product
- how much is used
- the purity of the product (products that contain *S. divinorum* may be mixed with other substances)

- how it is taken, for example, whether the product is chewed, swallowed or smoked
- the user's mood and expectations

While scientists know which brain receptors are targeted by the main active ingredient, salvinorin A, very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or if it can cause permanent damage
- how it interacts with other substances, including other drugs, natural health products and alcohol
- the potential of *S. divinorum* to produce physical dependence and/or addiction

### Minimizing Your Risk

Hallucinogens like *S. divinorum* work by modifying functions in the brain. Health Canada recommends that you should not use *S. divinorum* because very little is known about the long-term effects it may have on your body and/or brain functions. There is also no way to predict how it will affect you with each use. Just because a drug is plant-based or "natural", does not mean that it is safe.

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Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs, such as marijuana, cocaine, ecstasy, LSD and other substances that distort reality. See the "*Need More Info?*" section below for links to resources that can help you with this.

### Legal Status of *Salvia divinorum*

#### In Canada

As *S. divinorum* is a plant with hallucinogenic properties when consumed by humans, it currently meets the definition of a natural health product (NHP) under the *Natural Health Products Regulations*. As of February 2011, Health Canada has not authorized for sale any natural health products which contain *S. divinorum* as an ingredient. The sale of unauthorized natural health products containing *S. divinorum* or its main active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

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While *S. divinorum* and salvinorin A are not currently scheduled under the *Controlled Drugs and Substances Act* (CDSA), Health Canada is now developing a regulatory proposal that would add *S. divinorum* and salvinorin A to Schedule III to the CDSA.

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#### In Other Countries

Several countries including but not limited to Australia, Belgium, Germany, Italy and Japan, have placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A.

In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on their sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution. In some states, for example, it is illegal for *S. divinorum* to be sold to anyone under the age of 18.

## Background

The leaves of this plant have been used traditionally by the Mazatec people for medicinal and mystical purposes.

The products are sold in a number of forms, including fresh or dried leaves, liquids or seeds and plant cuttings for growing purposes.

Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *S. divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *S. divinorum* in the past year. The 2009 *Ontario Student Drug Use and Health Survey (OSDUHS)* indicated that 5.4% of Ontario students in grades 7-12 reported ever using *S. divinorum* and 4.4% of these students reported using this substance in the past year. For more information on these surveys, see the *Need More Info* section below.

## Health Canada's Role

In light of the health and safety risks associated with the use of *S. divinorum* and particularly the risks to youth, Health Canada is taking steps to schedule *S. divinorum* and salvinorin A as controlled substances. As a first step in this process, Health Canada published a *Notice to Interested Parties (NOI)* in *Canada Gazette, Part I*, on February 19, 2011. In the interim, Health Canada will continue to monitor the sale of unauthorized health products that contain *S. divinorum* or its main active ingredient salvinorin A. It will take appropriate action should it become aware of any unauthorized health products that may pose a risk to Canadians.

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## Need More Info?

- For information on how to submit a consumer or trade complaint about the unauthorized sale of health products containing *S. divinorum* please consult the following documents:  
Consumers: [http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_44\\_consumer\\_consommateur\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_44_consumer_consommateur_cp-pc-eng.php)  
Trade: [http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_38\\_trade-industrie\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_38_trade-industrie_cp-pc-eng.php). Or contact the **Health Products and Food Branch Inspectorate** directly by calling toll-free 1-800-267-9675.

- You can report any adverse reactions to the Canada Vigilance Program by one of the following three ways:  
Report online at the MedEffect™ Canada website at: <http://www.hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>  
Call toll-free at 1-866-234-2345  
Complete a Canada Vigilance Reporting Form and either:  
Fax toll-free to 1-866-678-6789  
Mail to: Canada Vigilance Program  
Health Canada  
AL 0701C  
Ottawa, ON K1A 0K9  
To have postage pre-paid, download the postage paid label from the MedEffect™ Canada website. The Canada Vigilance Reporting Form and the adverse reaction reporting guidelines may also be obtained via this website at: [http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei\\_form-eng.php](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei_form-eng.php)
- For information about the Government of Canada's National Anti-Drug Strategy, go to: [www.nationalantidrugstrategy.gc.ca/](http://www.nationalantidrugstrategy.gc.ca/)  
The Prevention section on this site has a number of helpful resources for parents, including:
  - **Tips on Talking to Your Teenager**, at: [www.hc-sc.gc.ca/hc-ps/pubs/adp-apd/talk-aborder/index-eng.php](http://www.hc-sc.gc.ca/hc-ps/pubs/adp-apd/talk-aborder/index-eng.php)
  - **What to Do if Your Teen is Using Drugs**, at:  
[www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html](http://www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html)
  - Health Canada's **Not4Me** youth drug prevention section at:  
<http://www.hc-sc.gc.ca/hc-ps/drugs-drogues/youth-jeunes/facts-faits/index-eng.php>
- Information on natural health products and the Natural Health Products Regulations can be found at: [www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php)

For more on the surveys that have collected information about *Salvia divinorum* use in Canada, see:

- **The 2008-2009 Youth Smoking Survey**, at:  
<http://www.yss.uwaterloo.ca/index.cfm?section=5&page=288>
- **The 2009 Canadian Alcohol and Drug Use Monitoring Survey**, at:  
<http://www.hc-sc.gc.ca/hc-ps/drugs-drogues/stat/index-eng.php>
- **The 2009 Ontario Student Drug Use and Health Survey**, at:  
[http://www.camh.net/News\\_events/News\\_releases\\_and\\_media\\_advisories\\_and\\_b\\_ackgrounders/osduhs2009\\_advisory.html](http://www.camh.net/News_events/News_releases_and_media_advisories_and_b_ackgrounders/osduhs2009_advisory.html)

Additional Resources:

- U.S. Drug Enforcement Administration: **Drugs and Chemicals of Concern: *Salvia divinorum* and Salvinorin A** at: [www.dea diversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.dea diversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)
- U.S. Department of Health & Human Services, **National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006** at: [www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf](http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf)
- For additional articles on health and safety issues go to the ***It's Your Health*** web section at: [www.healthcanada.gc.ca/iyh](http://www.healthcanada.gc.ca/iyh)

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

Original:

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Catalogue#  
ISBN#

Version/date: Draft 17. September 8, 2010.

PACCB IYH - Lisa Mackay: 613-954-0105 – [Lisa.Mackay@hc-sc.gc.ca](mailto:Lisa.Mackay@hc-sc.gc.ca)

Comments from: HECSB - CSTD (OCS&ODARS) & HPFB – NHPD, MHPD & HPFBI

**Approved by:**

- Jocelyn Kula, A/Director, OCS, CSTD, HECS (Jan 19, 2011 and Jan 27, 2011)
- Suzanne Desjardins, Director, ODARS, CSTD, HECS (Approved Jan 20, 2011)
- Cathy Sabiston, DG, CSTD, HECS
- Chris Turner, DG, MHPD
- Scott Sawler, DG, NHPD
- Diana Dowthwaite, DG, HPFB
- Sharon Mullin, Director, Compliance and Enforcement Coordination, HPFB
- Robin Marles, Director, Bureau of Clinical Trials, NHPD
- David Gotlieb, A/Communications Executive, HPFB (pending)
- Ken Polk, A/Director, Public Affairs, PACCB (pending)
- Charles Mojsej, DG, PACCB (pending)
- HECS Legal
- HPFB Legal
- Judith O'Brien, A/Communications Executive, HECS
- Paul Glover, ADM, HPFB (pending)
- Hillary Geller A/ADM, HECS (pending)
- Anne Lamar, ADM, PACCB (pending)
- DMO (pending)
- MO (pending)
- PCO (pending)

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Deleted: Meena Ballantyne,

Deleted: PFB





**Re: Revised Salvia NOI**

Suzanne Desjardins to: Christine Roush

2011-02-07 11:40 AM

Cc: Jocelyn Kula, stephanie.chandler, Denis Arsenault, Stephanie Szick

Hi Christine,

I am fine with the yellow highlighted text.  
Thanks

Suzanne

Christine Roush

Hi All - I revised all the documents based on co...

2011-02-07 11:20:36 AM

From: Christine Roush/HC-SC/GC/CA  
To: Suzanne Desjardins/HC-SC/GC/CA@HWC  
Cc: Jocelyn Kula/HC-SC/GC/CA@HWC, stephanie.chandler@hc-sc.gc.ca, Denis Arsenault/HC-SC/GC/CA@HWC, Stephanie Szick/HC-SC/GC/CA@HWC  
Date: 2011-02-07 11:20 AM  
Subject: Re: Revised Salvia NOI

Hi All - I revised all the documents based on comments from HPFB & HECS Legal services, and your revised NOI. As a quick signal check to ensure consistency throughout all documents in how we refer to the known effects (short and long-term), I have highlighted in yellow the references to these in all docs. Could you please take a quick look and let me know by 1:00 pm today if all are OK with the revisions, before seeking HECS and HPFB ADMO approvals. thx.

[attachment "DRAFT Salvia NOI\_Feb 4 EN\_clean.wpd" deleted by Suzanne Desjardins/HC-SC/GC/CA]  
[attachment "Salvia NR\_CSTD-DG\_07-02-11.doc" deleted by Suzanne Desjardins/HC-SC/GC/CA]  
[attachment "Salvia MLs\_CSTD-DG\_07-02-11.doc" deleted by Suzanne Desjardins/HC-SC/GC/CA]  
[attachment "IYH Salvia divinatorum\_v24\_CSTD-DG\_07-02-11.doc" deleted by Suzanne Desjardins/HC-SC/GC/CA]

Christine Roush  
Senior Communications Advisor/

Suzanne Desjardins	thank you both for the clarification Suzanne	2011-02-07 07:56:44 AM
Jocelyn Kula	Suzanne Only to echo what Stephanie just said,...	2011-02-04 03:14:25 PM
Stephanie Chandler	Hi Suzanne, As far as the NOI is concerned w...	2011-02-04 03:08:42 PM
Suzanne Desjardins	Hi All, I wouldn't mind commenting, but the NO...	2011-02-04 02:58:10 PM
Stephanie Chandler	Hi Christine, Hope you are feeling better soon!	2011-02-04 02:09:37 PM
Christine Roush	Thanks Stephanie - I am home sick today and w...	2011-02-04 01:44:07 PM
Stephanie Chandler		

----- Original Message -----

**From:** Stephanie Chandler  
**Sent:** 2011-02-04 01:17 PM EST  
**To:** Christine Roush  
**Cc:** Jocelyn Kula; Denis Arsenault; Stephanie Chandler; Stephanie Szick  
**Subject:** Re: Revised Salvia NOI

Hi Christine,

This is the revised NOI that Cathy has just signed. We have not included the suggested reference by HPFB to include "short and long-term effects" and we have changed "The regulation of Salvia" to "The



**Re: Revised Salvia NOI** 

Christine Roush to: Denis Arsenault

2011-02-07 03:14 PM

Cc: Suzanne Desjardins, Jocelyn Kula, stephanie.chandler, Stephanie Szick

---

Thanks Denis - will do. The documents are currently with HPFB (Paul) for ADM approval.

Christine Roush  
Senior Communications Advisor/

---

Denis Arsenault

Hi Christine, For the sake of consistency with th...

2011-02-07 01:11:41 PM

From: Denis Arsenault/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Cc: Suzanne Desjardins/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, stephanie.chandler@hc-sc.gc.ca, Stephanie Szick/HC-SC/GC/CA@HWC  
Date: 2011-02-07 01:11 PM  
Subject: Re: Revised Salvia NOI

---

Hi Christine,

For the sake of consistency with the other documents, we may want to take out "very" in the highlighted portion of the NR and the "Minimizing Your Risk" section of the IYH. (i.e. "very little is known about its long-term effects...")

Denis

---

Denis Arsenault, A/Manager / Gestionnaire p.i.  
Regulatory Policy Division /  
Division des politiques réglementaires,  
Office of Controlled Substances /  
Bureau des substances contrôlées,  
Health Canada / Santé Canada  
Tel/Tél: (613) 957-6828  
Fax / Télécopieur : (613) 946-4224  
E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca

---

Christine Roush

Hi All - I revised all the documents based on co...

2011-02-07 11:20:32 AM

From: Christine Roush/HC-SC/GC/CA  
To: Suzanne Desjardins/HC-SC/GC/CA@HWC  
Cc: Jocelyn Kula/HC-SC/GC/CA@HWC, stephanie.chandler@hc-sc.gc.ca, Denis Arsenault/HC-SC/GC/CA@HWC, Stephanie Szick/HC-SC/GC/CA@HWC  
Date: 2011-02-07 11:20 AM  
Subject: Re: Revised Salvia NOI

---

Hi All - I revised all the documents based on comments from HPFB & HECS Legal services, and your revised NOI. As a quick signal check to ensure consistency throughout all documents in how we refer to the known effects (short and long-term), I have highlighted in yellow the references to these in all docs. Could you please take a quick look and let me know by 1:00 pm today if all are OK with the revisions, before seeking HECS and HPFB ADMO approvals. thx.

[attachment "DRAFT Salvia NOI\_Feb 4 EN\_clean.wpd" deleted by Denis Arsenault/HC-SC/GC/CA]  
[attachment "Salvia NR\_CSTD-DG\_07-02-11.doc" deleted by Denis Arsenault/HC-SC/GC/CA]



**Re: Salvia Event is ON!** 

Jocelyn Kula to: Christine Roush

2011-02-08 07:58 PM

Cc: "Denis Arsenault", "Stephanie Chandler", Stephanie Szick, Nicole Prentice

Hi Christine,

Well I can't say I am surprised about the event, although I really can't understand the logic here given that it will only bring more pressure on us to get through the regulatory process as fast as we can.....which is exactly what I now understand MO is asking for per your conversation with Stephanie C this afternoon. And not sure exactly what to tell you other than what we have already said in the NOI package, i.e, we will have a package intended for pre-publication in CG I ready for departmental approvals in May 2011. I am not able to commit how long it will take DMO and MO to review our package (and I suspect they will not commit to a timeline) and hence, we just can't be any more specific than that. Typically, the reg process documents in HC say that program areas should allow 4-8 weeks for ministerial concurrence, which would take us to the end of June 2011.....I just don't want to be held to that, in case there are shifts in priorities in the meantime, etc. Obviously, we would like to get through TB before the house rises for the Summer but honestly, it is not I or anyone else in CSTD who will decide that.

Re. partners, I think RCMP or possibly CBSA would be more important than DOJ as they are the ones who see Salvia coming into the country/ on the street.

Happy to discuss, and sorry for being so late to reply. I left the office 

Jocelyn

s.19(1)

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Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

Christine Roush

Hi Jocelyn, Dave just got off the weekly call with...

2011-02-08 02:16:42 PM

From: Christine Roush/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: "Denis Arsenault" <denis.arsenault@hc-sc.gc.ca>, "Stephanie Chandler" <stephanie.chandler@hc-sc.gc.ca>, Stephanie Szick/HC-SC/GC/CA@HWC, Nicole Prentice/HC-SC/GC/CA@HWC  
Date: 2011-02-08 02:16 PM  
Subject: Salvia Event is ON!

Hi Jocelyn,

Dave just got off the weekly call with MO Comms and they want a Salvia event next Wednesday, February 16th. The documents are currently in HECS-ADMO for Hillary's approval - though Jesse has just asked if we could shorten the IYH article. Dave is looking at it now and I will let you know what edits are done to it. There will be a planning meeting held soon. HPFB has fully approved the documents - Paul Glover signed off this morning on them. We will likely receive a request to prepare a Ministerial Event Proposal, which I will draft - and a speech, which our Ministerial Services unit will draft with assistance from your group. Not sure whether there would be any partner depts involved, though it would make sense to have Justice or

RCMP there too. More to come, I'm sure.

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
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Tel/Tél : (613) 954-0712/Cell: (613) 219-7194  
Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca

Jocelyn Kula great! Denis/ Stephanie- I think we still have to c... 2011-02-04 10:01:50 AM

From: Jocelyn Kula/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Cc: "Denis Arsenault" <denis.arsenault@hc-sc.gc.ca>, "Stephanie Chandler" <stephanie.chandler@hc-sc.gc.ca>  
Date: 2011-02-04 10:01 AM  
Subject: Re: Fw: Fw: Salvia NR, MLs, NOI and IYH article - DLSU input

great!  
Denis/ Stephanie- I think we still have to change the NOI, and I assume that means Cathy will have to resign. That means another docket, which we will need to get Arafo to rush as today is her last day. Please add note to docket explaining why she needs to sign again.  
JK

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

Christine Roush Jocelyn - NHPD is ok with dropping the hallucin... 2011-02-04 08:55:50 AM

From: Christine Roush/HC-SC/GC/CA  
To: "Jocelyn Kula" <jocelyn.kula@hc-sc.gc.ca>  
Cc: "Denis Arsenault" <denis.arsenault@hc-sc.gc.ca>, "Stephanie Chandler" <stephanie.chandler@hc-sc.gc.ca>  
Date: 2011-02-04 08:55 AM  
Subject: Fw: Fw: Salvia NR, MLs, NOI and IYH article - DLSU input

Jocelyn - NHPD is ok with dropping the hallucinogen statement. I'll make the rest of the changes to the docs and keep them moving.  
That was easier than I expected.

C  
Elizabeth Keeping

----- Original Message -----

From: Elizabeth Keeping  
Sent: 2011-02-04 08:46 AM EST

**To:** Christine Roush

**Subject:** Re: Fw: Salvia NR, MLs, NOI and IYH article - DLSU input

Hey Christine,

NHPD says it's okay to drop the hallucinogen statement - per legal advice.

Cheers,  
Beth

Christine Roush

Hi Beth - I will address points 1 and 2 below in S...

2011-02-04 07:40:33 AM

**Re: Revised Qs&As re: Timing for Regulatory Process** 

Christine Roush to: Jocelyn Kula

2011-02-09 12:50 PM

Cc: Denis Arsenault, Stephanie Chandler

Noted thx.

Jocelyn Kula

----- Original Message -----

**From:** Jocelyn Kula

**Sent:** 2011-02-09 12:24 PM EST

**To:** Christine Roush

**Cc:** Denis Arsenault; Stephanie Chandler

**Subject:** Re: Revised Qs&As re: Timing for Regulatory Process

Hi Christine,

No I was not inferring that it could be considerably shorter, I was suggesting that making a big fuss over the NOI might lead to increased pressure for us to work faster. Not the same thing at all! I say we stick with the 18-24 month timeline that we have already stated.

JK

---

Jocelyn Kula

Acting Director/ Directrice par intérim

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs

Health Canada/ Santé Canada

Tel: (613) 952-2177 Fax: (613) 946-4224

---

Christine Roush

Thx Jocelyn - I'll ensure these changes are mad...

2011-02-09 08:30:37 AM

**From:** Christine Roush/HC-SC/GC/CA

**To:** Jocelyn Kula/HC-SC/GC/CA@HWC

**Cc:** Denis Arsenault/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC

**Date:** 2011-02-09 08:30 AM

**Subject:** Re: Revised Qs&As re: Timing for Regulatory Process

---

Thx Jocelyn - I'll ensure these changes are made. So to be clear, you are Ok with saying that the regulatory process could take 18 to 24 months to complete? I thought I understood from your email last night that it could be considerably shorter?

Jocelyn Kula

----- Original Message -----

**From:** Jocelyn Kula

**Sent:** 2011-02-08 11:53 PM EST

**To:** Christine Roush

**Cc:** Denis Arsenault; Stephanie Chandler

**Subject:** Re: Revised Qs&As re: Timing for Regulatory Process

Hi Christine,

For Q2, the Q should read "Why has the Gov't now decided to schedule these substances under the CDSA?" (in order to be consistent with wording elsewhere and in the NOI/ IYH)

I personally also think that the word "control" is vague unless you say "control as controlled substances"

(which is repetitive)

For Q3, all good. Per previous message to Stephanie, I do not think we should try and change the language to read "illegal" etc.

Lastly, for Q1, there is a mistake that is quite important to fix. In the edited text, you refer to Schedule II, when it should read Schedule III (Schedule II is for cannabis only).

JK

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

---

Christine Roush      Stephanie, Can you please take a look at Qs 2...      2011-02-08 03:32:07 PM

---

From: Christine Roush/HC-SC/GC/CA  
To: Stephanie Chandler/HC-SC/GC/CA@HWC  
Cc: Jocelyn Kula/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2011-02-08 03:32 PM  
Subject: Revised Qs&As re: Timing for Regulatory Process

---

Stephanie,  
Can you please take a look at Qs 2 & 3 and let me know ASAP if you are OK with the answers. I need to keep the products moving. I also included the revised IYH article - we just deleted some repetition in it.

[attachment "Salvia MLs\_CSTD-DG\_08-02-11\_15h25.doc" deleted by Christine Roush/HC-SC/GC/CA]

[attachment "IYH Salvia divinorum\_v24\_HECS-ADM\_08-02-11\_14h27.doc" deleted by Christine Roush/HC-SC/GC/CA]

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
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Tel/Tél : (613) 954-0712/Cell: (613) 219-7194  
Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca

**DRAFT**  
07/02/2011

**Media Lines**  
***Salvia divinorum***

**Issue**

There is ongoing media interest regarding the availability of *Salvia divinorum* in Canada as well as Canadian surveillance data suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has concluded that *Salvia divinorum* and its main active ingredient salvinorin A should be scheduled under the *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth. A Notice to Interested Parties outlining Health Canada's proposal to regulate this substance will be published in *Canada Gazette*, Part I, on February 19, 2011.

**Key Messages:**

- After reviewing available information and reports that suggest this substance has the potential for abuse, especially among young people, Health Canada is proposing to schedule both *Salvia divinorum* and its main active ingredient salvinorin A as controlled substances.
- The Government of Canada is taking these steps in order to protect the health and safety of Canadians, particularly youth, from the potentially harmful effects of these substances.
- Canadians should not use products containing *Salvia divinorum* and/or salvinorin A because they are hallucinogenic and little is known about the long-term effects of these substances on the brain and body.
- The proposed inclusion of *Salvia divinorum* and salvinorin A in Schedule III to the Controlled Drugs and Substances Act will make possession, trafficking, importation, exportation, production (or cultivation), possession for the purpose of trafficking or possession for the purposes of exporting illegal unless authorized by regulation.

**Supplementary Messages:**

- Though it is a hallucinogen, the plant *Salvia divinorum* is not currently scheduled under the CDSA. At the present time, products containing *Salvia divinorum* would meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations*.
- To date, Health Canada has not authorized for sale any natural health products which contain *Salvia divinorum* as an ingredient. The sale of unauthorized

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Last saved by Christine Roush

Created by Christine Roush  
2011-02-09



DRAFT  
07/02/2011

natural health products containing *Salvia divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act and its associated regulations*.

Questions and Answers:

Q1 – What is involved in scheduling *Salvia divinorum* as a controlled substance and what stage is it at?

A1 - Health Canada considers several factors in determining whether the scheduling of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- Overall risk to public health and safety posed by the substance.
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- International requirements and trends in international control.

Health Canada recently concluded its assessment of *Salvia divinorum* and salvinorin A against these factors and proposes to include both substances in Schedule III to the CDSA. The first step in the process of scheduling a substance under the CDSA is the publication of a *Notice to Interested Parties* (NOI) in *Canada Gazette, Part I*, which will be published on February 19, 2011 for a 30-day comment period. This notice provides interested stakeholders with the opportunity to provide comments on Health Canada's proposal to add *Salvia divinorum* and its main active ingredient salvinorin A to Schedule II to the CDSA. Any comments received are considered during the preparation of a regulatory proposal. There will be additional opportunities for comment as the federal regulatory process progresses, which usually takes about 18 to 24 months to complete.

Q2. Why has the Government now decided to control these substances?

A2. Controlling these products will reduce the potential risks to the health and safety of Canadians associated with their ready availability, with their increased use and their unknown effects. The scheduling of *Salvia divinorum* and salvinorin A will also eliminate the current misconception that these substances are a safe alternative to other illegal drugs. Furthermore, the scheduling will also enable law enforcement agencies to take action against suspected illegal activities involving these substances.

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Last saved by Christine Roush

Created by Christine Roush  
2011-02-09

DRAFT  
07/02/2011

**Q3 – Are *Salvia divinorum* and/or salvinorin A controlled internationally? How are these substances regulated in other countries?**

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A3 - Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions; as a result, there is no requirement for them to be scheduled as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

The move to include *Salvia divinorum* and salvinorin A in Schedule III to the CDSA is consistent with actions taken by several countries (e.g., Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Some individual U.S. states have implemented laws restricting their use, sale and/or distribution.

**Q4 – Is there any research on the use of *Salvia divinorum* in Canada?**

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A4 - Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *Salvia divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *Salvia divinorum* in the past year. The 2009 *Ontario Student Drug Use and Health Survey (OSDUHS)* indicated that 5.4% of Ontario students in grades 7-12 reported ever using *Salvia divinorum* and 4.4% of these students reported using this substance in the past year.

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**Q5 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum*, why is it not controlled under the Controlled Drugs and Substances Act?**

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A5 – The move to schedule *Salvia divinorum* and salvinorin A as controlled substances is based on surveillance data from surveys such as the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)*, *Youth Smoking Survey (YSS)* and the *Ontario Student Drug Use and Health Survey (OSDUHS)*, some of which only became available in 2010.

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In the interim, as *Salvia divinorum* is a plant with hallucinogenic properties, it currently meets the definition of a natural health product under the *Natural Health Products Regulations (NHPR)*. The sale of unauthorized natural health products may be subject to compliance and enforcement action in accordance with the *Food and Drugs Act* and its associated regulations.

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2011-02-09

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07/02/2011

**Q6 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

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**A6 – Once *Salvia divinorum* and salvinorin A are included in Schedule III to the CDSA, law enforcement will be able to take appropriate action in response to suspected illegal activities with these substances.**

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Currently, however, *Salvia divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. For more information on how to submit a consumer complaint about the unauthorized sale of drugs containing *Salvia divinorum* and/or salvinorin A, visit: [www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_44\\_consumer\\_consommateur\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_44_consumer_consommateur_cp-pc-eng.php).

**Q7 - Has Health Canada issued any kind of warning to Canadians about *Salvia divinorum*?**

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**A7 - Health Canada has developed an *It's Your Health* article about *Salvia divinorum* to help inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at: (link to come). Health Canada also issued a news release on February 17<sup>th</sup> announcing the Government of Canada's intention to schedule *Salvia divinorum* and salvinorin A, as controlled substances. A Notice to Interested Parties, outlining Health Canada's proposal, was published in *Canada Gazette*, Part I, on February 19, 2011, giving interested parties a 30-day period to submit their comments. There will be additional opportunities for comment as the federal regulatory process progresses.**

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**Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff, incense special, and salvia. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

**Data from the 2008-2009 Youth Smoking Survey indicates that:**

- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;

Deleted: The use of *Salvia divinorum* as a psychotropic agent first came to Health Canada's attention some years ago. ¶

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2011-02-09

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07/02/2011

- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year; and
- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using Salvia in their lifetime (0.2% in the past year); and
- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that:

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;
- 5.4% of students (grades 7-12) ever used *Salvia divinorum*; and
- use of *Salvia divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

**Prepared by:** Stephanie Chandler and Denis Arsenault, OCS, CSTD  
**Reviewed and revised by:** Christine Roush, Senior Communications Advisor, HECS, Communications

**Approved by:**

Jocelyn Kula, A/Director, OCS, CSTD, HECS (Jan 19, 2011 and Jan 27, 2011)  
Suzanne Desjardins, Director, ODARS, CSTD, HECS (Approved Jan 20, 2011)  
Cathy Sabiston, DG, CSTD, HECS  
Chris Turner, DG, MHPD  
Scott Sawler, DG, NHPD  
Diana Dowthwaite, DG, HPFB  
Sharon Mullin, Director, Compliance and Enforcement Coordination, HPFB  
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Sherrey Collier, Legal Counsel, HPFB  
David Gotlieb, A/Communications Executive, HPFB  
Judith O'Brien, A/Communications Executive, HECS  
Ken Polk, A/Director, Public Affairs, PACCB (pending)  
Charles Mojsej, DG, PACCB (pending)  
Paul Glover, ADM, HPFB  
Hillary Geller, A/ADM, HECS (pending)  
Anne Lamar, ADM, PACCB (pending)  
DMO (pending)  
MO (pending)  
PCO (pending)

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Created by Christine Roush  
2011-02-09

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2011-02-09

## Salvia divinorum - It's Your Health Article

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### Issue

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff, incense special, and salvia.

Certain websites promote the use of *S. divinorum* as a "legal" alternative to street drugs. Recent Canadian surveillance data indicates that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. Scientific reports also suggest that it has the potential for abuse.

Canadians should not use products containing *S. divinorum* and/or salvinorin A because they are hallucinogenic and little is known about the long-term effects of these substances on the brain and body. There is also no way to predict how it will affect you with each use.

In light of this information, Health Canada is proposing to schedule both *S. divinorum* and its main active ingredient salvinorin A under Schedule III to the *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth.

### Risks Associated with the Use of *Salvia divinorum*

*S. divinorum* is known to have both physical and mental effects. The effects of *S. divinorum*, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product
- how much is used
- the purity of the product (products that contain *S. divinorum* may be mixed with other substances)

- how it is taken, for example, whether the product is chewed, swallowed or smoked
- the user's mood and expectations

While scientists know which brain receptors are targeted by the main active ingredient, salvinorin A, very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or if it can cause permanent damage
- how it interacts with other substances, including other drugs, natural health products and alcohol
- the potential of *S. divinorum* to produce physical dependence and/or addiction

### **Minimizing Your Risk**

Hallucinogens like *S. divinorum* work by modifying functions in the brain. Health Canada recommends that you should not use *S. divinorum* because little is known about the long-term effects it may have on your body and/or brain functions. There is also no way to predict how it will affect you with each use. Just because a drug is plant-based or "natural", does not mean that it is safe.

Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs, such as marijuana, cocaine, ecstasy, LSD and other substances that distort reality. See the "***Need More Info?***" section below for links to resources that can help you with this.

### **Legal Status of *Salvia divinorum***

#### In Canada

As *S. divinorum* is a plant with hallucinogenic properties when consumed by humans, it currently meets the definition of a natural health product (NHP) under the *Natural Health Products Regulations*. As of February 2011, Health Canada has not authorized for sale any natural health products which contain *S. divinorum* as an ingredient. The sale of unauthorized natural health products containing *S. divinorum* or its main active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

While *S. divinorum* and salvinorin A are not currently scheduled under the *Controlled Drugs and Substances Act* (CDSA), Health Canada has issued a Notice to Interested Parties which proposes to add *S. divinorum* and salvinorin A to Schedule III to the CDSA.

**Deleted:** is now developing a regulatory proposal that would

#### In Other Countries

Several countries including but not limited to Australia, Belgium, Germany, Italy and Japan, have placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A.

In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed restrictions on their sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution. In some states, for example, it is illegal for *S. divinorum* to be sold to anyone under the age of 18.

## Background

The leaves of this plant have been used traditionally by the Mazatec people for medicinal and mystical purposes.

The products are sold in a number of forms, including fresh or dried leaves, liquids or seeds and plant cuttings for growing purposes.

Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *S. divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *S. divinorum* in the past year. The 2009 *Ontario Student Drug Use and Health Survey (OSDUHS)* indicated that 5.4% of Ontario students in grades 7-12 reported ever using *S. divinorum* and 4.4% of these students reported using this substance in the past year. For more information on these surveys, see the *Need More Info* section below.

## Need More Info?

- For information on how to submit a consumer or trade complaint about the unauthorized sale of health products containing *S. divinorum* please consult the following documents:  
Consumers: [http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_44\\_consumer\\_consommateur\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_44_consumer_consommateur_cp-pc-eng.php)  
Trade: [http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_38\\_trade-industrie\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_38_trade-industrie_cp-pc-eng.php). Or contact the **Health Products and Food Branch Inspectorate** directly by calling toll-free 1-800-267-9675.
- You can report any adverse reactions to the Canada Vigilance Program by one of the following three ways:  
Report online at the MedEffect™ Canada website at: <http://www.hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>  
Call toll-free at 1-866-234-2345  
Complete a Canada Vigilance Reporting Form and either:  
Fax toll-free to 1-866-678-6789  
Mail to: Canada Vigilance Program  
Health Canada  
AL 0701C

### Deleted: Health Canada's Role¶

¶ In light of the health and safety risks associated with the use of *S. divinorum* and particularly the risks to youth, Health Canada is taking steps to schedule *S. divinorum* and salvinorin A as controlled substances. As a first step in this process, Health Canada published a *Notice to Interested Parties (NOI)* in *Canada Gazette, Part I*, on February 19, 2011. In the interim, Health Canada will continue to monitor the sale of unauthorized health products that contain *S. divinorum* or its main active ingredient salvinorin A. It will take appropriate action should it become aware of any unauthorized health products that may pose a risk to Canadians.¶



Ottawa, ON K1A 0K9

To have postage pre-paid, download the postage paid label from the MedEffect™ Canada website. The Canada Vigilance Reporting Form and the adverse reaction reporting guidelines may also be obtained via this website at: [http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei\\_form-eng.php](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei_form-eng.php)

- For information about the Government of Canada's National Anti-Drug Strategy, go to: [www.nationalantidrugstrategy.gc.ca/](http://www.nationalantidrugstrategy.gc.ca/)  
The Prevention section on this site has a number of helpful resources for parents, including:
  - **Tips on Talking to Your Teenager**, at: [www.hc-sc.gc.ca/hc-ps/pubs/adp-adp/talk-aborder/index-eng.php](http://www.hc-sc.gc.ca/hc-ps/pubs/adp-adp/talk-aborder/index-eng.php)
  - **What to Do if Your Teen is Using Drugs**, at:  
[www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html](http://www.nationalantidrugstrategy.gc.ca/parents/pubs/talking-aborder/talking-aborder.html)
  - Health Canada's **Not4Me** youth drug prevention section at:  
<http://www.hc-sc.gc.ca/hc-ps/drugs-drogues/youth-jeunes/facts-faits/index-eng.php>
- Information on natural health products and the Natural Health Products Regulations can be found at: [www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php)

For more on the surveys that have collected information about *Salvia divinorum* use in Canada, see:

- **The 2008-2009 Youth Smoking Survey**, at:  
<http://www.yss.uwaterloo.ca/index.cfm?section=5&page=288>
- **The 2009 Canadian Alcohol and Drug Use Monitoring Survey**, at:  
<http://www.hc-sc.gc.ca/hc-ps/drugs-drogues/stat/index-eng.php>
- **The 2009 Ontario Student Drug Use and Health Survey**, at:  
[http://www.camh.net/News\\_events/News\\_releases\\_and\\_media\\_advisories\\_and\\_b\\_ackgrounders/osduhs2009\\_advisory.html](http://www.camh.net/News_events/News_releases_and_media_advisories_and_b_ackgrounders/osduhs2009_advisory.html)

**Additional Resources:**

- U.S. Drug Enforcement Administration: **Drugs and Chemicals of Concern: *Salvia divinorum* and Salvinorin A** at:  
[www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm)
- U.S. Department of Health & Human Services, **National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006** at:  
[www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf](http://www.oas.samhsa.gov/2k8/hallucinogens/hallucinogens.pdf)
- For additional articles on health and safety issues go to the It's Your Health web section at: [www.healthcanada.gc.ca/iyh](http://www.healthcanada.gc.ca/iyh)

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

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Catalogue#  
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Version/date: Draft 17. September 8, 2010.


PACCB IYH - Lisa Mackay: 613-954-0105 – [Lisa.Mackay@hc-sc.gc.ca](mailto:Lisa.Mackay@hc-sc.gc.ca)

Comments from: HECSB - CSTD (OCS&ODARS) & HPFB – NHPD, MHPD & HPFBI

**Approved by:**

Jocelyn Kula, A/Director, OCS, CSTD, HECS (Jan 19, 2011 and Jan 27, 2011)  
Suzanne Desjardins, Director, ODARS, CSTD, HECS (Approved Jan 20, 2011)  
Cathy Sabiston, DG, CSTD, HECS  
Chris Turner, DG, MHPD  
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Ken Polk, A/Director, Public Affairs, PACCB (pending)  
Charles Mojsej, DG, PACCB (pending)  
Paul Glover, ADM, HPFB  
Hillary Geller, A/ADM, HECS (pending)  
Anne Lamar, ADM, PACCB (pending)  
DMO (pending)  
MO (pending)  
PCO (pending)



**Re: pictures for IYH**   
Lisa MacKay to: Stephanie Chandler  
Cc: Jocelyn Kula

2011-02-09 01:48 PM

Thank you both. The pics bellow should be sufficient.

Lisa Mackay  
It's Your Health Project Manager/Gestionnaire du projet Votre santé et vous  
Consumer Information Bureau / Bureau d'information aux consommateurs  
Marketing and Communications Services Directorate/Direction des services de marketing et de  
communications  
Public Affairs, Consultation and Communications Branch/ Direction générale des affaires publiques, de la  
consultation et des communications  
Health Canada | Santé Canada  
Tel 613.954.0105  
Lisa\_Mackay@hc-sc.gc.caa

Stephanie Chandler Hi both, Just to confirm that no, OCS does not...

2011-02-09 01:47:09 PM

From: Stephanie Chandler/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Lisa MacKay/HC-SC/GC/CA@HWC  
Date: 2011-02-09 01:47 PM  
Subject: Re: pictures for IYH

Hi both,

Just to confirm that no, OCS does not have any other pictures of Salvia for the IYH.

Regards,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

Jocelyn Kula I am enclosing the most relevant of the bunch y...

2011-02-09 01:36:39 PM

From: Jocelyn Kula/HC-SC/GC/CA  
To: Lisa MacKay/HC-SC/GC/CA@HWC  
Cc: stephanie.chandler@hc-sc.gc.ca  
Date: 2011-02-09 01:36 PM  
Subject: pictures for IYH

I am enclosing the most relevant of the bunch you sent me; personally, the more we show actual labelling  
indicating is sold as incense, but then suggesting how to use, the better. The original 2nd pic you  
suggested with the baggies with spades on them is rather meaningless to me, as it could be anything.

Same goes for the vial and leaf extract.....I don't think we have any others but am copying Stephanie Chandler in case she knows.....

[attachment "Salvia Divinorum (Natural)0001.jpg" deleted by Stephanie Chandler/HC-SC/GC/CA]

[attachment "Salvia Divinorum (Natural)0002.jpg" deleted by Stephanie Chandler/HC-SC/GC/CA]

[attachment "PURPLE STICKY SALVIA0003.jpg" deleted by Stephanie Chandler/HC-SC/GC/CA]

[attachment "Salvia Divinorum (Apple)0001.jpg" deleted by Stephanie Chandler/HC-SC/GC/CA]

[attachment "Salvia Divinorum (Apple)0002.jpg" deleted by Stephanie Chandler/HC-SC/GC/CA]

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Jocelyn Kula

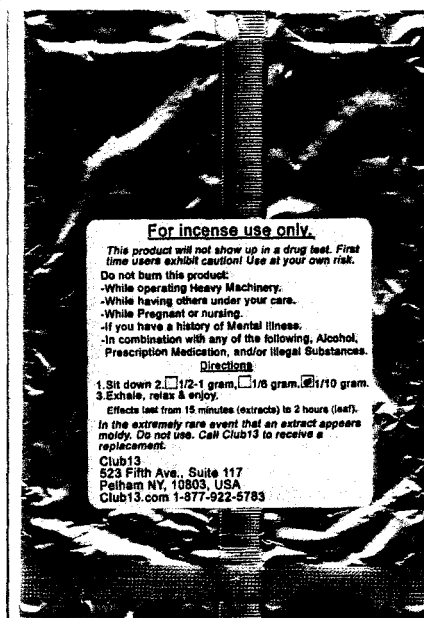
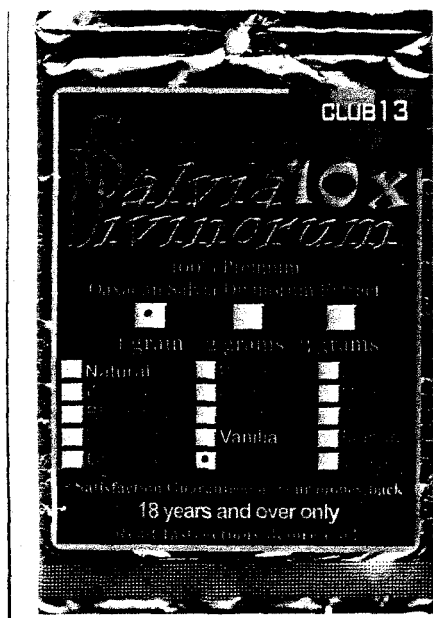
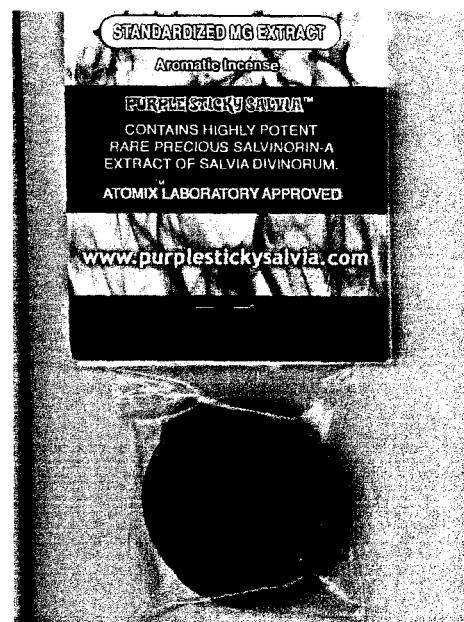
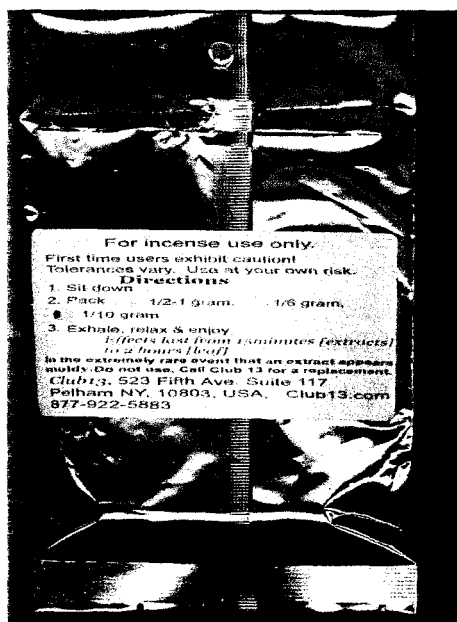
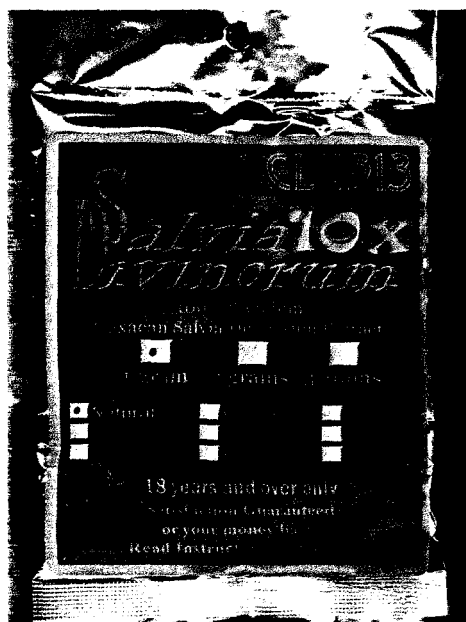
Acting Director/ Directrice par intérim

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs

Health Canada/ Santé Canada

Tel: (613) 952-2177 Fax: (613) 946-4224





**Fw: ADMO Q re: Salvia**  
Jocelyn Kula to: stephanie.chandler

2011-02-09 02:47 PM

for the file

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la  
santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224  
----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2011-02-09 02:46 PM -----

From: Stephanie Szick/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Christine Roush/HC-SC/GC/CA@HWC  
Date: 2011-02-09 02:16 PM  
Subject: Re: ADMO Q re: Salvia

Thanks Jocelyn, this should do it. Will forward and noting the suggestion  
of a CDSA overview briefing for Hilary...

From: Jocelyn Kula/HC-SC/GC/CA  
To: Stephanie Szick/HC-SC/GC/CA@HWC  
Cc: Christine Roush/HC-SC/GC/CA@HWC  
Date: 2011-02-09 02:00 PM  
Subject: Re: ADMO Q re: Salvia

Sorry for the delay.

1. In general, the impact of our proposing to regulate salvia as a controlled substance in Canada will result in the same activities being illegal here as are illegal in other countries where they have taken similar action. That said, it does depend on the country. In Australian and Japan for instance, it is illegal to import and/or sell Salvia. In the US however, some states have gone so far as to impose an age limit on sale and use, i.e., the product cannot be sold to anyone under the age of 18 etc.

2. Yes and no. While the offences are the same for marihuana (Schedule II) and what they will be for Salvia (Schedule III), some of the applicable penalties are different, e.g., a possession offence for marihuana will incur varying penalties depending on the amount (this is the whole impact of Sch VII and Sch VIII to the CDSA) while a possession offence for a Schedule III substance is liable to imprisonment up to 3 years. For illegal production, the penalty for marihuana is imprisonment up to 7 years but only up to 3 years for a substance in Schedule III. (this sounds confusion I know but this is the CDSA- perhaps we should think about doing a general overview on the Act with Hilary, or at least

providing her with the info sheets we have.....)

JK

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la  
santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

From: Stephanie Szick/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Christine Roush/HC-SC/GC/CA@HWC  
Date: 2011-02-09 10:12 AM  
Subject: ADMO Q re: Salvia

Hi Jocelyn

Follow up from Jesse/Hilary -- -- can you provide As to these Qs after you  
are settled this morning?

Thanks, S

----- Forwarded by Stephanie Szick/HC-SC/GC/CA on 2011-02-09 10:06 AM  
-----

From: Jesse Arnup-Blondin/HC-SC/GC/CA  
To: Stephanie Szick/HC-SC/GC/CA@HWC  
Cc: "Senior Communications Advisor Christine Roush"  
<christine.roush@hc-sc.gc.ca>  
Date: 2011-02-09 09:52 AM  
Subject: Re: Fw: ADMO Q re: Salvia

I spoke with Hilary about this again this morning. What she is really  
getting at is will Canada's scheduling be in line with what other  
countries are doing? e.g. in those other countries/states we mention, are  
possession, trafficking, import/export, and production illegal?

She doesn't want a country by country or offence by offence comparison,  
but wants to understand if the things we're making illegal are illegal in  
other places.

Also, she would like to know if this will put similar controls as we have  
on marihuana?

Thanks,

Jesse

From: Stephanie Szick/HC-SC/GC/CA  
To: "Jesse Arnup-Blondin" <jesse.arnup-blondin@hc-sc.gc.ca>, "Senior  
Communications Advisor Christine Roush" <christine.roush@hc-sc.gc.ca>  
Date: 2011-02-08 08:18 PM  
Subject: Fw: ADMO Q re: Salvia

Hi Jesse,  
Please see Jocelyn's reply below.  
Illegal activities with a given controlled substance constitutes different  
things in different countries (even state to state as in the US)  
contingent on the legislation of the country/state.

Have a look at Jocelyn's reply and let us know if this does the trick or  
if you want more specifics, which folks can pull from the IAS if need be.

Thanks, S

----- Original Message -----

From: Jocelyn Kula  
Sent: 2011-02-08 08:04 PM EST  
To: Stephanie Szick  
Cc: Christine Roush  
Subject: Re: ADMO Q re: Salvia

A central principle of our legislative framework for controlled substances  
is that a substance is never "illegal", only activities, e.g., sale,  
importation, cultivation, possession, etc., with a given substance can be  
illegal depending on what Schedule it is in. This mirrors the way the UN  
drug control conventions are set up. In other countries, depending on  
the legislation in place, the activities that are illegal will differ from  
country to country, or in the US, where there are no national controls in  
place, from state to state.

Our IAS on Salvia has more specific information in it, and Stephanie C can  
provide if needed. I would not suggest however that we try to clarify the  
IYH, it will only lead to more confusion...the wording we use here is  
consistent with the media lines, and all of our previous dockets etc.....

JK

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la  
santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

From: Stephanie Szick/HC-SC/GC/CA  
To: "Jocelyn Kula" <jocelyn.kula@hc-sc.gc.ca>, "Senior Communications  
Advisor Christine Roush" <christine.roush@hc-sc.gc.ca>  
Date: 2011-02-08 07:47 PM  
Subject: ADMO Q re: Salvia

Hi Jocelyn,




Plse see Jesse's email below and Q from Hilary re: controls place on  
salvia in other countries -  
Are you able to provide a reply before noon tomorrow?  
Thanks, S

From: Jesse Arnup-Blondin  
Sent: 2011-02-08 05:35 PM EST  
To: Stephanie Szick; Christine Roush  
Subject: Salvia - Question from ADM

Both the NOI and It's Your Health make reference to other countries  
"placing controls on the import and/or sale of salvia". Hilary wants to  
know if this means they are illegal. Can you please clarify? We may need  
to revise language to make it more clear.

Thanks!



**Re: Authority for publishing Salvia NOI**   
Stephanie Chandler to: Jocelyn Kula  
Cc: Denis Arsenault

2011-02-10 09:45 AM

Hi Jocelyn,

The BZP NOI was published under the authority of "Section 55 (1)(a) and Section 60 of the CDSA". I will revise the Salvia NOI insertion form to reflect this.

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

---

Jocelyn Kula                      hmmm.....sounds good to me, but perhaps we s...                      2011-02-09 04:44:08 PM

From:                      Jocelyn Kula/HC-SC/GC/CA  
To:                              Stephanie Chandler/HC-SC/GC/CA@HWC  
Cc:                              Denis Arsenault/HC-SC/GC/CA@HWC  
Date:                          2011-02-09 04:44 PM  
Subject:                      Re: Authority for publishing Salvia NOI

---

hmmm.....sounds good to me, but perhaps we should double check with past precedent.....what did we say with the BZP NOI back in 2008?

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada

---

Stephanie Chandler                      Hi Jocelyn, With regards to the authority of the...                      2011-02-09 04:27:17 PM

From:                      Stephanie Chandler/HC-SC/GC/CA  
To:                              Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc:                              Denis Arsenault/HC-SC/GC/CA@HWC  
Date:                          2011-02-09 04:27 PM  
Subject:                      Authority for publishing Salvia NOI

Hi Jocelyn,

With regards to the authority of the CDSA under which the Salvia NOI will be published, Section 60 of the Act states:

The Governor in Council may, by order,

amend any of Schedules I to VIII by adding to them or deleting from them any item or portion of an item, where the Governor in Council deems the amendment to be necessary in the public interest

Please advise as to whether we should include this Section on the NOI insertion form as opposed to Section 55?

Thanks,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca



**For review - Minister's Speech - Salvia**

Christine Roush to: Jocelyn Kula

2011-02-10 03:10 PM

Cc: Stephanie Chandler, Denis Arsenault, Dave Stephens,  
CSTD-OCS-DO

---

Hi Jocelyn,

In case MO would like to revisit the idea of a Salvia event sometime soon, we have proceeded with the drafting of a speech for the Minister. I have reviewed the speech and my changes are in red. Could you please do the same and return your comments to me by **Friday, Feb 11 at 10:00 am**.

Thanks,



Sp-Min-Salvia-v3(revcr)\_Feb10\_15h00.doc

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
Health Canada/Santé Canada  
Tel/Tél : (613) 954-0712/Cell: (613) 219-7194  
Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca

**Speech for the Minister**  
**The Honourable Leona Aglukkaq**

**Issue: Proposal to add Salvia Divinorum and “Salvinorin  
A” to Schedule III to the *Controlled Drugs and  
Substances Act.***

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**Date: TBD**

**Location TBD**

**Time: TBD**

**Word Count: 328**  
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Good Morning/Afternoon: Thank you for being here.

A substance known as Salvia is being used - and abused - by some young people.

It has been getting more popular because it's currently not an illegal substance, but it can have some of the same effects as illegal drugs.

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It's also popular among youth because it's easily available and because of the perception that it doesn't do any harm.

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Deleted: as if it were a drug

We are still learning about Salvia, but we do know that when it is used, it is most commonly smoked. And we know that smoking Salvia can produce hallucinations.

Those two facts alone tells us that is has potential to cause damage to the body or the brain....or both.

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If it's producing hallucinations, then it is interfering with the normal functions of the brain. When you are young, your brain is going through an important period of development. Anything that interferes with that development could have serious, long-term consequences.

Comment [S1]: To my knowledge, there is no evidence it affects development.

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Because of the way it is being used and because of its potential for abuse, we believe this substance needs to be controlled. This will reduce the potential risks to the health and safety of Canadians from its ready availability, its increased use and its unknown effects if used long-term.

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That's why we will be moving to control Salvia and its main active ingredient, "Salvinorin A", as controlled substances.

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As a first step, a notice will be published in the *Canada Gazette* in a few days. This will give Canadians an opportunity to comment on our proposal to include these substances under Schedule III to the Controlled Drugs and Substances Act.

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Making Salvia a controlled substance will make activities such as possession, trafficking, importing or cultivating salvia illegal.

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This will make it much harder to get Salvia, and it also sends the message to young Canadians that they should not be taking this substance. It will also allow law enforcement agencies to take action against illegal activities involving this substance.

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Legislation is an important step in controlling the availability and use of Salvia, but our most important task is to get the message to young people that this substance is dangerous. That is why we are taking these steps now and why we have posted information on our website about Salvia and the risks of using it. We want to eliminate the misconception that Salvia is safe compared to illegal drugs.

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Any non-prescription substance that interferes with the normal functions of a person's brain should not be taken by anyone at anytime.

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Though all of the dangers of Salvia are not known, we do know from our own review of information that it is not safe. And we don't want young people to find out the hard way and suffer for the rest of their lives.

Comment [S2]: Will the IYH have been posted prior to event?

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Comment [S3]: I would suggest deleting... seems a bit too forceful, and what about OTCs and NHPs that affect the brain?

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Comment [S4]: No evidence of long-term effects at this point, so do we want to say this?

Thank you.



**Fw: For review - Minister's Speech - Salvia**  
Denis Arsenault to: Jocelyn Kula  
Cc: Stephanie Chandler

2011-02-10 03:56 PM

Hi Jocelyn,

Stephanie and I have made a number of edits and suggestions.

That being said, there are several fairly definitive statements about the health effects of salvia that should be reviewed by Suzanne's group as we may want to clarify and/or tone down some of these statements.

Denis

---

Denis Arsenault, A/Manager / Gestionnaire p.i.  
Regulatory Policy Division /  
Division des politiques réglementaires,  
Office of Controlled Substances /  
Bureau des substances contrôlées,  
Health Canada / Santé Canada  
Tel/Tél: (613) 957-6828  
Fax / Télécopieur : (613) 946-4224  
E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca

----- Forwarded by Denis Arsenault/HC-SC/GC/CA on 2011-02-10 03:53 PM -----

From: Stephanie Chandler/HC-SC/GC/CA  
To: Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2011-02-10 03:46 PM  
Subject: Fw: For review - Minister's Speech - Salvia

Hi Denis,

I have reviewed the Minister's Speech (see attached). Would it be possible to discuss some of my comments for a few minutes this afternoon? Christine would like back by 10:00am tomorrow, though she seems to be suggesting that the event is not happening...do you know if this is the case?



Sp-Min-Salvia-v3(revcr)\_Feb10\_15h43.doc

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
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Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

----- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2011-02-10 03:44 PM -----

From: Christine Roush/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Stephanie Chandler/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, Dave  
Stephens/HC-SC/GC/CA@HWC, CSTD-OCS-DO



Date: 2011-02-10 03:10 PM  
Subject: For review - Minister's Speech - Salvia

---

Hi Jocelyn,

In case MO would like to revisit the idea of a Salvia event sometime soon, we have proceeded with the drafting of a speech for the Minister. I have reviewed the speech and my changes are in red. Could you please do the same and return your comments to me by Friday, Feb 11 at 10:00 am.

Thanks,

[attachment "Sp-Min-Salvia-v3(revcr)\_Feb10\_15h00.doc" deleted by Stephanie  
Chandler/HC-SC/GC/CA]

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
Health Canada/Santé Canada  
Tel/Tél : (613) 954-0712/Cell: (613) 219-7194  
Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca

**Speech for the Minister**  
**The Honourable Leona Aglukkaq**

**Issue: Proposal to add Salvia Divinorum and “Salvinorin  
A” to Schedule III the *Controlled Drugs and Substances  
Act*.**

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**Date: TBD**

**Location TBD**

**Time: TBD**

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We are still learning about Salvia, but we do know that when it is used, it is most commonly smoked. And we know that smoking Salvia can produce hallucinations.

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Those two facts alone tells us that is has potential to cause damage to the body or the brain....or both.

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If it's producing hallucinations, then it is interfering with the normal functions of the brain. When you are young, your brain is going through an important period of development. Anything that interferes with that development could have serious, long-term consequences.

Comment [S1]: To my knowledge, there is no evidence it affects development.

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Because of the way it is being used and because of its potential for abuse, we believe this substance needs to be controlled. This will reduce the potential risks to the health and safety of Canadians from its ready availability, its increased use and its unknown effects if used long-term.

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That's why we will be moving to control Salvia and its main active ingredient, "Salvinorin A", as controlled substances.

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As a first step, a notice will be published in the *Canada Gazette* in a few days. This will give Canadians an opportunity to comment on our proposal to include these substances under Schedule III to the *Controlled Drugs and Substances Act*.

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This will make it much harder to get Salvia, and it also sends the message to young Canadians that they should not be taking this substance. It will also allow law enforcement agencies to take action against illegal activities involving this substance.

Legislation is an important step in controlling the availability and use of Salvia, but our most important task is to get the message to young people that this substance is dangerous. That is why we are taking these steps now and why we have posted information on our website about Salvia and the risks of using it. We want to eliminate the misconception that Salvia is safe compared to illegal drugs.

Any non-prescription substance that interferes with the normal functions of a person's brain should not be taken by anyone at anytime.

Though all of the dangers of Salvia are not known, we do know from our own review of information that it is not safe. And we don't want young people to find out the hard way and suffer for the rest of their lives.

Thank you.

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**Fw: For review - Minister's Speech - Salvia**  
Jocelyn Kula to: stephanie.chandler, Denis Arsenault

2011-02-10 04:03 PM

can you both pls review and perhaps we should huddle at 9:30 to go over comments....  
JK

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224  
----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2011-02-10 04:02 PM -----

From: Christine Roush/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Stephanie Chandler/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, Dave  
Stephens/HC-SC/GC/CA@HWC, CSTD-OCS-DO  
Date: 2011-02-10 03:10 PM  
Subject: For review - Minister's Speech - Salvia

---

Hi Jocelyn,  
In case MO would like to revisit the idea of a Salvia event sometime soon, we have proceeded with the  
drafting of a speech for the Minister. I have reviewed the speech and my changes are in red. Could you  
please do the same and return your comments to me **by Friday, Feb 11 at 10:00 am.**

Thanks,



Sp-Min-Salvia-v3(revcr)\_Feb10\_15h00.doc

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
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Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca



**Fw: Salvia news release**  
Denis Arsenault to: Jocelyn Kula  
Cc: Stephanie Chandler

2011-02-10 04:25 PM

FYI - Further to my conversation with Christine.

Denis

Denis Arsenault, A/Manager / Gestionnaire p.i.  
Regulatory Policy Division /  
Division des politiques réglementaires,  
Office of Controlled Substances /  
Bureau des substances contrôlées,  
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----- Forwarded by Denis Arsenault/HC-SC/GC/CA on 2011-02-10 04:24 PM -----

From: Christine Roush/HC-SC/GC/CA  
To: Denis Arsenault/HC-SC/GC/CA@HWC  
Cc: Jocelyn Kula/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2011-02-10 04:07 PM  
Subject: Fw: Salvia news release

Hi Denis - as discussed, Dave just forwarded an email to me from MO (I wasn't copied on it) saying program is OK to go ahead and publish the NOI in CGI on Feb. 19th. See below.

Christine Roush  
Senior Communications Advisor/

From: Dave Stephens/HC-SC/GC/CA  
To: christine.roush@hc-sc.gc.ca  
Date: 2011-02-10 04:04 PM  
Subject: Fw: Salvia news release

it should be posted next week regardless

Dave Stephens  
Senior Communications Executive-Gestionnaire Principal des Communications  
HECSB/DGSCSE  
Health Canada/Sante Canada  
6th Floor, Room 6-033, 269 Laurier Ave. W., Ottawa, ON  
Tel: (613) 946-8107  
Cell: (613) 859-3581  
----- Forwarded by Dave Stephens/HC-SC/GC/CA on 2011-02-10 04:04 PM -----

From: Alexis M Tervo/HC-SC/GC/CA  
To: "Dave Stephens" <dave.stephens@hc-sc.gc.ca>  
Cc: "Ken Polk" <ken.polk@hc-sc.gc.ca>, "Charles Mojsej" <charles.mojsej@hc-sc.gc.ca>, "Blossom Leung" <blossom.leung@hc-sc.gc.ca>  
Date: 2011-02-10 08:07 AM  
Subject: Salvia news release

Hi Dave, Tim is checking if they want a Salvia news release next week (now that there mostly likely won't be an event). Tim also said that program can still proceed with going to CG1 for Feb 19th.

**DRAFT**  
11/02/2011

**Media Lines**  
***Salvia divinorum***

**Issue**

There is ongoing media interest regarding the availability of *Salvia divinorum* in Canada as well as Canadian surveillance data suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has concluded that *Salvia divinorum* and its main active ingredient salvinorin A should be scheduled under the *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth. A Notice to Interested Parties outlining Health Canada's proposal to regulate this substance will be published in *Canada Gazette*, Part I, on February 19, 2011 (TBC).

**Key Messages:**

- The Government of Canada is taking these steps in order to protect the health and safety of Canadians, particularly youth, from the potentially harmful effects of *Salvia divinorum* and/or salvinorin A.
- After reviewing available information and reports that suggest these substances have the potential for abuse, especially among young people, Health Canada is proposing to schedule both *Salvia divinorum* and its main active ingredient salvinorin A as controlled substances.
- Health Canada is continuing to survey the prevalence of salvia use and have based our proposed scheduling on available information and reports that suggest these substances have the potential for abuse, especially among young Canadians. The risks of salvia use include hallucinations, loss of consciousness and short-term memory loss.
- The proposed inclusion of *Salvia divinorum* and salvinorin A in Schedule III to the *Controlled Drugs and Substances Act* would make possession, trafficking, importation, exportation, production (or cultivation), possession for the purpose of trafficking or possession for the purposes of exporting illegal unless authorized by regulation.

**Supplementary Messages:**

- Though it is a hallucinogen, the plant *Salvia divinorum* is not currently scheduled under the CDSA.
- To date, Health Canada has not authorized for sale any natural health products which contain *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products containing *Salvia divinorum* or its active ingredient



**DRAFT**  
11/02/2011

salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act and its associated regulations*.

**Questions and Answers:**

**Q1 - What are the risks associated with the use of *Salvia divinorum***

A1 - *S. divinorum* is known to have both physical and mental effects. The effects of *S. divinorum*, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

There is no way to predict what effect these substances may have on an individual. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product;
- how much is used;
- the purity of the product (products that contain *S. divinorum* may be mixed with other substances);
- how it is taken, for example, whether the product is chewed, swallowed or smoked; and
- the user's mood and expectations.

While scientists know which brain receptors are targeted by the main active ingredient, salvinorin A, very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or if it can cause permanent damage;
- how it interacts with other substances, including other drugs, natural health products and alcohol;
- the potential of *S. divinorum* to produce physical dependence and/or addiction.

For more information on *Salvia divinorum* and the risks associated with its use, please see *It's Your Health* at: (insert link to the *It's Your Health* article.)

**Q2 – What is involved in scheduling *Salvia divinorum* as a controlled substance and what stage is it at?**

**DRAFT**

11/02/2011

A2 - Health Canada considers several factors in determining whether the scheduling of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- Overall risk to public health and safety posed by the substance.
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- International requirements and trends in international control.

Health Canada recently concluded its assessment of *Salvia divinorum* and salvinorin A against these factors and proposes to include both substances in Schedule III to the CDSA. The first step in the process of scheduling a substance under the CDSA is the publication of a *Notice to Interested Parties* (NOI) in *Canada Gazette*, Part I, which will be published on February 19, 2011 (TBC) for a 30-day comment period. This notice provides interested stakeholders with the opportunity to provide comments on Health Canada's proposal to add *Salvia divinorum* and its main active ingredient salvinorin A to Schedule III to the CDSA. Any comments received are considered during the preparation of a regulatory proposal. There will be additional opportunities for comment as the federal regulatory process progresses, which usually takes about 18 to 24 months to complete.

**Q3. Why has the Government now decided to schedule these substances under the CDSA?**

A3. Scheduling these products will reduce the potential risks to the health and safety of Canadians associated with their ready availability, with their increased use and their unknown effects. The scheduling of *Salvia divinorum* and salvinorin A will also eliminate the current misconception that these substances are a safe alternative to other illegal drugs. Furthermore, the scheduling will also enable law enforcement agencies to take action against suspected illegal activities involving these substances.

**Q4 – Are *Salvia divinorum* and/or salvinorin A controlled internationally? How are these substances regulated in other countries?**

A4 - Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions; as a result, there is no requirement for them to be scheduled as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

The move to include *Salvia divinorum* and salvinorin A in Schedule III to the CDSA is consistent with actions taken by several countries (e.g., Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden) that have also placed similar controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A.

**DRAFT**  
11/02/2011

Some individual U.S. states have implemented similar laws restricting their use, sale and/or distribution.

**Q5 – Is there any research on the use of *Salvia divinorum* in Canada?**

A5 - Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *Salvia divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *Salvia divinorum* in the past year. The 2009 *Ontario Student Drug Use and Health Survey (OSDUHS)* indicated that 5.4% of Ontario students in grades 7-12 reported ever using *Salvia divinorum* and 4.4% of these students reported using this substance in the past year.

**Q6 – If Health Canada is aware that the use of *Salvia divinorum* can produce negative health effects such as hallucinations, feelings of anxiety, etc., why is it not controlled under the Controlled Drugs and Substances Act?**

A6 – The move to schedule *Salvia divinorum* and salvinorin A as controlled substances is based on surveillance data from surveys such as the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)*, *Youth Smoking Survey (YSS)* and the *Ontario Student Drug Use and Health Survey (OSDUHS)*, some of which only became available in 2010.

In the interim, as *Salvia divinorum* is a plant with hallucinogenic properties, it currently meets the definition of a natural health product under the *Natural Health Products Regulations (NHPR)*. The sale of unauthorized natural health products may be subject to compliance and enforcement action in accordance with the *Food and Drugs Act* and its associated regulations.

**Q7 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A7 – Once *Salvia divinorum* and salvinorin A are included in Schedule III to the CDSA, law enforcement will be able to take appropriate action in response to suspected illegal activities with these substances.

Currently, however, *Salvia divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. For more information on how to submit a consumer complaint about the unauthorized sale of drugs containing *Salvia divinorum* and/or salvinorin A, visit: [www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_44\\_consumer\\_consommateur\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_44_consumer_consommateur_cp-pc-eng.php).

**DRAFT**

11/02/2011

**Q8 - Has Health Canada issued any kind of warning to Canadians about *Salvia divinorum*?**

A8 - Health Canada has developed an *It's Your Health* article about *Salvia divinorum* to help inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at: (link to come). Health Canada also issued a news release on February XX announcing the Government of Canada's intention to schedule *Salvia divinorum* and salvinorin A, as controlled substances. A Notice to Interested Parties, outlining Health Canada's proposal, was published in *Canada Gazette*, Part I, on February 19, 2011 (TBC), giving interested parties a 30-day period to submit their comments. There will be additional opportunities for comment as the federal regulatory process progresses.

**Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff, incense special, and salvia. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

Data from the 2008-2009 Youth Smoking Survey indicates that:

- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;
- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year; and
- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using Salvia in their lifetime (0.2% in the past year); and
- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that:

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;
- 5.4% of students (grades 7-12) ever used *Salvia divinorum*; and
- use of *Salvia divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

**DRAFT**  
11/02/2011

**Prepared by:** Stephanie Chandler and Denis Arsenault, OCS, CSTD  
Reviewed and revised by: Christine Roush, Senior Communications  
Advisor, HECS, Communications

**Approved by:**

Jocelyn Kula, A/Director, OCS, CSTD, HECS (Jan 19, 2011 and Jan 27, 2011)  
Suzanne Desjardins, Director, ODARS, CSTD, HECS (Approved Jan 20, 2011)  
Cathy Sabiston, DG, CSTD, HECS  
Chris Turner, DG, MHPD  
Scott Sawler, DG, NHPD  
Diana Dowthwaite, DG, HPFB  
Sharon Mullin, Director, Compliance and Enforcement Coordination, HPFB  
Robin Marles, Director, Bureau of Clinical Trials, NHPD  
Chantal Trepanier, Legal Counsel, HECS  
Sherrey Collier, Legal Counsel, HPFB  
David Gotlieb, A/Communications Executive, HPFB  
Judith O'Brien, A/Communications Executive, HECS  
Ken Polk, A/Director, Public Affairs, PACCB  
Charles Mojsej, DG, PACCB  
Paul Glover, ADM, HPFB  
Hillary Geller, A/ADM, HECS  
Anne Lamar, ADM, PACCB  
DMO (pending)  
MO (pending)  
PCO (pending)



**Re: Fw: For review - Minister's Speech - Salvia** 

Suzanne Desjardins to: Stephanie Chandler

2011-02-11 08:58 AM

Cc: Denis Arsenault, Jocelyn Kula, Christine Roush, Hanan Abramovici

History: This message has been replied to and forwarded.

Hi Stephanie,

Please find our comments attached. You were right that the health effects were not quite accurate (that's reflected by the number of comments).



Sp-Min-Salvia-v3(revcr)\_Feb10\_15h43 SD cmts 16h38\_HA.doc

Thanks  
Suzanne

Stephanie Chandler Hi Suzanne, Would it be possible for you to rev... 2011-02-10 04:26:13 PM

From: Stephanie Chandler/HC-SC/GC/CA  
To: Suzanne Desjardins/HC-SC/GC/CA@HWC  
Cc: Jocelyn Kula/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2011-02-10 04:26 PM  
Subject: Fw: For review - Minister's Speech - Salvia

Hi Suzanne,

Would it be possible for you to review the Minister's Speech for the (potential) Salvia NOI event? There are several fairly definitive statements about the health effects of Salvia, so your input would be appreciated.

[attachment "Sp-Min-Salvia-v3(revcr)\_Feb10\_15h43.doc" deleted by Suzanne Desjardins/HC-SC/GC/CA]

My apologies for the short-turn around time, but Comms would like it back from OCS by 10:00am tomorrow, so if you could review ASAP it would be much appreciated.

Thanks,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca  
----- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2011-02-10 04:21 PM -----

From: Denis Arsenault/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC

002727

**Speech for the Minister**  
**The Honourable Leona Aglukkaq**

**Issue: Proposal to add Salvia Divinorum and “Salvinorin  
A” to Schedule III of the Controlled Drugs and  
Substances Act.**

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**Date: TBD**

**Location TBD**

**Time: TBD**

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Good Morning/Afternoon: Thank you for being here.

A substance known as Salvia divinorum is being abused - by some young people.

It has been getting more popular because it's currently not an illegal substance, but it can have some of the same effects as certain illegal drugs.

It's also popular among youth because it's easily available and because of the false perception that it doesn't do any harm.

We are still learning about Salvia, but we do know that when it is used, it is most commonly smoked. And we know that smoking Salvia can produce hallucinations.

While we are still learning about Salvia divinorum, we know that when it is used, it is most commonly smoked and that smoking Salvia can produce hallucinations.

Those two facts alone tells us that it has the potential to harm health, cause damage to the body or the brain... or both.

If it's producing hallucinations, then it is interfering with the normal functions of the brain. When you are young, your brain is going through an important period of development. Anything that interferes with that development could have serious, long-term consequences.

Therefore, because of the way it is being used, and its potential for abuse and harm to health we will be moving to control Salvia divinorum and its main active ingredient, "Salvinorin A", as controlled substances to reduce the known and potential risks to the health and safety of Canadians. Because of the way it is being used and because of its potential for abuse, we believe this substance needs to be controlled. This will reduce the potential risks to the health and safety of Canadians from its ready availability, its increased use and its unknown effects if used long-term.

That's why we will be moving to control Salvia divinorum and its main active ingredient, "Salvinorin A", as controlled substances.

**Comment [HABR1]:** Should we not be specifying that we are talking about Salvia divinorum in particular? There are many species of Salvia.

**Comment [S2]:** This substance is only being used for its psychoactive effects, therefore it is abused

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**Comment [HABR3]:** I think we should be more precise, even if we're being vague: "some of the same effects as CERTAIN illegal drugs."

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**Comment [HABR4]:** "because of the FALSE perception that it doesn't do any harm"

**Comment [HABR5]:** Unsure about this statement. Some websites claim it's relatively safe, but many who've used it report very unpleasant experiences. Maybe we should remove the second half of this sentence. Or alternatively we could say: "...and because of the false perception that it is safe compared to other illegal drugs"

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**Comment [HABR7]:** Is... [2]

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As a first step, a notice will be published in the *Canada Gazette* in a few days. This will give Canadians an opportunity to comment on our proposal to include these substances under Schedule III to the *Controlled Drugs and Substances Act*.

Making *Salvia divinorum* (and "Salvinorin A") a controlled substances will make activities such as possession, trafficking, importing or cultivating illegal.

This will make it much harder to get *Salvia*, and it will also send the message to young Canadians that they should not be taking this substance. It will also allow law enforcement agencies to take action against illegal activities involving these substances.

Legislation is an important step in controlling the availability and use of *Salvia divinorum*, but our most important task is to get the message to young people that this substance is dangerous. That is why we are taking these steps now and why we have posted information on our website about *Salvia* and the risks of using it. We want to eliminate the misconception that *Salvia* is safe compared to illegal drugs.

Any substance that interferes with the normal functions of a person's brain should not be taken by anyone at anytime, unless it is prescribed by a physician for the treatment of a disease.

Though all of the dangers of *Salvia* are not known, we do know from our own review of information that it is not safe. And we don't want young people to find out the hard way and suffer for the rest of their lives.

Thank you.

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- Comment [S12]: Agree ... [8]
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<b>Page 2: [1] Comment [S6]</b>	<b>STCHANDL</b>	<b>2011-02-10 3:32:00 PM</b>
To my knowledge, there is no evidence it affects development.		
<b>Page 2: [2] Comment [HABR7]</b>	<b>Hanan Abramovici</b>	<b>2011-02-10 5:48:00 PM</b>
Is this paragraph really needed in light of the information provided above? I would remove this.		
<b>Page 3: [3] Deleted</b>	<b>CROUSH</b>	<b>2011-02-10 2:31:00 PM</b>
If it's producing hallucinations, then it is interfering with the normal functions of the brain. When you are young, your brain is going through an important period of development. Anything that interferes with that development could have serious long-term consequences.		
<b>Page 3: [4] Comment [S8]</b>	<b>STCHANDL</b>	<b>2011-02-10 3:25:00 PM</b>
Will the IYH have been posted prior to event?		
<b>Page 3: [5] Comment [S9]</b>	<b>SDESJARD</b>	<b>2011-02-10 4:36:00 PM</b>
Agreed that this para should be deleted; it is too hard to explain in a sentence and would confuse the message i.e. it is OK to interfere with brain functions if you are sick, but not if you are healthy??? What about alcohol??? It does interfere with the brain functions		
<b>Page 3: [6] Comment [S10]</b>	<b>STCHANDL</b>	<b>2011-02-10 3:38:00 PM</b>
I would suggest deleting...seems a bit too forceful, and what about OTCs and NHPs that affect the brain?		
<b>Page 3: [7] Comment [S11]</b>	<b>STCHANDL</b>	<b>2011-02-10 3:43:00 PM</b>
No evidence of long-term effects at this point, so do we want to say this?		
<b>Page 3: [8] Comment [S12]</b>	<b>SDESJARD</b>	<b>2011-02-10 4:37:00 PM</b>
Agreed that we should delete this part as we don't know long-term effects.		



**Speech on Salvia**

Carmen Berube to: Denis Arsenault, Suzanne Desjardins, Stephanie Chandler

2011-02-11 09:18 AM

Jocelyn will be a few minutes late. Please come by her office at around 9:40

----- Forwarded by Carmen Berube/HC-SC/GC/CA on 2011-02-11 09:17 AM -----



**Calendar Entry**

Type: Meeting  
Chair: Jocelyn Kula/HC-SC/GC/CA

<input type="checkbox"/>	Mark Private
<input type="checkbox"/>	Mark Available

Subject:	Speech on Salvia
----------	------------------

When:	Starts:	2011-02-11 Fri	09:30 AM	Local time	
	Ends:	2011-02-11 Fri	10:00 AM	Local time	30 mins
Who:	Required:	Denis Arsenault/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC			
Where:	Location:	D387 (OCS DO)			

-----

**Description**

**Speech for the Minister**  
**The Honourable Leona Aglukkaq**

**Issue: Proposal to add Salvia Divinorum and Salvinorin  
A to Schedule III to the *Controlled Drugs and  
Substances Act*.**

**Date: TBD**

**Location TBD**

**Time: TBD**

Word Count: 328  
Check Against Delivery

Good Morning/Afternoon: Thank you for being here.

A substance known as Salvia divinorum is being abused by some young people.

*Its use has been increasing in popularity*  
It has been getting more popular because it's currently not a controlled substance, but it can have some of the same effects as certain illegal drugs. *even though it*

It's also popular among youth because it's easily available and because of the false perception that it doesn't do any harm. *become* *illicit drugs*  
*↳ that it is safer than other drugs*

While we are still learning about Salvia divinorum, we know that when it is used, it is most commonly smoked and that smoking Salvia can produce hallucinations.

Those two facts alone tells us that is has the potential to harm health.

Therefore, because of the way it is being used, and its potential for abuse and harm to health, we will be moving to control Salvia *like illicit drug* divinorum, and its main active ingredient salvinorin A, as controlled substances to reduce the known and potential risks to the health and safety of Canadians, particularly youth.

As a first step, a notice will be published in the *Canada Gazette* in a few days. This will give Canadians an opportunity to comment on our proposal to include these substances under Schedule III to the *Controlled Drugs and Substances Act*.

Making Salvia divinorum (and salvinorin A) controlled substances will make activities such as possession, trafficking, importing or cultivating illegal.

This will make it much harder to get Salvia, and will also send the message to young Canadians that they should not be using this substance. It will also allow law enforcement agencies to take action against illegal activities involving these substances.

**Comment [HABR1]:** Should we not be specifying that we are talking about Salvia divinorum in particular? There are many species of Salvia.

**Comment [S2]:** This substance is only being used for its psychoactive effects, therefore it is abused

**Comment [HABR3]:** I think we should be more precise, even if we're being vague: "some of the same effects as CERTAIN illegal drugs."

**Comment [HABR4]:** "because of the FALSE perception that it doesn't do any harm"

Legislation is an important step in controlling the availability and use of Salvia divinorum, but our most important task is to get the message to young people that this substance is dangerous. That is why we are taking these steps now and why we have posted information ~~on our website~~ about Salvia and the risks of using it. We want to eliminate the misconception that Salvia is safe compared to ~~legal~~ drugs.

on our website.

other illicit

Comment [S5]: Will the IYH have been posted prior to event?

Though all of the dangers of Salvia are not known, we do know from our own review of information that it is not safe. And we don't want young people to find out the hard way.

Thank you.

**Speech for the Minister**  
**The Honourable Leona Aglukkaq**

**Issue: Proposal to add Salvia Divinorum and Salvinorin A to Schedule III to the Controlled Drugs and Substances Act.**

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**Date: TBD**

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Those two facts alone tells us that it has the potential to harm health.

Therefore, because of the way it is being used, and its potential for abuse and harm to health, we will be moving to control Salvia divinorum, and its main active ingredient salvinorin A, as controlled substances to reduce the known and potential risks to the health and safety of Canadians.

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**Comment [HABR1]:** Should we not be specifying that we are talking about Salvia divinorum in particular? There are many species of Salvia.

**Comment [S2]:** This substance is only being used for its psychoactive effects, therefore it is abused

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**Comment [HABR3]:** I think we should be more precise, even if we're being vague: "some of the same effects as CERTAIN illegal drugs."

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**Comment [HABR4]:** "because of the FALSE perception that it doesn't do any harm"

**Comment [HABR5]:** Unsure about this statement. Some websites claim it's relatively safe, but many who've used it ref ... [2]

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Legislation is an important step in controlling the availability and use of Salvia divinorum, but our most important task is to get the message to young people that this substance is dangerous. That is why we are taking these steps now and why we have posted information on our website about Salvia and the risks of using it. We want to eliminate the misconception that Salvia is safe compared to illegal drugs.

Though all of the dangers of Salvia are not known, we do know from our own review of information that it is not safe. And we don't want young people to find out the hard way.

Thank you.

**Deleted:** If it's producing hallucinations, then it is interfering with the normal functions of the brain. When you are young, your brain is going through an important period of development. Anything that interferes with that development could have serious long-term consequences.¶

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**Comment [S8]:** Will the IYH have been posted prior to event?

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**Comment [S9]:** Agreed that this para should be deleted; it is too hard to explain in a sentence and would confuse the message i.e. it is OK to interfere with brain functions if you are sick, but not if you are healthy??? What about alcohol??? It does interfere with the brain functions

**Comment [S10]:** I would suggest deleting... seems a bit too forceful, and what about OTCs and NHPs that affect the brain?

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**Comment [S11]:** No evidence of long-term effects at this point, so do we want to say this?

**Comment [S12]:** Agreed that we should delete this part as we don't know long-term effects.

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Page 2: [2] Comment [HABR5]	Hanan Abramovici	2011-02-10 6:07:00 PM
Unsure about this statement. Some websites claim it's relatively safe, but many who've used it report very unpleasant experiences. Maybe we should remove the second half of this sentence. Or alternatively we could say: "...and because of the false perception that it is safe compared to other illegal drugs"		
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<del>cause damage to the body or the brain....or both.</del>		
Page 2: [7] Comment [S6]	STCHANDL	2011-02-10 3:32:00 PM
To my knowledge, there is no evidence it affects development.		
Page 2: [8] Comment [HABR7]	Hanan Abramovici	2011-02-10 5:48:00 PM
Is this paragraph really needed in light of the information provided above? I would remove this.		
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If it's producing hallucinations, then it is interfering with the normal functions of the brain. When you are young, your brain is going through an important period of development. Anything that interferes with that development could have serious, long-term consequences.

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~~That's the same law that makes it illegal to possess or sell common street drugs.~~

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**Speech for the Minister**  
**The Honourable Leona Aglukkaq**

**Issue: Proposal to add Salvia Divinorum and “Salvinorin A” to Schedule III of the Controlled Drugs and Substances Act.**

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Good Morning/Afternoon: Thank you for being here.

A substance known as Salvia divinorum is being abused - by some young people.

It has been getting more popular because it's currently not an illegal substance, but it can have some of the same effects as certain illegal drugs.

It's also popular among youth because it's easily available and because of the false perception that it doesn't do any harm.

We are still learning about Salvia, but we do know that when it is used, it is most commonly smoked. And we know that smoking Salvia can produce hallucinations.

While we are still learning about Salvia divinorum, we know that when it is used, it is most commonly smoked and that smoking Salvia can produce hallucinations.

Those two facts alone tells us that it has the potential to harm health, cause damage to the body or the brain... or both.

If it's producing hallucinations, then it is interfering with the normal functions of the brain. When you are young, your brain is going through an important period of development. Anything that interferes with that development could have serious, long-term consequences.

Therefore, because of the way it is being used, and its potential for abuse and harm to health we will be moving to control Salvia divinorum and its main active ingredient, "Salvinorin A", as controlled substances to reduce the known and potential risks to the health and safety of Canadians. Because of the way it is being used and because of its potential for abuse, we believe this substance needs to be controlled. This will reduce the potential risks to the health and safety of Canadians from its ready availability, its increased use and its unknown effects if used long-term.

That's why we will be moving to control Salvia divinorum and its main active ingredient, "Salvinorin A", as controlled substances.

**Comment [HABR1]:** Should we not be specifying that we are talking about Salvia divinorum in particular? There are many species of Salvia.

**Comment [S2]:** This substance is only being used for its psychoactive effects, therefore it is abused

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**Comment [HABR3]:** I think we should be more precise, even if we're being vague: "some of the same effects as CERTAIN illegal drugs."

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**Comment [HABR4]:** "because of the FALSE perception that it doesn't do any harm?"

**Comment [HABR5]:** Unsure about this statement. Some websites claim it's relatively safe, but many who've used it report very unpleasant experiences. Maybe we should remove the second half of this sentence. Or alternatively we could say: "...and because of the false perception that it is safe compared to other illegal drugs?"

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As a first step, a notice will be published in the *Canada Gazette* in a few days. This will give Canadians an opportunity to comment on our proposal to include these substances under Schedule III to the *Controlled Drugs and Substances Act*.

Making *Salvia divinorum* (and "Salvinorin A") a controlled substances will make activities such as possession, trafficking, importing or cultivating illegal.

This will make it much harder to get *Salvia*, and it will also send the message to young Canadians that they should not be taking this substance. It will also allow law enforcement agencies to take action against illegal activities involving these substances.

Legislation is an important step in controlling the availability and use of *Salvia divinorum*, but our most important task is to get the message to young people that this substance is dangerous. That is why we are taking these steps now and why we have posted information on our website about *Salvia* and the risks of using it. We want to eliminate the misconception that *Salvia* is safe compared to illegal drugs.

Any substance that interferes with the normal functions of a person's brain should not be taken by anyone at anytime, unless it is prescribed by a physician for the treatment of a disease.

Though all of the dangers of *Salvia* are not known, we do know from our own review of information that it is not safe. And we don't want young people to find out the hard way and suffer for the rest of their lives.

Thank you.

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<b>Page 3: [4] Comment [S8]</b>	<b>STCHANDL</b>	<b>2011-02-10 3:25:00 PM</b>
Will the IYH have been posted prior to event?		
<b>Page 3: [5] Comment [S9]</b>	<b>SDESJARD</b>	<b>2011-02-10 4:36:00 PM</b>
Agreed that this para should be deleted; it is too hard to explain in a sentence and would confuse the message i.e. it is OK to interfere with brain functions if you are sick, but not if you are healthy??? What about alcohol??? It does interfere with the brain functions		
<b>Page 3: [6] Comment [S10]</b>	<b>STCHANDL</b>	<b>2011-02-10 3:38:00 PM</b>
I would suggest deleting...seems a bit too forceful, and what about OTCs and NHPs that affect the brain?		
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Agreed that we should delete this part as we don't know long-term effects.		



**Fw: For review - Minister's Speech - Salvia**  
Suzanne Desjardins to: Stephanie Chandler  
Cc: Hanan Abramovici

2011-02-11 11:13 AM

History: This message has been forwarded.

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Hi Stephanie,

I support Hanan's input below.

Thanks

Suzanne

----- Forwarded by Suzanne Desjardins/HC-SC/GC/CA on 2011-02-11 11:11 AM -----

From: Hanan Abramovici/HC-SC/GC/CA  
To: Suzanne Desjardins/HC-SC/GC/CA@HWC  
Date: 2011-02-11 10:26 AM  
Subject: Re: Fw: For review - Minister's Speech - Salvia

---

Hi Suzanne,

I have made some additional changes to the document (please see attached word document).

Clean versions of these paragraphs (and explanations) below:

I have modified the original paragraphs 2 and 3 to yield (I think it makes more sense this way):  
"Its use has been increasing in popularity, even though it can have some of the same effects as certain illicit drugs. It has also become popular among youth because it is not currently a controlled substance, it's easily available, and because of the false perception that it is safer than illicit drugs."

Last paragraph has been eliminated and merged to the second to last paragraph to yield (also the word "out" in bold has been added):

"Legislation is an important step in controlling the availability and use of Salvia divinorum, but our most important task is to get the message **out** to young people that this substance is dangerous. That is why we are taking these steps now and why we have posted information about Salvia and the risks of using it on our website. We want to eliminate the misconception that Salvia is safe compared to other illicit drugs and we don't want young people to find out the hard way."

Thanks,  
Hanan



Sp-Min-Salvia-v3(revcr)\_Feb11\_9h59\_OCS+ORS\_HA.doc



Stephanie Chandler Hi Suzanne, I have incorporated the comments... 2011-02-11 10:04:35 AM

From: Stephanie Chandler/HC-SC/GC/CA  
To: Suzanne Desjardins/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Hanan Abramovici/HC-SC/GC/CA@HWC, Christine Roush/HC-SC/GC/CA@HWC  
Date: 2011-02-11 10:04 AM  
Subject: Re: Fw: For review - Minister's Speech - Salvia

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Hi Suzanne,

I have incorporated the comments from today's meeting and would appreciate if you could have one last look to make sure you are okay with the changes.

[attachment "Sp-Min-Salvia-v3(revcr)\_Feb11\_9h59\_OCS+ORS.doc" deleted by Hanan Abramovici/HC-SC/GC/CA]

Thank you!

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

Suzanne Desjardins Hi Stephanie, Please find our comments attac... 2011-02-11 08:58:45 AM

From: Suzanne Desjardins/HC-SC/GC/CA  
To: Stephanie Chandler/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Christine Roush/HC-SC/GC/CA@HWC, Hanan Abramovici/HC-SC/GC/CA@HWC  
Date: 2011-02-11 08:58 AM  
Subject: Re: Fw: For review - Minister's Speech - Salvia

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Hi Stephanie,

Please find our comments attached. You were right that the health effects were not quite accurate (that's reflected by the number of comments).

[attachment "Sp-Min-Salvia-v3(revcr)\_Feb10\_15h43 SD cmts 16h38\_HA.doc" deleted by Stephanie Chandler/HC-SC/GC/CA]

Thanks  
Suzanne

Stephanie Chandler Hi Suzanne, Would it be possible for you to rev... 2011-02-10 04:26:13 PM

**Speech for the Minister**  
**The Honourable Leona Aglukkaq**

**Issue: Proposal to add Salvia Divinorum and Salvinorin A to Schedule III to the *Controlled Drugs and Substances Act*.**

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Good Morning/Afternoon: Thank you for being here.

A substance known as Salvia divinorum is being abused by some young people.

~~Its use has been increasing in popularity because it's currently not a controlled substance, even though it can have some of the same effects as certain illicit drugs.~~

Its use has been increasing in popularity, even though it can have some of the same effects as certain illicit drugs. It has also become popular among youth because it is not currently a controlled substance, it's easily available, and because of the false perception that it is safer than illicit drugs.

~~It has also become popular among youth because it's easily available and because of the false perception that it is safer than illicit drugs.~~

While we are still learning about Salvia divinorum, we know that when it is used, it is most commonly smoked and that smoking Salvia can produce hallucinations.

Those two facts alone tells us that is has the potential to harm health.

Therefore, because of the way it is being used, and its potential for abuse and harm to health, we will be moving to control Salvia divinorum, and its main active ingredient salvinorin A, like other illicit drugs in order to reduce the known and potential risks to the health and safety of Canadians, particularly youth.

As a first step, a notice will be published in the *Canada Gazette* in a few days. This will give Canadians an opportunity to comment on our proposal to include these substances in Schedule III to the *Controlled Drugs and Substances Act*.

Making Salvia divinorum (and salvinorin A) controlled substances will make activities such as possession, trafficking, importing or cultivating illegal.

**Comment [HABR1]:** Should we not be specifying that we are talking about Salvia divinorum in particular? There are many species of Salvia.

**Comment [S2]:** This substance is only being used for its psychoactive effects, therefore it is abused

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**Comment [HABR3]:** I think we should be more precise, even if we're being vague: "some of the same effects as CERTAIN illegal drugs."

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**Comment [HABR4]:** "because of the FALSE perception that it doesn't do any harm"

**Comment [HABR5]:** Unsure about this statement. Some websites claim it's relatively safe, but many who've used it report very unpleasant experiences. Maybe we should remove t... [3]

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This will make it much harder to get Salvia, and will also send the message to young Canadians that they should not be using this substance. It will also allow law enforcement agencies to take action against illegal activities involving these substances.

Legislation is an important step in controlling the availability and use of Salvia divinorum, but our most important task is to get the message out to young people that this substance is dangerous. That is why we are taking these steps now and why we have posted information about Salvia and the risks of using it on our website. We want to eliminate the misconception that Salvia is safe compared to other illicit drugs, and we don't want young people to find out the hard way.

~~Though all of the dangers of Salvia are not known, we do know from our own review of information that it is not safe. And we don't want young people to find out the hard way.~~

Thank you.

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Page 2: [4] Deleted <del>that it doesn't do any harm</del> <small>[[HABR1]]</small>	STCHANDL	2011-02-11 9:58:00 AM
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Strikethrough, Not Highlight		
Page 3: [23] Comment [S11]	STCHANDL	2011-02-10 3:43:00 PM
No evidence of long-term effects at this point, so do we want to say this?		
Page 3: [24] Comment [S12]	SDESJARD	2011-02-10 4:37:00 PM
Agreed that we should delete this part as we don't know long-term effects.		
Page 3: [25] Deleted	STCHANDL	2011-02-11 9:08:00 AM
and suffer for the rest of their lives <sup>[S3]</sup>		



**Fw: Salvia NOI**  
Denis Arsenault to: Jocelyn Kula  
Cc: Stephanie Chandler

2011-02-11 09:38 AM

FYI - We will deliver the package this morning after our meeting with Suzanne.

Denis

---

Denis Arsenault, A/Manager / Gestionnaire p.i.  
Regulatory Policy Division /  
Division des politiques réglementaires,  
Office of Controlled Substances /  
Bureau des substances contrôlées,  
Health Canada / Santé Canada  
Tel/Tél: (613) 957-6828  
Fax / Télécopieur : (613) 946-4224  
E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca  
----- Forwarded by Denis Arsenault/HC-SC/GC/CA on 2011-02-11 09:38 AM -----

From: Jesse Arnup-Blondin/HC-SC/GC/CA  
To: Stephanie Szick/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2011-02-11 09:19 AM  
Subject: Re: Salvia NOI

Yep!

Stephanie Szick

----- Original Message -----

**From:** Stephanie Szick  
**Sent:** 2011-02-11 09:03 AM EST  
**To:** Jesse Arnup-Blondin  
**Cc:** Denis Arsenault  
**Subject:** Salvia NOI

hi Jesse,

Salvia NOI is being delivered today -- by 10:00 for CG1 Sat. Feb. 26.

Assuming this is all still fine to proceed?

Stephanie Szick  
Director General's Office / Bureau du directeur général  
Controlled Substances & Tobacco Directorate (CSTD) /  
Direction des substances contrôlées et de la lutte au tabagisme (DSCLT)  
Health Canada / Santé Canada  
Tel / Tél: (613) 948-8651





**Re: Fw: For review - Minister's Speech - Salvia**   
Jocelyn Kula to: Stephanie Chandler

2011-02-11 11:19 AM

History: This message has been forwarded.

approved; pls send to Christine

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

Stephanie Chandler Hi Jocelyn, Hanan has suggested some minor... 2011-02-11 11:19:29 AM

---

From: Stephanie Chandler/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC, Hanan Abramovici/HC-SC/GC/CA@HWC, Suzanne  
Desjardins/HC-SC/GC/CA@HWC  
Date: 2011-02-11 11:19 AM  
Subject: Fw: For review - Minister's Speech - Salvia

Hi Jocelyn,

Hanan has suggested some minor changes and Suzanne has approved them. For your review.



Sp-Min-Salvia-v3(revcr)\_Feb11\_11h17\_OCS+ORS.doc

Thanks,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca  
----- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2011-02-11 11:17 AM -----

---

From: Suzanne Desjardins/HC-SC/GC/CA  
To: Stephanie Chandler/HC-SC/GC/CA@HWC  
Cc: Hanan Abramovici/HC-SC/GC/CA@HWC  
Date: 2011-02-11 11:13 AM  
Subject: Fw: For review - Minister's Speech - Salvia

Hi Stephanie,

002754



**Re: REVISED- Minister's Speech - Salvia**   
Hanan Abramovici to: Stephanie Chandler

2011-02-11 11:34 AM

History: This message has been replied to.

Thanks Stephanie! My apologies for not catching that one earlier.

h.

Stephanie Chandler Hi Christine, Sorry but Hanan just caught one...

2011-02-11 11:31:46 AM

From: Stephanie Chandler/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Cc: Hanan Abramovici/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2011-02-11 11:31 AM  
Subject: REVISED- Minister's Speech - Salvia

Hi Christine,

Sorry but Hanan just caught one error in the version I last sent you. In the last paragraph, the word "other" should be removed so as not to give the impression that Salvia is an illicit drug. I have fixed in the version attached below:

[attachment "Sp-Min-Salvia-v3(revcr)\_Feb11\_11h29\_OCS+ORS.doc" deleted by Hanan Abramovici/HC-SC/GC/CA]

Sorry about that!

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca  
----- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2011-02-11 11:29 AM -----

From: Stephanie Chandler/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Cc: Jocelyn Kula/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC, Hanan Abramovici/HC-SC/GC/CA@HWC  
Date: 2011-02-11 11:21 AM  
Subject: Fw: For review - Minister's Speech - Salvia

Hi Christine,

Both Jocelyn and Suzanne have approved. My apologies for the delay.

002755

[attachment "Sp-Min-Salvia-v3(revcr)\_Feb11\_11h17\_OCS+ORS.doc" deleted by Stephanie  
Chandler/HC-SC/GC/CA]

Regards,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca  
---- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2011-02-11 11:20 AM ----

From: Jocelyn Kula/HC-SC/GC/CA  
To: Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2011-02-11 11:19 AM  
Subject: Re: Fw: For review - Minister's Speech - Salvia

---

approved; pls send to Christine

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

Stephanie Chandler	Hi Jocelyn, Hanan has suggested some minor...	2011-02-11 11:19:29 AM
Stephanie Chandler	Hi Suzanne, I have incorporated the comments...	2011-02-11 10:04:35 AM
Suzanne Desjardins	Hi Stephanie, Please find our comments attac...	2011-02-11 08:58:45 AM
Stephanie Chandler	Hi Suzanne, Would it be possible for you to rev...	2011-02-10 04:26:13 PM



Re: REVISED- Minister's Speech - Salvia 

Stephanie Chandler to: Christine Roush

2011-02-11 03:10 PM

Cc: Hanan Abramovici, Suzanne Desjardins, Jocelyn Kula, Denis  
Arsenault

Hi Christine,

I think saying "even though" is referring to the potential negative effects of illicit drugs, but I see what you mean. I don't think we should use "because" as that isn't necessarily the reason that Salvia is increasing in popularity. What about if we said just said "and"?

Its use has been increasing in popularity, and it can have some of the same effects as certain illicit drugs.

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

Christine Roush

Hi Stephanie - I have a question about a revisio...

2011-02-11 02:54:58 PM

From: Christine Roush/HC-SC/GC/CA  
To: Stephanie Chandler/HC-SC/GC/CA@HWC  
Cc: Hanan Abramovici/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2011-02-11 02:54 PM  
Subject: Re: REVISED- Minister's Speech - Salvia

Hi Stephanie - I have a question about a revision that Hanan made to the speech. Should we not say below  
**"because"** it can have some of the same effects as certain illicit drugs, instead of "even though"? I thought Salvia had become popular because people discovered it wasn't illegal and it had some of the same effects as illicit drugs?

Its use has been increasing in popularity, even though it can have some of the same effects as certain illicit drugs.

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
Health Canada/Santé Canada

Tel/Tél : (613) 954-0712/Cell: (613) 219-7194  
Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca

Stephanie Chandler	Hi Christine, Sorry but Hanan just caught one...	2011-02-11 11:31:46 AM
Stephanie Chandler	Hi Jocelyn, Hanan has suggested some minor...	2011-02-11 11:19:29 AM
Stephanie Chandler	Hi Suzanne, I have incorporated the comments...	2011-02-11 10:04:35 AM
Suzanne Desjardins	Hi Stephanie, Please find our comments attac...	2011-02-11 08:58:45 AM
Stephanie Chandler	Hi Suzanne, Would it be possible for you to rev...	2011-02-10 04:26:13 PM



**Re: Salvia Media Lines - DG, Comms requested changes** 

Suzanne Desjardins to: Jocelyn Kula

2011-02-11 11:37 AM

Cc: Christine Roush, stephanie.chandler, Denis Arsenault, Stephanie Szick, Hanan Abramovici

Hi Jocelyn,

Hanan just reminded me that adverse effects have been reported in the literature and these include more than hallucinations and anxiety; anyway since this is our question, we can use "negative health effects" if you think it is easier.

Thanks

Suzanne

Jocelyn Kula

Christine, I think we have to be careful that we d...

2011-02-11 11:02:09 AM

From: Jocelyn Kula/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Cc: Suzanne Desjardins/HC-SC/GC/CA@HWC, stephanie.chandler@hc-sc.gc.ca, Denis Arsenault/HC-SC/GC/CA@HWC, Stephanie Szick/HC-SC/GC/CA@HWC  
Date: 2011-02-11 11:02 AM  
Subject: Re: Salvia Media Lines - DG, Comms requested changes

Christine,

I think we have to be careful that we don't end up back with the old old content re the four "red herring" adverse event reports etc. that got HPFB all twisted around back in 2007-08, and since the Qs in these media lines come from us, I would like to suggest that we rephrase the question to make it easier for us to answer, i.e.,

**Q5 – If Health Canada is aware that the use of *Salvia divinorum* can produce negative health effects such as hallucinations, feelings of anxiety, etc., why is it not controlled under the Controlled Drugs and Substances Act?**

Then we could stick with the existing answer.

Suzanne- any thoughts?

JK

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

Christine Roush

Hi Suzanne, The Salvia package is with our DG...

2011-02-11 09:42:07 AM

From: Christine Roush/HC-SC/GC/CA  
To: Suzanne Desjardins/HC-SC/GC/CA@HWC  
Cc: Jocelyn Kula/HC-SC/GC/CA@HWC, stephanie.chandler@hc-sc.gc.ca, Denis

Date: Arsenault/HC-SC/GC/CA@HWC, Stephanie Szick/HC-SC/GC/CA@HWC  
2011-02-11 09:42 AM  
Subject: Re: Salvia Media Lines - DG, Comms requested changes

---

Hi Suzanne,

The Salvia package is with our DG, Comms for approval, but they have requested that we include a response (or sentence- maybe as part of Q5) on whether we are aware of any Adverse Reactions caused by Salvia use. Could you please provide a line or two on this by noon today and return to me so I can continue with approvals.

Thanks.

**Q5 – If Health Canada is aware of adverse effects associated with the use of *Salvia divinorum* , why is it not controlled under the Controlled Drugs and Substances Act?**

A5 – The move to schedule *Salvia divinorum* and salvinorin A as controlled substances is based on surveillance data from surveys such as the *Canadian Alcohol and Drug Use Monitoring Survey* (CADUMS), *Youth Smoking Survey* (YSS) and the *Ontario Student Drug Use and Health Survey* (OSDUHS), some of which only became available in 2010.

In the interim, as *Salvia divinorum* is a plant with hallucinogenic properties, it currently meets the definition of a natural health product under the *Natural Health Products Regulations* (NHPR) . The sale of unauthorized natural health products may be subject to compliance and enforcement action in accordance with the *Food and Drugs Act* and its associated regulations.

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
Health Canada/Santé Canada  
Tel/Tél : (613) 954-0712/Cell: (613) 219-7194  
Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca

Suzanne Desjardins Hi Christine, I am fine with the yellow highlight... 2011-02-07 11:40:39 AM

From: Suzanne Desjardins/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Cc: Jocelyn Kula/HC-SC/GC/CA@HWC, stephanie.chandler@hc-sc.gc.ca, Denis Arsenault/HC-SC/GC/CA@HWC, Stephanie Szick/HC-SC/GC/CA@HWC  
Date: 2011-02-07 11:40 AM  
Subject: Re: Revised Salvia NOI

---

Hi Christine,

I am fine with the yellow highlighted text.  
Thanks

Suzanne

Christine Roush      Hi All - I revised all the documents based on co...      2011-02-07 11:20:36 AM

From: Christine Roush/HC-SC/GC/CA  
To: Suzanne Desjardins/HC-SC/GC/CA@HWC  
Cc: Jocelyn Kula/HC-SC/GC/CA@HWC, stephanie.chandler@hc-sc.gc.ca, Denis Arsenault/HC-SC/GC/CA@HWC, Stephanie Szick/HC-SC/GC/CA@HWC  
Date: 2011-02-07 11:20 AM  
Subject: Re: Revised Salvia NOI

Hi All - I revised all the documents based on comments from HPFB & HECS Legal services, and your revised NOI. As a quick signal check to ensure consistency throughout all documents in how we refer to the known effects (short and long-term), I have highlighted in yellow the references to these in all docs. Could you please take a quick look and let me know by 1:00 pm today if all are OK with the revisions, before seeking HECS and HPFB ADMO approvals. thx.

[attachment "DRAFT Salvia NOI\_Feb 4 EN\_clean.wpd" deleted by Suzanne Desjardins/HC-SC/GC/CA]  
[attachment "Salvia NR\_CSTD-DG\_07-02-11.doc" deleted by Suzanne Desjardins/HC-SC/GC/CA]  
[attachment "Salvia MLs\_CSTD-DG\_07-02-11.doc" deleted by Suzanne Desjardins/HC-SC/GC/CA]  
[attachment "IYH Salvia divinatorum\_v24\_CSTD-DG\_07-02-11.doc" deleted by Suzanne Desjardins/HC-SC/GC/CA]

Christine Roush  
Senior Communications Advisor/

Suzanne Desjardins      thank you both for the clarification Suzanne      2011-02-07 07:56:44 AM

From: Suzanne Desjardins/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: stephanie.chandler@hc-sc.gc.ca, Christine Roush/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, Stephanie Szick/HC-SC/GC/CA@HWC  
Date: 2011-02-07 07:56 AM  
Subject: Re: Revised Salvia NOI

thank you both for the clarification

Suzanne

Jocelyn Kula	Suzanne Only to echo what Stephanie just said,...	2011-02-04 03:14:25 PM
Stephanie Chandler	Hi Suzanne, As far as the NOI is concerned w...	2011-02-04 03:08:42 PM
Suzanne Desjardins	Hi All, I wouldn't mind commenting, but the NO...	2011-02-04 02:58:10 PM
Stephanie Chandler	Hi Christine, Hope you are feeling better soon!	2011-02-04 02:09:37 PM
Christine Roush	Thanks Stephanie - I am home sick today and w...	2011-02-04 01:44:07 PM
Stephanie Chandler		

----- Original Message -----

**From:** Stephanie Chandler  
**Sent:** 2011-02-04 01:17 PM EST  
**To:** Christine Roush  
**Cc:** Jocelyn Kula; Denis Arsenault; Stephanie Chandler; Stephanie Szick  
**Subject:** Re: Revised Salvia NOI

Hi Christine,

This is the revised NOI that Cathy has just signed. We have not included the suggested reference by HPFB to include "short and long-term effects" and we have changed "The regulation of Salvia" to "The



scheduling of Salvia" in the fifth paragraph. We have also revised the OCS email for consistency, however I don't believe any of the comms products include our email.

[attachment "DRAFT Salvia NOI\_Feb 4 EN\_clean.wpd" deleted by Christine Roush/HC-SC/GC/CA]

DGO would also like to confirm that it is not necessary for Cathy to re-approve any of the comms products and that we are still on track as far as comms is concerned for publication on Feb 19. Could you please confirm?

Thanks,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

Christine Roush	Hi all - could you please share the updated NOI...	2011-02-04 10:33:36 AM
Jocelyn Kula	great! Denis/ Stephanie- I think we still have to c...	2011-02-04 10:01:50 AM
Christine Roush	Jocelyn - NHPD is ok with dropping the hallucin...	2011-02-04 08:55:50 AM



**Re: Confirmation for Salvia NOI on Monday**   
Denis Arsenault to: Stephanie Chandler

2011-02-11 11:37 AM

Thanks.

Denis

---

Denis Arsenault, A/Manager / Gestionnaire p.i.  
Regulatory Policy Division /  
Division des politiques réglementaires,  
Office of Controlled Substances /  
Bureau des substances contrôlées,  
Health Canada / Santé Canada  
Tel/Tél: (613) 957-6828  
Fax / Télécopieur : (613) 946-4224  
E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca

---


Stephanie Chandler Hi Denis, As you are aware, due to my absenc...

2011-02-11 11:35:44 AM

From: Stephanie Chandler/HC-SC/GC/CA  
To: Denis Arsenault/HC-SC/GC/CA@HWC  
Cc: Isabel Shanahan/HC-SC/GC/CA@HWC  
Date: 2011-02-11 11:35 AM  
Subject: Confirmation for Salvia NOI on Monday

Hi Denis,

As you are aware, due to my absence on Monday, Feb 14th, you have been listed as the person Canada Gazette should contact to confirm receipt of the Salvia NOI and to confirm the publication date. If by noon on Monday you have not received a call confirming the NOI, please contact Canada Gazette at 613-996-1268.

I am in training all day Monday and Tuesday, but if you need to get in touch with me, you can contact me on my cell at 

Thanks,

**s.19(1)**

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca



**Fw: For review - Minister's Speech - Salvia**

Christine Roush to: Stephanie Chandler

2011-02-11 11:43 AM

Cc: Suzanne Desjardins, Denis Arsenault, Jocelyn Kula, Hanan  
Abramovici

Hello all - any further comments on the Salvia speech - Jocelyn, Suzanne? Comments were due by 10:00 am - thx

Christine Roush  
Senior Communications Advisor/

Stephanie Chandler Hi Suzanne, I have incorporated the comments...

2011-02-11 10:04:35 AM

From: Stephanie Chandler/HC-SC/GC/CA  
To: Suzanne Desjardins/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Hanan  
Abramovici/HC-SC/GC/CA@HWC, Christine Roush/HC-SC/GC/CA@HWC  
Date: 2011-02-11 10:04 AM  
Subject: Re: Fw: For review - Minister's Speech - Salvia

Hi Suzanne,

I have incorporated the comments from today's meeting and would appreciate if you could have one last look to make sure you are okay with the changes.



Sp-Min-Salvia-v3(revcr)\_Feb11\_9h59\_OCS+ORS.doc

Thank you!

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

Suzanne Desjardins Hi Stephanie, Please find our comments attac...

2011-02-11 08:58:45 AM

From: Suzanne Desjardins/HC-SC/GC/CA  
To: Stephanie Chandler/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Christine  
Roush/HC-SC/GC/CA@HWC, Hanan Abramovici/HC-SC/GC/CA@HWC  
Date: 2011-02-11 08:58 AM  
Subject: Re: Fw: For review - Minister's Speech - Salvia

Hi Stephanie,

**Speech for the Minister**  
**The Honourable Leona Aglukkaq**

**Issue: Proposal to add Salvia Divinorum and Salvinorin A to Schedule III to the Controlled Drugs and Substances Act.**

Deleted: A

Deleted: ing

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Deleted: of

**Date: TBD**

**Location TBD**

**Time: TBD**

**Word Count: 328**  
**Check Against Delivery**

Formatted: Highlight

Good Morning/Afternoon: Thank you for being here.

A substance known as Salvia divinorum is being abused by some young people.

**Comment [HABR1]:** Should we not be specifying that we are talking about Salvia divinorum in particular? There are many species of Salvia.

**Comment [S2]:** This substance is only being used for its psychoactive effects, therefore it is abused

Its use has been increasing in popularity because it's currently not a controlled substance, even though it can have some of the same effects as certain illicit drugs.

**Deleted:** used - and

**Deleted:** -

**Deleted:** 's

It has also become popular among youth because it's easily available and because of the false perception that it is safer than illicit drugs.

**Deleted:** getting more...n...illegal...but ... [1]

**Comment [HABR3]:** I think we should be more precise, even if we're being vague: "some of the same effects as CERTAIN illegal drugs."

While we are still learning about Salvia divinorum, we know that when it is used, it is most commonly smoked and that smoking Salvia can produce hallucinations.

**Deleted:** 's...been gettir... [2]

**Comment [HABR4]:** "because of the FALSE perception th... [3]

Those two facts alone tells us that is has the potential to harm health.

**Comment [HABR5]:** U... [4]

**Deleted:** that it doesn't (... [5]

Therefore, because of the way it is being used, and its potential for abuse and harm to health, we will be moving to control Salvia divinorum, and its main active ingredient salvinorin A, like other illicit drugs in order to reduce the known and potential risks to the health and safety of Canadians, particularly youth.

**Deleted:** The fact is that... [6]

**Deleted:** We are still lea... [7]

**Formatted** ... [8]

As a first step, a notice will be published in the *Canada Gazette* in a few days. This will give Canadians an opportunity to comment on our proposal to include these substances in Schedule III to the *Controlled Drugs and Substances Act*.

**Deleted:** enormous ...e... [9]

**Comment [S6]:** To my... [10]

**Comment [HABR7]:** I... [11]

Making Salvia divinorum (and salvinorin A) controlled substances will make activities such as possession, trafficking, importing or cultivating illegal.

**Deleted:** ¶ ... [12]

**Deleted:** ¶

This will make it much harder to get Salvia, and will also send the message to young Canadians that they should not be using this substance. It will also allow law enforcement agencies to take action against illegal activities involving these substances.

**Deleted:** ¶ ... [13]

**Deleted:** regulated

**Deleted:** - This will red... [14]

**Deleted:** ¶ ... [15]

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**Deleted:** That's the sar... [17]

**Deleted:** "S..."...it...a... [18]

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**Deleted:** but...taking ... [19]

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**Deleted:** ¶

Legislation is an important step in controlling the availability and use of Salvia divinorum, but our most important task is to get the message to young people that this substance is dangerous. That is why we are taking these steps now and why we have posted information about Salvia and the risks of using it on our website. We want to eliminate the misconception that Salvia is safe compared to other illicit drugs.

Though all of the dangers of Salvia are not known, we do know from our own review of information that it is not safe. And we don't want young people to find out the hard way.

Thank you.

**Deleted:** If it's producing hallucinations, then it is interfering with the normal functions of the brain. When you are young, your brain is going through an important period of development. Anything that interferes with that development could have serious long-term consequences. ¶

**Deleted:** Using I

**Deleted:** to our website

**Comment [S8]:** Will the IYH have been posted prior to event?

**Deleted:** have

**Deleted:** illegal

**Comment [S9]:** Agreed that this para should be deleted; it is too hard to explain in a sentence and would confuse the message i.e. it is OK to interfere with brain functions if you are sick, but not if you are healthy??? What about alcohol??? It does interfere with the brain functions

**Comment [S10]:** I would suggest deleting... seems a bit too forceful, and what about OTCs and NHPs that affect the brain?

**Deleted:** ¶  
Any

**Deleted:** non-prescription

**Deleted:** substance that interferes with the normal functions of a person's brain should not be taken by anyone at anytime, unless it is prescribed by a physician for the treatment of a disease.

**Deleted:** ¶

**Deleted:** It is not safe.

**Deleted:** A

**Deleted:** they

**Deleted:** are

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**Comment [S11]:** No evidence of long-term effects at this point, so do we want to say this?

**Comment [S12]:** Agreed that we should delete this part as we don't know long-term effects.

**Deleted:** and suffer for the rest of their lives.

Page 2: [1] Deleted getting more	STCHANDL	2011-02-11 9:57:00 AM
Page 2: [1] Deleted n	STCHANDL	2011-02-11 9:57:00 AM
Page 2: [1] Deleted illegal	STCHANDL	2011-02-11 9:57:00 AM
Page 2: [1] Deleted but	STCHANDL	2011-02-11 9:57:00 AM
Page 2: [1] Deleted egal	STCHANDL	2011-02-11 9:57:00 AM
Page 2: [2] Deleted 's	STCHANDL	2011-02-10 3:29:00 PM
Page 2: [2] Deleted been getting	STCHANDL	2011-02-10 3:29:00 PM
Page 2: [3] Comment [HABR4] "because of the FALSE perception that it doesn't do any harm"	Hanan Abramovici	2011-02-10 4:58:00 PM
Page 2: [4] Comment [HABR5] Unsure about this statement. Some websites claim it's relatively safe, but many who've used it report very unpleasant experiences. Maybe we should remove the second half of this sentence. Or alternatively we could say: "...and because of the false perception that it is safe compared to other illegal drugs"	Hanan Abramovici	2011-02-10 6:07:00 PM
Page 2: [5] Deleted that it doesn't do any harm <sup>[HABR1]</sup>	STCHANDL	2011-02-11 9:58:00 AM
Page 2: [6] Deleted The fact is that we don't know what kind of harm it can cause.	CROUSH	2011-02-10 2:02:00 PM
Page 2: [7] Deleted <del>We are still learning about Salvia, but we do know that when it is used, it is most commonly smoked as if it were a drug. And we know that smoking Salvia can produce hallucinations.</del>	STCHANDL	2011-02-11 9:05:00 AM
Page 2: [8] Formatted Strikethrough	Hanan Abramovici	2011-02-10 5:45:00 PM
Page 2: [8] Formatted Strikethrough	Hanan Abramovici	2011-02-10 5:45:00 PM
Page 2: [9] Deleted enormous	STCHANDL	2011-02-10 3:19:00 PM
Page 2: [9] Deleted <del>cause damage to the body or the brain....or both.</del>	STCHANDL	2011-02-11 9:05:00 AM
Page 2: [10] Comment [S6] To my knowledge, there is no evidence it affects development.	STCHANDL	2011-02-10 3:32:00 PM
Page 2: [11] Comment [HABR7] Is this paragraph really needed in light of the information provided above? I would remove this.	Hanan Abramovici	2011-02-10 5:48:00 PM
Page 2: [12] Deleted	STCHANDL	2011-02-11 9:06:00 AM

If it's producing hallucinations, then it is interfering with the normal functions of the brain. When you are young, your brain is going through an important period of development. Anything that interferes with that development could have serious, long-term consequences.

Page 2: [13] Deleted	STCHANDL	2011-02-11 9:06:00 AM
Page 2: [13] Deleted	STCHANDL	2011-02-11 9:09:00 AM
Page 2: [13] Deleted	STCHANDL	2011-02-11 9:09:00 AM
Page 2: [13] Deleted	STCHANDL	2011-02-11 9:58:00 AM
Page 2: [13] Deleted	STCHANDL	2011-02-11 9:06:00 AM
Page 2: [14] Deleted	STCHANDL	2011-02-11 9:06:00 AM
Page 2: [15] Deleted	STCHANDL	2011-02-11 9:06:00 AM
Page 2: [16] Deleted	STCHANDL	2011-02-10 3:23:00 PM
Page 2: [16] Deleted	STCHANDL	2011-02-11 9:59:00 AM
Page 2: [16] Deleted	STCHANDL	2011-02-10 3:23:00 PM
Page 2: [17] Deleted	CROUSH	2011-02-10 2:08:00 PM
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a

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Salvia

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Page 2: [19] Deleted	STCHANDL	2011-02-10 3:24:00 PM
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but

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Page 2: [19] Deleted	STCHANDL	2011-02-11 9:07:00 AM
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taking

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Page 2: [19] Deleted	STCHANDL	2011-02-10 3:41:00 PM
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ould



**Re: Salvia Media Lines - DG, Comms requested changes**

Suzanne Desjardins to: Christine Roush

2011-02-11 12:01 PM

Cc: Jocelyn Kula, stephanie.chandler, Denis Arsenault, Stephanie Szick,  
Hanan Abramovici

Hi Christine,

I am fine with Jocelyn's suggested Q and A. Not sure what else to add.

Thanks

Suzanne

Christine Roush

Hi Suzanne - I need to get these revised MLs ba...

2011-02-11 11:55:59 AM

From: Christine Roush/HC-SC/GC/CA  
To: Suzanne Desjardins/HC-SC/GC/CA@HWC  
Cc: Jocelyn Kula/HC-SC/GC/CA@HWC, stephanie.chandler@hc-sc.gc.ca, Denis  
Arsenault/HC-SC/GC/CA@HWC, Stephanie Szick/HC-SC/GC/CA@HWC, Hanan  
Abramovici/HC-SC/GC/CA@HWC  
Date: 2011-02-11 11:55 AM  
Subject: Re: Salvia Media Lines - DG, Comms requested changes

Hi Suzanne - I need to get these revised MLs back to our DG, Comms asap. Could you please provide a line or two on this **by noon today** and return to me so I can continue with approvals. thx.

Christine Roush  
Senior Communications Advisor/

Suzanne Desjardins

Hi Jocelyn, Hanan just reminded me that adve...

2011-02-11 11:37:20 AM

From: Suzanne Desjardins/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Christine Roush/HC-SC/GC/CA@HWC, stephanie.chandler@hc-sc.gc.ca, Denis  
Arsenault/HC-SC/GC/CA@HWC, Stephanie Szick/HC-SC/GC/CA@HWC, Hanan  
Abramovici/HC-SC/GC/CA@HWC  
Date: 2011-02-11 11:37 AM  
Subject: Re: Salvia Media Lines - DG, Comms requested changes

Hi Jocelyn,

Hanan just reminded me that adverse effects have been reported in the literature and these include more than hallucinations and anxiety; anyway since this is our question, we can use "negative health effects" if you think it is easier.

Thanks

Suzanne

Jocelyn Kula

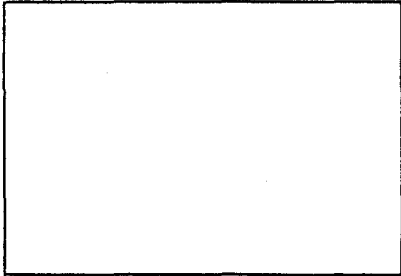
Christine, I think we have to be careful that we d...

2011-02-11 11:02:09 AM

From: Jocelyn Kula/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Cc: Suzanne Desjardins/HC-SC/GC/CA@HWC, stephanie.chandler@hc-sc.gc.ca, Denis  
Arsenault/HC-SC/GC/CA@HWC, Stephanie Szick/HC-SC/GC/CA@HWC  
Date: 2011-02-11 11:02 AM



Government of Canada / Gouvernement du Canada



**REQUEST FOR INSERTION FORM  
FEDERAL DEPARTMENTS AND AGENCIES**  
**FORMULAIRE DE DEMANDE D'INSERTION  
MINISTÈRES ET ORGANISMES FÉDÉRAUX**

Sections 1, 2 and 3 are mandatory. Missing information might delay the publication of your notice.  
Les renseignements des sections 1, 2 et 3 sont obligatoires. Un formulaire incomplet pourrait retarder la publication de votre avis.

To Canada Gazette Directorate Public Works and Government Services Canada 350 Albert Street, 5th Floor Ottawa, Ontario K1A 0S5 Telephone: 1-866-429-3885 Web Site: www.gazette.gc.ca	Destinataire Direction de la Gazette du Canada Travaux publics et Services gouvernementaux Canada 350, rue Albert, 5 <sup>e</sup> étage Ottawa (Ontario) K1A 0S5 Téléphone : 1-866-429-3885 Site web : www.gazette.gc.ca
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**SECTION 1 ▶ CLIENT INFORMATION - RENSEIGNEMENTS SUR LE CLIENT**

Date Submitted - Date de la demande 2011-02-11	<input checked="" type="checkbox"/> Part I Partie I	<input type="checkbox"/> Part II Partie II
Requesting Organization's Name - Nom de l'organisme demandeur Health Canada		Address - Adresse 123 Slater St., Ottawa, ON, K1A 0K9 A.L. 3503D
Contact Name - Nom de la personne-ressource Denis Arsenault	Telephone No. - N° de téléphone 613-957-6828	Email - Courriel denis.arsenault@hc-sc.gc.ca
Consignee Code Code de destinataire 0900	Department Number Numéro du ministère 0220	IS Organization Code Code d'organisme 9000851092
		IS Reference Code Code de référence 1101064579

**SECTION 2 ▶ NOTICES - AVIS**

Title of Document Submitted - Titre du document présenté  
Proposal regarding the addition of Salvia divinorum and salvinorin A to Schedule III to the CDSA

Published under the authority of (section of Act, Regulations, etc.) - Publié sous le régime de (article de la Loi, du Règlement, etc.)  
Section 55(1)(a) and Section 60 of the Controlled Drugs and Substances Act (CDSA)

If you wish hot links to appear in the electronic versions of your notice, please give us specific instructions.  
Si vous désirez des liaisons interactives dans les versions électroniques de votre avis, veuillez nous fournir des indications précises.  
OCS.Policy.and.Regulatory.Affairs@hc-sc.gc.ca

Extracts Extraits	<input type="checkbox"/> Part I Partie I	<input type="checkbox"/> Part II Partie II	Number of Copies (Minimum of 100) Nombre d'exemplaires (Minimum de 100)	▶	N/A
Date of Publication Expected Date de publication anticipée 2011-02-19	Text Provided - Texte joint English Anglais		<input checked="" type="checkbox"/> Original	<input type="checkbox"/> Copy Copie	French Français
			<input checked="" type="checkbox"/> Original	<input type="checkbox"/> Copy Copie	

**Note** If you have not received a call from us confirming receipt of your notice and its publication date by Monday, 12 p.m. (Eastern standard time) of the week of the expected publication date, please contact us.  
**Nota** Veuillez communiquer avec nous si vous n'avez pas reçu d'appel de notre part pour confirmer la réception et la date de publication de votre avis au plus tard à midi (heure normale de l'Est), le lundi de la semaine de la publication anticipée de votre avis.

**SECTION 3 ▶ INVOICING - FACTURATION**

The invoice will be sent to the contact and email address indicated below.  
La facture sera envoyée à la personne-ressource et à l'adresse courriel inscrites ci-dessous.

Organization's Name - Nom de l'organisme Health Canada	Address - Adresse 123 Slater St., Ottawa, ON, K1A 0K9, A.L. 3503A
Contact Name - Nom de la personne-ressource Edith Anderson	Telephone No. - N° de téléphone 613-954-6536
Email - Courriel Edith.Anderson@hc-sc.gc.ca	
Are you submitting a CD-ROM or a diskette with your text? Soumettez-vous un cédérom ou une disquette avec votre texte?	<input checked="" type="checkbox"/> Yes Oui
	<input type="checkbox"/> No Non
Estimated Cost - Coût estimatif \$490.00	

**Note** If you publish a notice in the Canada Gazette, Part I, a free copy will be sent to the address indicated in section 3.  
**Nota** Si vous publiez un avis dans la Partie I de la Gazette du Canada, un exemplaire gratuit sera envoyé à l'adresse inscrite à la section 3.

If required - Pursuant to section 32 of the Financial Administration Act, funds are available.  
Si requis - Conformément à l'article 32 de la Loi sur la gestion des finances publiques, des fonds sont disponibles.

Signature J. KD Date 2011-02-11

**SECTION 4 ▶ FOR USE BY THE CANADA GAZETTE DIRECTORATE - À L'USAGE DE LA DIRECTION DE LA GAZETTE DU CANADA**

Date of Publication - Date de publication	Issue Number - Numéro de fascicule	Number of Pages - Nombre de pages
SIGMA Invoice Number - Numéro de facture SIGMA		Cost - Coût



Health  
Canada

Santé  
Canada

Healthy Environments  
and Consumer Safety  
Branch

Direction générale,  
Santé environnementale et  
sécurité des consommateurs

Address Locator: 3503D  
Ottawa ON K1A 0K9

Your file Votre référence

Our file Notre référence

11-101374-981

Josée Boisvert  
A/Manager, Editing Services  
Canada Gazette Directorate  
Government of Canada  
350 Albert Street, 5th Floor  
Ottawa, Ontario  
K1A 0S5

Dear Ms. Boisvert:

**Re: Notice to Interested Parties - Proposal regarding the addition of *Salvia divinorum* and salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA).**

Please find enclosed, in both official languages, the following documents:

- two hard copies of a Notice to Interested Parties regarding these substances;
- electronic copies of the notice, with English and French versions in two separate files; and
- a signed and completed "Request for Insertion" form.

We ask that the notice be published in *Canada Gazette*, Part I, on February 19, 2011. The departmental contact for this notice is Denis Arseneault, who can be reached at 613-957-6828.

Yours sincerely,

Jocelyn Kula  
A/Director  
Office of Controlled Substances  
Controlled Substances and Tobacco Directorate

Attachments



**Fw: Salvia event confirmed for wednesday**  
Jocelyn Kula to: Denis Arsenault, stephanie.chandler

2011-02-14 10:57 AM

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Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224  
----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2011-02-14 10:57 AM -----

From: Dave Stephens/HC-SC/GC/CA  
To: "Christine Roush" <christine.roush@hc-sc.gc.ca>, Jesse Arnup-Blondin/HC-SC/GC/CA@HWC,  
"Brenda Paine" <brenda.paine@hc-sc.gc.ca>, "Jocelyn Kula" <jocelyn.kula@hc-sc.gc.ca>  
Cc: "Nicole Prentice" <nicole.prentice@hc-sc.gc.ca>  
Date: 2011-02-14 10:44 AM  
Subject: Fw: Salvia event confirmed for wednesday

---

Fyi  
Alexis M Tervo

----- Original Message -----

**From:** Alexis M Tervo  
**Sent:** 2011-02-14 10:42 AM EST  
**To:** Dave Stephens; Charles Mojsej; Ken Polk; Blossom Leung; Alastair  
Sinclair; Stephane Shank; Adam Blondin  
**Subject:** Salvia event confirmed for wednesday

Hi all, Cailin just confirmed that we will be doing an event for Salvia on wednesday.

It will not be our minister making the announcement. She will be up north.

Dave - can you start a MEP? I can work with someone from your team to pull it together.

The event will take place in BC building or the press gallery tbc



Re: URGENT REVISED- Minister's Speech - Salvia 

Christine Roush to: Suzanne Desjardins, Jocelyn Kula

2011-02-14 11:02 AM

Cc: Hanan Abramovici, Denis Arsenault, Stephanie Chandler, Stephanie Szick, Dave Stephens

Jocelyn/Suzanne,

Can I please get your final approval of the Salvia speech below by 11:30 today. Seems like the event is happening this Wednesday. Further details to follow, as we get them.



Sp-Min-Salvia-v6\_Feb14\_10h58.doc

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
Health Canada/Santé Canada  
Tel/Tél : (613) 954-0712/Cell: (613) 219-7194  
Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca

Stephanie Chandler Hi Christine, I think saying "even though" is ref...

2011-02-11 03:11:06 PM

From: Stephanie Chandler/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Cc: Hanan Abramovici/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2011-02-11 03:11 PM  
Subject: Re: REVISED- Minister's Speech - Salvia

Hi Christine,

I think saying "even though" is referring to the potential negative effects of illicit drugs, but I see what you mean. I don't think we should use "because" as that isn't necessarily the reason that Salvia is increasing in popularity. What about if we said just said "and"?

Its use has been increasing in popularity, and it can have some of the same effects as certain illicit drugs.

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224

E-Mail: stephanie.chandler@hc-sc.gc.ca

Christine Roush	Hi Stephanie - I have a question about a revisio...	2011-02-11 02:54:58 PM
From:	Christine Roush/HC-SC/GC/CA	
To:	Stephanie Chandler/HC-SC/GC/CA@HWC	
Cc:	Hanan Abramovici/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC	
Date:	2011-02-11 02:54 PM	
Subject:	Re: REVISED- Minister's Speech - Salvia	

Hi Stephanie - I have a question about a revision that Hanan made to the speech. Should we not say below

"because" it can have some of the same effects as certain illicit drugs, instead of "even though"? I thought Salvia had become popular because people discovered it wasn't illegal and it had some of the same effects as illicit drugs?

Its use has been increasing in popularity, even though it can have some of the same effects as certain illicit drugs.

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
Health Canada/Santé Canada  
Tel/Tél : (613) 954-0712/Cell: (613) 219-7194  
Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca

Stephanie Chandler	Hi Christine, Sorry but Hanan just caught one...	2011-02-11 11:31:46 AM
Stephanie Chandler	Hi Jocelyn, Hanan has suggested some minor...	2011-02-11 11:19:29 AM
Stephanie Chandler	Hi Suzanne, I have incorporated the comments...	2011-02-11 10:04:35 AM
Suzanne Desjardins	Hi Stephanie, Please find our comments attac...	2011-02-11 08:58:45 AM
Stephanie Chandler	Hi Suzanne, Would it be possible for you to rev...	2011-02-10 04:26:13 PM

**Speech for the Minister**  
**The Honourable Leona Aglukkaq**

**Issue: Proposal to add Salvia Divinorum and Salvinorin A to Schedule III to the *Controlled Drugs and Substances Act*.**

**Date: Wednesday, February 16, 2011**

**Location Brooke Claxton Bldg, or National Press Gallery TBD**

**Time: TBD**

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Word Count: 394  
Check Against Delivery

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Good Morning/Afternoon: Thank you for being here.

Among today's generation of our youth, a substance known as Salvia has been gaining popularity and is being abused by some young people.

Its popularity comes from the fact that it can have some of the same effects as certain illicit drugs. It's easily available, and there is a false perception that it is safe.

Deleted: and the

But it isn't safe.

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We are still learning about Salvia, but we know that when it is used, it is most commonly smoked, and smoking it can produce hallucinations.

Deleted: but at this early stage there is evidence that it could cause long-term damage to the body and the brain. ¶  
¶  
W

Those two facts alone tells us that it has the potential to harm health.

Deleted: it

Deleted: when it is smoked

Because of the way it is being used, and its potential for abuse, we are proposing to add Salvia divinorum, and its main active ingredient salvinorin A, to the Controlled Drugs and Substances Act.

Deleted: And at the moment it is not a controlled substance and it's easily available. ¶  
¶

Deleted: will be moving to control S

We believe these substances should be controlled, just like other illicit drugs, because of their potential risks to the health and safety of Canadians, particularly our young people.

Deleted: .

Deleted: Salvia

As a first step to controlling these substances, a notice will be published in the *Canada Gazette* in a few days. That will start a process during which Canadians will have an opportunity to comment on our proposal.

Deleted: We are proposing Salvia be added to the *Controlled Drugs and Substances Act*.

Making it a controlled substance will make activities such as possessing, trafficking, importing or cultivating Salvia illegal.

That will make Salvia harder to get and send the message to young Canadians that they should not be using it. It will also allow law

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enforcement agencies to take action against illegal activities involving these substances.

Legislation is an important step in controlling the availability and use of Salvia divinorum, but our most important task is to get the message out to young people that Salvia is dangerous.

That is why we are taking these steps now and why we have posted information about Salvia and the risks of using it on our website.

We want to eliminate the misconception that Salvia is safe compared to illicit drugs and we don't want young people to find out the hard way.

**Deleted:** For anyone who would like to know more, we have posted

Thank you.



Re: URGENT REVISED- Minister's Speech - Salvia 

Jocelyn Kula to: Christine Roush

2011-02-14 11:05 AM

Cc: Suzanne Desjardins, Hanan Abramovici, Denis Arsenault, Stephanie  
Chandler, Stephanie Szick, Dave Stephens

Only comment is a minor change to the following para:

Making it a controlled substance will make activities such as possessing,  
trafficking, importing or cultivating Salvia illegal.

to read

Regulating Salvia and Salvinorin A as controlled substances will make  
activities such as possessing, trafficking, importing or cultivating Salvia  
illegal.

---

Jocelyn Kula

Acting Director/ Directrice par intérim

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs

Health Canada/ Santé Canada

Tel: (613) 952-2177 Fax: (613) 946-4224

Christine Roush

Jocelyn/Suzanne, Can I please get your final ap...

2011-02-14 11:02:03 AM

From: Christine Roush/HC-SC/GC/CA

To: Suzanne Desjardins/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC

Cc: Hanan Abramovici/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, Stephanie  
Chandler/HC-SC/GC/CA@HWC, Stephanie Szick/HC-SC/GC/CA@HWC, Dave  
Stephens/HC-SC/GC/CA@HWC

Date: 2011-02-14 11:02 AM

Subject: Re: URGENT REVISED- Minister's Speech - Salvia

---

Jocelyn/Suzanne,

Can I please get your final approval of the Salvia speech below by **11:30 today**. Seems like the event is  
happening this Wednesday. Further details to follow, as we get them.



Sp-Min-Salvia-v6\_Feb14\_10h58.doc

Christine Roush

Senior Communications Advisor/

Conseillère principale en communications

Public Affairs, Consultation and Communications Branch/

Direction générale des affaires publiques,

de la consultation et des communications

Health Canada/Santé Canada

Tel/Tél : (613) 954-0712/Cell: (613) 219-7194

Fax/Facsimile : 948-8085

E-mail / courriel : christine\_roush@hc-sc.gc.ca



**Re: URGENT REVISED- Minister's Speech - Salvia**

Brenda Paine to: Christine Roush

2011-02-14 12:54 PM

Jocelyn Kula, Hanan Abramovici, Denis Arsenaault, Stephanie  
Cc: Chandler, Stephanie Szick, Dave Stephens, Suzanne Desjardins,  
Michael Assad, CSTD-DGO

Stephanie is working on getting it back to you with our joint comments.  
Christine Roush

----- Original Message -----

**From:** Christine Roush  
**Sent:** 2011-02-14 12:01 PM EST  
**To:** Brenda Paine  
**Cc:** Jocelyn Kula; Hanan Abramovici; Denis Arsenaault; Stephanie Chandler;  
Stephanie Szick; Dave Stephens; Suzanne Desjardins; Michael Assad; CSTD-DGO  
**Subject:** Re: URGENT REVISED- Minister's Speech - Salvia

Hi Brenda - for your urgent approval (**by 12:30 please**) - the speech that will be used on Wednesday to announce the Gov't's proposal to schedule Saliva. Thanks,

[attachment "Sp-Min-Salvia-v6\_Feb14\_10h58.doc" deleted by Brenda Paine/HC-SC/GC/CA]

Christine Roush  
Senior Communications Advisor/

Suzanne Desjardins      Approved Thanks      2011-02-14 11:51:22 AM


**From:** Suzanne Desjardins/HC-SC/GC/CA  
**To:** Christine Roush/HC-SC/GC/CA@HWC  
**Cc:** Jocelyn Kula/HC-SC/GC/CA@HWC, Hanan Abramovici/HC-SC/GC/CA@HWC, Denis  
Arsenaault/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC, Stephanie  
Szick/HC-SC/GC/CA@HWC, Dave Stephens/HC-SC/GC/CA@HWC  
**Date:** 2011-02-14 11:51 AM  
**Subject:** Re: URGENT REVISED- Minister's Speech - Salvia

Approved  
Thanks

Suzanne

Christine Roush	Jocelyn/Suzanne, Can I please get your final ap...	2011-02-14 11:02:02 AM
Stephanie Chandler	Hi Christine, I think saying "even though" is ref...	2011-02-11 03:11:06 PM
Christine Roush	Hi Stephanie - I have a question about a revisio...	2011-02-11 02:54:58 PM
Stephanie Chandler	Hi Christine, Sorry but Hanan just caught one...	2011-02-11 11:31:46 AM
Stephanie Chandler	Hi Jocelyn, Hanan has suggested some minor...	2011-02-11 11:19:29 AM
Stephanie Chandler	Hi Suzanne, I have incorporated the comments...	2011-02-11 10:04:35 AM
Suzanne Desjardins	Hi Stephanie, Please find our comments attac...	2011-02-11 08:58:45 AM
Stephanie Chandler	Hi Suzanne, Would it be possible for you to rev...	2011-02-10 04:26:13 PM



**Salvia event off for now** 

Christine Roush to: Stephanie Szick

2011-02-14 02:08 PM

Cc: Michael Assad, Brenda Paine, Jocelyn Kula, Stephanie Chandler, Denis Arsenault

Please don't shoot the messenger - but we are told that the Salvia event will not be taking place this Wednesday, but as per before, MO would like us to keep the products moving. The speech is now with HECS-ADMO for approval, as well as HPFB.

Christine Roush  
Senior Communications Advisor/

Stephanie Szick hi Christine, With regrets for this delay. Please c...

2011-02-14 01:21:59 PM

From: Stephanie Szick/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Cc: Michael Assad/HC-SC/GC/CA@HWC, Brenda Paine/HC-SC/GC/CA@HWC  
Date: 2011-02-14 01:21 PM  
Subject: Re: Fw: URGENT REVISED- Minister's Speech - Salvia

hi Christine,

With regrets for this delay. Please consider the attached A/DG approve with revisions as indicated in track changes.

Keep us posted on this - how things progress!

Thanks,

Stephanie Szick  
Director General's Office / Bureau du directeur général  
Controlled Substances & Tobacco Directorate (CSTD) /  
Direction des substances contrôlées et de la lutte au tabagisme (DSCLT)  
Health Canada / Santé Canada  
Tel / Tél: (613) 948-8651



Min\_Speech\_Salvia\_CSTD DGO\_14-02-11.doc

Christine Roush Hi - is there anything either of you can do to get...

2011-02-14 12:55:45 PM

From: Christine Roush/HC-SC/GC/CA  
To: Stephanie Szick/HC-SC/GC/CA@HWC, Michael Assad/HC-SC/GC/CA@HWC  
Date: 2011-02-14 12:55 PM  
Subject: Fw: URGENT REVISED- Minister's Speech - Salvia

Hi - is there anything either of you can do to get Brenda's approval of the Salvia speech by 1pm. I need to have full approvals of the speech before 3pm today - to allow for translation etc. Thanks.

Christine Roush  
Senior Communications Advisor/

From: Christine Roush/HC-SC/GC/CA  
To: Brenda Paine/HC-SC/GC/CA@HWC  
Cc: Jocelyn Kula/HC-SC/GC/CA@HWC, Hanan Abramovici/HC-SC/GC/CA@HWC, Denis  
Arsenault/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC, Stephanie  
Szick/HC-SC/GC/CA@HWC, Dave Stephens/HC-SC/GC/CA@HWC, Suzanne  
Desjardins/HC-SC/GC/CA@HWC, Michael Assad/HC-SC/GC/CA@HWC, CSTD-DGO  
Date: 2011-02-14 12:01 PM  
Subject: Re: URGENT REVISED- Minister's Speech - Salvia

---

Hi Brenda - for your urgent approval (**by 12:30 please**) - the speech that will be used on Wednesday to announce the Govt's proposal to schedule Saliva. Thanks,

[attachment "Sp-Min-Salvia-v6\_Feb14\_10h58.doc" deleted by Stephanie Szick/HC-SC/GC/CA]

Christine Roush  
Senior Communications Advisor/

Suzanne Desjardins	Approved Thanks	2011-02-14 11:51:22 AM
Christine Roush	Jocelyn/Suzanne, Can I please get your final ap...	2011-02-14 11:02:02 AM
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Stephanie Chandler	Hi Suzanne, Would it be possible for you to rev...	2011-02-10 04:26:13 PM

**Speech for the Minister**  
**The Honourable Leona Aglukkaq**

**Issue: Proposal to add Salvia Divinorum and Salvinorin A to Schedule III to the *Controlled Drugs and Substances Act*.**

**Date: Wednesday, February 16, 2011**

Deleted: TBD

**Location Brooke Claxton Bldg, or National Press Gallery TBD**

Deleted:

Formatted: Indent: Left: 3.81 cm

Deleted: TBD

**Time: TBD**

Word Count: 394  
Check Against Delivery

Deleted: 28

Good Morning/Afternoon: Thank you for being here.

Among today's youth, a substance known as Salvia has been gaining popularity and is being abused by some young people.

Its popularity comes from the fact that it can have some of the same effects as certain illicit drugs, and there is also a false perception that it is safe.

But it isn't safe.

Salvia has the real potential to be harmful.

It can cause hallucinations.

It presents potential risks to the health and safety of Canadians, particularly our young people.

That is why we are proposing to add Salvia divinorum, and its main active ingredient salvinorin A, to the *Controlled Drugs and Substances Act*.

These substances should be controlled, just like other illicit drugs.

As a first step to controlling these substances, a notice will be published in the *Canada Gazette* in a few days. That will start a process during which Canadians will have an opportunity to comment on our proposal.

Legislation is an important step in controlling the availability and use of Salvia divinorum and salvinorin A.

It will make activities with these substances, such as possession, trafficking, importing or cultivating illegal.

It sends a clear message that these substances are dangerous, and that they are illegal in Canada.

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- Deleted: . It's easily available,
- Deleted: s
- Deleted: and the
- Deleted: I
- Deleted: We are still learning about Salvia, but
- Deleted: but at this early stage there is evidence that it could cause long-term damage to the body and the brain. ¶  
¶  
W
- Deleted: we know that when it is used, it is most commonly smoked, and smoking it
- Deleted: it
- Deleted: can produce ¶ hallucinations
- Deleted: when it is smoked
- Deleted: . ¶  
¶  
Those two facts alone tells us that it has the potential to harm health. ¶  
¶
- Deleted: And at the moment it is not a controlled substance and it's easily available. ¶  
¶
- Deleted: Because of the way it is being used, and its
- Deleted: for abuse
- Deleted: , we
- Deleted: will be moving to control S
- Deleted: .
- Deleted: We believe these
- Deleted: Salvia
- Deleted: .
- Deleted: because of their potential risks to the health and safety of Canadians. ... [1]
- Deleted: We are propos ... [2]
- Deleted: ¶ ... [3]
- Deleted: Making it a cor ... [4]
- Deleted: Regulating Sal ... [5]
- Deleted: That will make ... [6]
- Deleted:
- Deleted: It will also allow ... [7]
- Deleted: ¶



It will allow law enforcement agencies to take action against illegal activities involving these substances.

Most importantly, it will protect our young people from the harms associated with Salvia.

**Deleted:** ,

This is why we are taking this step now and why we have also made information about Salvia available on the Health Canada web site.

We want to eliminate the misconceptions that Salvia is safe and legal.

**Deleted:** but our most important task is to get the message out to young people that Salvia is dangerous. ¶  
¶  
That is why we are taking these steps now and why we have posted

It's neither.

Thank you.

**Deleted:** For anyone who would like to know more, we have posted

**Deleted:** information about Salvia and the risks of using it on our website. ¶

**Deleted:** compared to illicit drugs and we don't want young people to find out the hard way. ¶  
¶

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Page 2: [1] Deleted SSZICK 2011-02-14 1:02:00 PM  
because of their potential risks to the health and safety of Canadians, particularly our young people.

---

Page 2: [2] Deleted CROUSH 2011-02-14 10:44:00 AM  
We are proposing Salvia be added to the *Controlled Drugs and Substances Act*.

---

Page 2: [3] Deleted SSZICK 2011-02-14 1:15:00 PM

---

Page 2: [4] Deleted SSZICK 2011-02-14 1:15:00 PM  
Making it a controlled substance will make possessing, trafficking, importing or cultivating Salvia illegal.

---

Page 2: [5] Deleted SSZICK 2011-02-14 1:15:00 PM  
Regulating Salvia and Salvinorin A as controlled substances will make activities such as possessing, trafficking, importing or cultivating Salvia illegal.

---

Page 2: [6] Deleted SSZICK 2011-02-14 1:05:00 PM  
That will make Salvia harder to get and send the message to young Canadians that they should not be using it.

---

Page 2: [7] Deleted SSZICK 2011-02-14 1:05:00 PM  
It will also allow law enforcement agencies to take action against illegal activities involving these substances.



**Re: Telephone call --- salvia**  
Jocelyn Kula to: Robin Marles  
Cc: Denis Arsenault, Stephanie Chandler

2011-02-14 10:40 PM

Thanks for forwarding. We will certainly add to our Salvia file.  
Jocelyn

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

---

Robin Marles                      Yeah, well, what did he expect from a store that...                      2011-02-14 04:31:11 PM

---

From:                      Robin Marles/HC-SC/GC/CA  
To:                          Joanne Regnier/HC-SC/GC/CA@HWC  
Cc:                          Jocelyn Kula/HC-SC/GC/CA@HWC  
Date:                      2011-02-14 04:31 PM  
Subject:                  Re: Telephone call --- salvia

---

Yeah, well, what did he expect from a store that sells bongos? Obviously it is a head-shop.

Since he is not registering a complaint, there is nothing we can do at this point.

I am copying OCS just so they know.

Robin

---

Joanne Regnier                      Good afternoon Robin, Mr. Roger McCleary (ag...                      2011-02-14 03:25:51 PM

---

From:                      Joanne Regnier/HC-SC/GC/CA  
To:                          Robin Marles/HC-SC/GC/CA@HWC  
Date:                      2011-02-14 03:25 PM  
Subject:                  Telephone call --- salvia

---

Good afternoon Robin,

██████████ called. It seems that he quit smoking, and was trying to find "herbal cigarettes." He went to a store that sold "\$400 bongos" and asked for herbal cigarettes to help him quit the habit. The 16 yr old who served him told him that she could not find the herbal cigarettes, and suggested he smoke salvia instead....

He just wanted to call HC to tell us that this is potent stuff and that it is a hallucinogenic. He is not outraged that this happened to him, he's actually laughing about it, but he wanted to warn HC since he says a 12 year old could probably purchase it, which should be of concern to HC.

He did not want to make a complaint, but I thought you might want to know.

Joanne Regnier

Natural Health Products Directorate / Direction des produits de santé naturels  
B350, Qualicum, Tower / Tour A  
AL 3301  
2936 chemin Baseline Road  
Ottawa, Ontario K1A 0L9

Tel: 613 952-9745  
Fax: 613 948-6810



**Salvia It's Your Health article**

Jocelyn Kula, Stephanie Chandler, Suzanne  
Desjardins, Denis Arsenault, Hanan Abramovici,  
Bruna Brands, Christine Roush, Robin Marles,  
Lisa MacKay to: Maggie Graham, Stephanie Collins, Scott  
Jordan, Robert Leitch, Mano Murty, Shahid  
Perwaiz, Elizabeth Keeping, Blossom Leung,  
Collin Pinto

2011-02-15 02:03 PM

Cc: Lisa MacKay

Hello all,

As I'm sure most of you know the IYH article on Salvia will be going live soon. We are still waiting on a final date and time for posting but I wanted to have everything on the servers ready to go live when we get confirmation on the date and time. I have asked that the article also be linked to the web pages below but I wondered if any of you wanted to link it to some of your content pages as well?

For example

Learn about drugs at -

<http://www.nationalantidrugstrategy.gc.ca/parents/drugs-drogues/drugs-drogues.html>

Natural Health Products - <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php>

etc.....please let me know if you would like it linked to any of your sections.

Here is the English and French that will be going on-line



IYH Salvia divinorum Final Eng HTML 15Feb2011.doc IYH Salvia divinorum Fr Final HTML 15Feb2011.doc

**New and Updated Articles**

[http://www.hc-sc.gc.ca/iyh-vsv/index\\_e.html](http://www.hc-sc.gc.ca/iyh-vsv/index_e.html)

Salvia divinorum - Updated

[http://www.hc-sc.gc.ca/iyh-vsv/index\\_f.html](http://www.hc-sc.gc.ca/iyh-vsv/index_f.html)

Salvia divinorum - Mises à jour

**IYH - A - Z Section**

S - Salvia divinorum

<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/alpha-eng.php#s>

D - Drugs - Salvia divinorum

<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/alpha-eng.php#d>

S - Salvia divinorum

<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/alpha-fra.php#s>

D - Drogues - Salvia divinorum

<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/alpha-fra.php#d>

**Lifestyles- Feature Articles**

<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/life-vie/index-eng.php>

Salvia divinorum

<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/med/index-fra.php>

Salvia divinorum

**Medical Information - Feature Articles**

<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/med/index-eng.php>

Salvia divinorum

<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/diseases-maladies/index-fra.php>

Salvia divinorum

**Products - Feature Articles**

<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/prod/index-eng.php>

Salvia divinorum

<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/prod/index-fra.php>

Salvia divinorum

**and the All the Audience sections - Feature Articles**

<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/index-eng.php>

<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/index-fra.php>

**Health Canada A-Z Section**

S - Salvia - Salvia divinorum (*It's Your Health*)

<http://www.hc-sc.gc.ca/home-accueil/search-recherche/a-z-eng.php#S>

D - Drugs - Controlled Substances - Salvia divinorum (*It's Your Health*)

<http://www.hc-sc.gc.ca/home-accueil/search-recherche/a-z-fra.php#D>

S - Salvia - Salvia divinorum (*Votre santé et vous*)

<http://www.hc-sc.gc.ca/home-accueil/search-recherche/a-z-fra.php#S>

D - Drogues - Abus des drogues - Salvia divinorum (*Votre santé et vous*)

<http://www.hc-sc.gc.ca/home-accueil/search-recherche/a-z-fra.php#D>

Thank you!

Lisa Mackay

It's Your Health Project Manager/Gestionnaire du projet Votre santé et vous

Strategic Communications and Ministerial Services Division / Division des communications stratégiques  
et des services ministériels

Public Affairs, Consultation and Communications Branch/ Direction générale des affaires publiques, de la  
consultation et des communications

Health Canada | Santé Canada

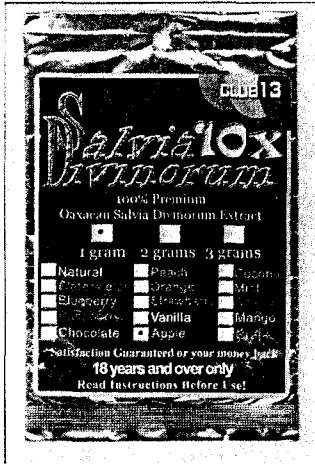
Tel 613.954.0105

Fax 613.952.8644

## It's Your Health

### Salvia divinorum

#### Issue



*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff, incense special, and salvia.

Certain websites promote the use of *S. divinorum* as a "legal" alternative to street drugs. Recent Canadian surveillance data indicates that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. Scientific reports also suggest that it has the potential for abuse.

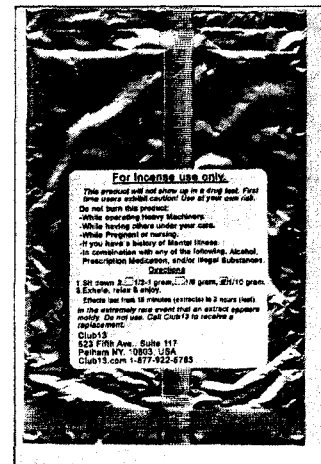
Canadians should not use products containing *S. divinorum* and/or salvininorin A because they are hallucinogenic and little is known about the long-term effects of these substances on the brain and body. There is also no way to predict how it will affect you with each use.

In light of this information, Health Canada is proposing to schedule both *S. divinorum* and its main active ingredient salvininorin A under Schedule III to the Controlled Drugs and Substances Act (CDSA) in order to protect the health and safety of Canadians, particularly youth.

#### Risks Associated with the Use of *Salvia divinorum*

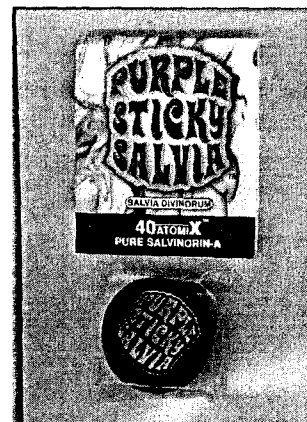
*S. divinorum* is known to have both physical and mental effects. The effects of *S. divinorum*, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns



There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product
- how much is used
- the purity of the product (products that contain *S. divinorum* may be mixed with other substances)
- how it is taken, for example, whether the product is chewed, swallowed or smoked
- the user's mood and expectations



While scientists know which brain receptors are targeted by the main active ingredient, salvinorin A, very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or if it can cause permanent damage
- how it interacts with other substances, including other drugs, natural health products and alcohol
- the potential of *S. divinorum* to produce physical dependence and/or addiction

### Minimizing Your Risk

Hallucinogens like *S. divinorum* work by modifying functions in the brain. Health Canada recommends that you should not use *S. divinorum* because little is known about the long-term effects it may have on your body and/or brain functions. There is also no way to predict how it will affect you with each use. Just because a drug is plant-based or “natural”, does not mean that it is safe.



Also, if you have children, talk to them about peer pressure and the risks of using illegal drugs, such as marijuana, cocaine, ecstasy, LSD and other substances that distort reality. See the “*Need More Info?*” section below for links to resources that can help you with this.

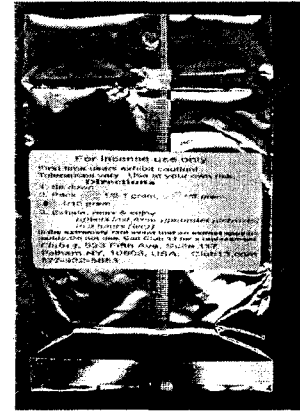
### Legal Status of *Salvia divinorum*

#### In Canada

As *S. divinorum* is a plant with hallucinogenic properties when consumed by humans, it currently meets the definition of a natural health product (NHP) under the Natural Health Products Regulations. As of February 2011, Health Canada has not authorized for sale any natural health products which contain *S. divinorum* as an ingredient. The sale of unauthorized natural health products containing *S. divinorum* or its main active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the Food and Drugs Act.



While *S. divinorum* and salvinorin A are not currently scheduled under the Controlled Drugs and Substances Act (CDSA), Health Canada has issued a Notice to Interested Parties which proposes to include *S. divinorum* and salvinorin A as controlled substances to the CDSA. This means that activities such as possession, trafficking, importation, exportation, production (or cultivation), possession for the purpose of trafficking or possession for the purposes of exporting would be illegal unless authorized by regulation.



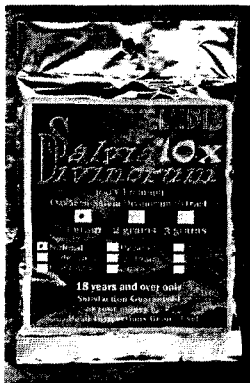
### In Other Countries

Several countries including but not limited to Australia, Belgium, Germany, Italy and Japan, have placed similar controls on the import and/or sale of *S. divinorum* and/or salvinorin A.

In the United States, *S. divinorum* and salvinorin A are not regulated under the Controlled Substances Act, but a number of individual states have placed similar restrictions on their sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution. In some states, for example, it is illegal for *S. divinorum* to be sold to anyone under the age of 18.

### **Background**

The leaves of this plant have been used traditionally by the Mazatec people for medicinal and mystical purposes.



The products are sold in a number of forms, including fresh or dried leaves, liquids or seeds and plant cuttings for growing purposes.

Results from the Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *S. divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24. The results from the Canadian 2008-2009 Youth Smoking Survey also show that 5% of 15 year olds have used *S. divinorum* in the past year. The 2009 Ontario Student Drug Use and Health Survey (OSDUHS) indicated that 5.4% of Ontario students in grades

7-12 reported ever using *S. divinorum* and 4.4% of these students reported using this substance in the past year. For more information on these surveys, see the ***Need More Info*** section below.

### **Health Canada's Role**

As noted above, in light of the health and safety risks associated with the use of *S. divinorum* and particularly the risks to youth, Health Canada is taking steps to regulate *S. divinorum* and salvinorin A as controlled substances.

## Need More Info?

For information on how to submit a consumer or trade complaint about the unauthorized sale of health products containing *S. divinorum* please consult the following documents:

- [How to Submit a Consumer Complaint](#)
- [How to Submit a Trade Complaint](#)

Or contact the Health Products and Food Branch Inspectorate directly by calling toll-free 1-800-267-9675.

To report an adverse reaction or interaction involving any health product, contact Health Canada at 1-866-234-2345 (toll free in Canada), or visit the [MedEffect Canada](#) web section

For information about the Government of Canada's [National Anti-Drug Strategy](#) The Prevention section on this site has a number of helpful resources for parents, including:

- [Tips on Talking to Your Teenager](#)
- [What to Do if Your Teen is Using Drugs](#)
- Health Canada's [Not4Me](#) youth drug prevention section

Information on natural health products and the [Natural Health Products Regulations](#)

For more on the surveys that have collected information about *Salvia divinorum* use in Canada, see:

- [The 2008-2009 Youth Smoking Survey](#)
- [The 2009 Canadian Alcohol and Drug Use Monitoring Survey](#)
- [The 2009 Ontario Student Drug Use and Health Survey](#)

Additional Resources:

- U.S. Drug Enforcement Administration: Drugs and Chemicals of Concern: [Salvia divinorum and Salvinorin A](#)
- U.S. Department of Health & Human Services, [National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006](#)

For additional articles on health and safety issues go to the [It's Your Health](#) web section at: [www.healthcanada.gc.ca/iyh](http://www.healthcanada.gc.ca/iyh)

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

Original: Febraury 2011

©Her Majesty the Queen in Right of Canada, represented by the Minister of Health, 2011

## Votre santé et vous

### Salvia

#### Enjeu

La salvia est une espèce de sauge de la famille des labiacées qui a plusieurs noms : Maria pastora, ska Maria pastora, ska pastora, sauge divinatoire, sauge des devins, menthe magique, herbe de la bergère, herbe de Marie, herbe de la Vierge, Sally D et Lady Sally.

Certains sites Web encouragent la consommation de salvia comme substitut *légal* aux drogues de la rue. De récentes données canadiennes de surveillance montrent que les adolescents et les jeunes adultes canadiens consomment de la salvia pour ses propriétés hallucinogènes. Des rapports scientifiques semblent indiquer qu'il y a risque d'abus.

Les Canadiens doivent éviter de consommer de produits contenant de la salvia, car il s'agit d'une substance hallucinogène dont on connaît mal les effets à long terme sur le cerveau et l'organisme. Votre réaction peut être différente chaque fois que vous en consommez.

À la lumière de ces renseignements, Santé Canada propose d'inscrire la salvia et son principal ingrédient actif, la salvinorine A, à l'annexe III de la Loi réglementant certaines drogues et autres substances afin de protéger la santé et la sécurité des Canadiens, surtout les jeunes.

#### Risques associés à la consommation de salvia

La salvia a des effets physiques et mentaux connus qui varient d'une personne à l'autre, qui sont souvent qualifiés de désagréables et qui peuvent comprendre les suivants :

- hallucinations
- dysphorie (sentiment d'angoisse, de dépression ou d'agitation)
- expériences extracorporelles
- rire incontrôlable
- évanouissement
- perte de mémoire immédiate
- manque de coordination des mouvements
- trouble de l'élocution et phrases maladroites

Il est impossible de prédire quels effets cette substance aura sur vous. De plus, les effets peuvent varier d'une fois à l'autre en fonction de divers facteurs, dont les suivants :

- la puissance du produit
- la quantité consommée
- la pureté du produit (les produits contenant de la salvia peuvent être mélangés à d'autres substances)

- le mode de consommation (si le produit est chiqué, avalé ou fumé)
- l'humeur et les attentes de l'utilisateur

Bien que les scientifiques sachent sur quels récepteurs du cerveau agit le principal ingrédient actif, la salvinine A, on connaît mal :

- les effets globaux de cette substance sur le cerveau, notamment si elle entraîne des effets à long terme ou si elle peut causer des lésions cérébrales permanentes
- la façon dont elle interagit avec d'autres substances, comme d'autres drogues, des produits de santé naturels et l'alcool
- le risque de dépendance physique ou de toxicomanie associé à la consommation de la salvia

### **Réduire les risques**

Les hallucinogènes comme la salvia altèrent les fonctions cérébrales. Santé Canada recommande d'éviter de consommer de la salvia, car ses effets à long terme sur les fonctions organiques et cérébrales sont peu connus. De plus, votre réaction peut être différente chaque fois que vous en consommez. Une drogue n'est pas forcément sûre simplement parce qu'elle est *naturelle* ou fabriquée à partir de plantes.

Par ailleurs, si vous avez des enfants, discutez avec eux de la pression du groupe et des risques liés à la consommation de drogues, comme la marijuana, la cocaïne, l'ecstasy, le LSD et autres substances psychotropes. Dans la section ***Pour en savoir plus*** ci-dessous vous trouverez des liens vers des ressources qui peuvent vous aider à vous préparer en vue d'une telle discussion.

### **Statut juridique de la salvia**

#### Au Canada

Comme la salvia est une plante aux propriétés hallucinogènes lorsqu'elle est consommée par des humains, elle est assimilable à un produit de santé naturel selon la définition qu'en donne le Règlement sur les produits de santé naturels. En février 2011, Santé Canada n'avait toujours pas homologué de produit de santé naturel contenant de la salvia. Conformément à la Loi sur les aliments et drogues, Santé Canada peut prendre des mesures coercitives à l'égard de quiconque vend des produits de santé naturels non homologués contenant de la salvia ou son principal ingrédient actif, la salvinine A.

Si la salvia et la salvinine A ne sont pas, à l'heure actuelle, considérées comme des substances contrôlées en vertu de la Loi réglementant certaines drogues et autres substances, Santé Canada a toutefois émis un avis aux parties intéressées dans lequel il propose de les ajouter à l'annexe III de la *Loi*.

#### À l'étranger

Plusieurs pays, notamment l'Australie, la Belgique, l'Allemagne, l'Italie et le Japon, réglementent l'importation et la vente de la salvia et de la salvinine A.

Aux États-Unis, la salvia et la salvinorine A ne sont pas réglementées en vertu de la *Loi sur les substances contrôlées*, mais certains États ont adopté des mesures visant à en restreindre la vente et l'importation. Par exemple, plusieurs États interdisent, à divers degrés, la fabrication, la distribution, l'importation, l'exportation, la possession, la consommation, l'achat et la vente de la salvia et de la salvinorine A, tandis que d'autres en limitent la distribution. Dans certains États, il est illégal de vendre de la salvia à une personne de moins de 18 ans.

### **Contexte**

Les Mazatèques font un usage traditionnel des feuilles de cette plante lors de rites divinatoires ou curatifs.

Les produits se vendent sous plusieurs formes, notamment en feuilles fraîches ou séchées, en liquides ou en graines et en boutures pour la culture.

L'Enquête de surveillance canadienne de la consommation d'alcool et de drogues révèle qu'en 2009, 1,6 % des Canadiens ont déclaré avoir consommé de la salvia au moins une fois et que la consommation est beaucoup plus élevée (7,3 %) chez les jeunes de 15 à 24 ans. L'Enquête canadienne 2008-2009 sur le tabagisme chez les jeunes montre que 5 % des jeunes de 15 ans avaient consommé de la salvia au cours de l'année précédente. Selon le Sondage 2009 sur la consommation de drogues et la santé des étudiants de l'Ontario, 5,4 % des étudiants ontariens de la 7<sup>e</sup> à la 12<sup>e</sup> année ont déclaré avoir déjà consommé de la salvia, et 4,4 % d'entre eux ont affirmé en avoir consommée au cours de l'année précédente. Pour obtenir de plus amples renseignements sur ces enquêtes, veuillez consulter la section *Pour en savoir plus* ci-dessous.

### **Rôle de Santé Canada**

À la lumière des risques pour la santé et la sécurité associés à la consommation de salvia, surtout chez les jeunes, Santé Canada prend des dispositions pour ajouter cette substance et la salvinorine A à la liste des substances contrôlées.

### **Pour en savoir plus**

Pour savoir comment présenter une plainte concernant la vente non autorisée de produits de santé contenant de la salvia, veuillez consulter le document pertinent ci-dessous :

- Plaintes de consommateur
- Plaintes de l'industrie

ou communiquer directement avec l'Inspectorat de la Direction générale des produits de santé et des aliments, en composant sans frais le 1-800-267-9675.

Pour signaler un effet indésirable ou une interaction mettant en cause un produit de santé, communiquez avec Santé Canada, au 1-866-234-2345 (sans frais au Canada), ou consultez la section MedEffet Canada

Pour vous renseigner sur la Stratégie nationale antidrogue du gouvernement du Canada. Vous y trouverez, dans la section Prévention, plusieurs ressources à l'intention des parents, dont les suivantes :

- Conseils pour aborder le sujet des drogues avec son adolescent
- Que faire si votre adolescent consomme de la drogue
- Site Web de Santé Canada, Section 0droguepourmoi sur la prévention de la toxicomanie

Vous trouverez des renseignements sur les produits de santé naturels et le Règlement sur les produits de santé naturels

Pour en savoir plus sur les enquêtes sur la consommation de salvia au Canada, consultez :

- L'Enquête 2008-2009 sur le tabagisme chez les jeunes
- L'Enquête de surveillance canadienne de la consommation d'alcool et de drogues 2009
- L'Enquête 2009 sur la consommation de drogues et la santé des étudiants de l'Ontario (en anglais seulement)

Autres ressources

- Drug Enforcement Administration (États-Unis) : Drugs and Chemicals of Concern: Salvia divinorum and Salvinorin A (en anglais seulement)
- Ministère de la Santé et des Services sociaux des États-Unis, National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006

Pour d'autres articles sur des questions de santé et de sécurité, consultez la section Votre santé et vous

Vous pouvez aussi composer sans frais le 1-866-225-0709 ou le 1-800-267-1245\* pour malentendants.

Original : février 2011

©Sa Majesté la Reine du chef du Canada, représentée par la ministre de la Santé, 2011

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Re: Fw: [REDACTED]  
Jocelyn Kula to: Christine Roush  
Cc: Chantal Trepanier, Stephanie Chandler

2011-02-15 04:36 PM

Sorry can't help you. [REDACTED]

JK

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

Christine Roush

Chantal - [REDACTED]

2011-02-15 03:00:36 PM

From: Christine Roush/HC-SC/GC/CA  
To: Chantal Trepanier/HC-SC/GC/CA@HWC  
Cc: Jocelyn Kula/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2011-02-15 03:00 PM  
Subject: Re: Fw: [REDACTED]

Chantal - [REDACTED]

Christine Roush  
Senior Communications Advisor/

Chantal Trepanier

Hello Christine, [REDACTED]

2011-02-15 02:37:45 PM

From: Chantal Trepanier/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Cc: Jocelyn Kula/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2011-02-15 02:37 PM  
Subject: Re: Fw: [REDACTED]

Hello Christine,

Thank you!

Chantal  
Tél/Tel: 613 946-5682  
Télé/Fax: 613 954-9485

Solicitor-Client Privilege/Protected

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Secret professionnel de l'avocat/Protégé

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Christine Roush/HC-SC/GC/CA



Christine  
Roush/HC-SC/GC/CA

15/02/2011 02:04 PM

To Chantal Trepanier/HC-SC/GC/CA@HWC

cc Jocelyn Kula/HC-SC/GC/CA@HWC, Stephanie  
Chandler/HC-SC/GC/CA@HWC

Subject Fw: [REDACTED]

Hi Chantal,

[REDACTED]

Thanks,

[REDACTED]

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
Health Canada/Santé Canada  
Tel/Tél : (613) 954-0712/Cell: (613) 219-7194  
Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca

----- Forwarded by Christine Roush/HC-SC/GC/CA on 2011-02-15 02:01 PM -----

From: Lisa MacKay/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Date: 2011-02-14 01:54 PM  
Subject: Re: Fw: [REDACTED]

002801



The images in the article are the ones she approved (except for the marajuana one in the Minimizing Your Risk section)

[attachment "IYH Salvia divinorum\_v28 Final Eng 14Feb2011.doc" deleted by Christine Roush/HC-SC/GC/CA]

Christine Roush OK - are these the ones she chose. If so, I will h... 2011-02-14 01:42:35 PM

From: Christine Roush/HC-SC/GC/CA  
To: Lisa MacKay/HC-SC/GC/CA@HWC  
Date: 2011-02-14 01:42 PM  
Subject: Re: Fw: Salvia event confirmed for wednesday

OK - are these the ones she chose. If so, I will have them vetted by Legal Services for HECS.

From: Jocelyn Kula/HC-SC/GC/CA  
To: Lisa MacKay/HC-SC/GC/CA@HWC  
Cc: stephanie.chandler@hc-sc.gc.ca  
Date: 2011-02-09 01:36 PM  
Subject: pictures for IYH

I am enclosing the most relevant of the bunch you sent me; personally, the more we show actual labelling indicating is sold as incense, but then suggesting how to use, the better. The original 2nd pic you suggested with the baggies with spades on them is rather meaningless to me, as it could be anything. Same goes for the vial and leaf extract.....I don't think we have any others but am copying Stephanie Chandler in case she knows.....

[attachment "Salvia Divinorum (Natural)0001.jpg" deleted by Lisa MacKay/HC-SC/GC/CA] [attachment "Salvia Divinorum (Natural)0002.jpg" deleted by Lisa MacKay/HC-SC/GC/CA]  
[attachment "PURPLE STICKY SALVIA0003.jpg" deleted by Lisa MacKay/HC-SC/GC/CA]  
[attachment "Salvia Divinorum (Apple)0001.jpg" deleted by Lisa MacKay/HC-SC/GC/CA] [attachment "Salvia Divinorum (Apple)0002.jpg" deleted by Lisa MacKay/HC-SC/GC/CA]

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
Health Canada/Santé Canada  
Tel/Tél : (613) 954-0712/Cell: (613) 219-7194  
Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca

Lisa MacKay Just a reminder that Jocelyn already approved t... 2011-02-14 01:36:15 PM

From: Lisa MacKay/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Date: 2011-02-14 01:36 PM  
Subject: Re: Fw: Salvia event confirmed for wednesday

Just a reminder that Jocelyn already approved these - it was the legal aspect that we were a little concerned with.

Thanks

Lisa

Christine Roush Lisa - I will check with program on the use of the... 2011-02-14 01:22:06 PM

From: Christine Roush/HC-SC/GC/CA  
To: Lisa MacKay/HC-SC/GC/CA@HWC  
Cc: Elizabeth Keeping/HC-SC/GC/CA@HWC, Lisa MacKay/HC-SC/GC/CA@HWC, Jaimie Banks/HC-SC/GC/CA@HWC, Alexis M Tervo/HC-SC/GC/CA@HWC, Dave Stephens/HC-SC/GC/CA@HWC  
Date: 2011-02-14 01:22 PM  
Subject: Re: Fw: Salvia event confirmed for wednesday

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Lisa - I will check with program on the use of the images you sent me.

Christine Roush  
Senior Communications Advisor/

Lisa MacKay Christine - Yes I should be able to have it up by... 2011-02-14 01:10:30 PM

From: Lisa MacKay/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Cc: Elizabeth Keeping/HC-SC/GC/CA@HWC, Lisa MacKay/HC-SC/GC/CA@HWC, Jaimie Banks/HC-SC/GC/CA@HWC, Alexis M Tervo/HC-SC/GC/CA@HWC  
Date: 2011-02-14 01:10 PM  
Subject: Re: Fw: Salvia event confirmed for wednesday

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Christine - Yes I should be able to have it up by Wednesday. Did you find out if there were any concerns with the images?

Alexis - Do you know if there have been any changes made to the IYH article?

Thanks

Lisa

Christine Roush Lisa - just learned this morning that the event is... 2011-02-14 01:07:44 PM

From: Christine Roush/HC-SC/GC/CA  
To: Lisa MacKay/HC-SC/GC/CA@HWC  
Date: 2011-02-14 01:07 PM  
Subject: Fw: Salvia event confirmed for wednesday

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Lisa - just learned this morning that the event is happening this Wednesday - see details below, as we currently know it. Apparently there is a planning meeting today at 3:30. Any chance of having the IYH article posted on Wednesday??

Beth - you will be receiving a speech shortly for HPFB's urgent review by 3pm today. thx.

Christine Roush  
Senior Communications Advisor/

From: Dave Stephens/HC-SC/GC/CA  
To: "Christine Roush" <christine.roush@hc-sc.gc.ca>, Jesse Arnup-Blondin/HC-SC/GC/CA@HWC, "Brenda Paine" <brenda.paine@hc-sc.gc.ca>, "Jocelyn Kula" <jocelyn.kula@hc-sc.gc.ca>  
Cc: "Nicole Prentice" <nicole.prentice@hc-sc.gc.ca>  
Date: 2011-02-14 10:44 AM  
Subject: Fw: Salvia event confirmed for wednesday

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**Re: Salvia It's Your Health article** 

Elizabeth Keeping to: Mano Murty

2011-02-16 09:01 AM

Cc: Lisa MacKay, MHPD\_MNHPD, MBBNHPB Assistants, Chris Turner, Robin Marles, Jocelyn Kula, Kyra Paterson, nancy\_richards, Scott Sawler, Blossom Leung, Bruna Brands, Christine Roush, Collin Pinto, Denis Arsenault, Hanan Abramovici, Maggie Graham, Robert Leitch, Scott Jordan, Shahid Perwaiz, Stephanie Chandler, Stephanie DiTrapani, Suzanne Desjardins, Ian Grimwood

Thanks all,

This point had been raised as well with respect to the draft speech - which previously lacked any reference to existing regulations, which could imply that no regulations would presently apply.

I think the solution for the interim (until it becomes scheduled) may be to emphasize that there are current regulations that would apply (NHPR), but that NO products have been approved under these regulations (nor would they) - but drop references to salvia products 'meeting the definition of a natural health product', since I believe that this is the part that leads to confusion.

Words to this effect are included in the revised attached speech.

Please advise if this works for everyone.

Thanks,  
Beth



Min\_Speech\_Salvia\_CSTD HECS-ADMO\_15-02-11\_12h10 bk.doc

Mano Murty

Hi Lisa I agree with Jocelyn and Robin.

2011-02-16 08:06:54 AM

From: Mano Murty/HC-SC/GC/CA  
To: Lisa MacKay/HC-SC/GC/CA@HWC  
Cc: MHPD\_MNHPD, MBBNHPB Assistants, Chris Turner/HC-SC/GC/CA@HWC, Robin Marles/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Kyra Paterson/HC-SC/GC/CA@HWC, nancy\_richards@hc-sc.gc.ca, Scott Sawler/HC-SC/GC/CA@HWC, Lisa MacKay/HC-SC/GC/CA@HWC, Blossom Leung/HC-SC/GC/CA@HWC, Bruna Brands/HC-SC/GC/CA@HWC, Christine Roush/HC-SC/GC/CA@HWC, Collin Pinto/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, Elizabeth Keeping/HC-SC/GC/CA@HWC, Hanan Abramovici/HC-SC/GC/CA@HWC, Maggie Graham/HC-SC/GC/CA@HWC, Robert Leitch/HC-SC/GC/CA@HWC, Scott Jordan/HC-SC/GC/CA@HWC, Shahid Perwaiz/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC, Stephanie DiTrapani/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC  
Date: 2011-02-16 08:06 AM  
Subject: Re: Salvia It's Your Health article

Hi Lisa

I agree with Jocelyn and Robin.

We do not want to add to the already existing confusion of the consumer and their parents....

The more clarity we give to this issue, the better..making Health Canada look 'proactive'.

Thanks

Mano

Mano Murty MD, CCFP, FCFP  
Manager - Gestionnaire  
Clinical Section - Section Clinique  
Marketed Biologicals, Biotechnology and Natural Health Products Bureau - Bureau des produits biologiques, biotechnologiques et de santé naturels Commercialisés  
Marketed Health Products Directorate - Direction des Produits de Santé Commercialisés  
Health Canada - Santé Canada  
Tel: (613) 946-8044  
Fax: (613) 954-2354  
mano.murty@hc-sc.gc.ca

---

Robin Marles                      Thank you, Jocelyn. You raise a good point. Cla...                      2011-02-15 05:09:50 PM

From: Robin Marles/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC, Kyra Paterson/HC-SC/GC/CA@HWC, nancy\_richards@hc-sc.gc.ca, Scott Sawler/HC-SC/GC/CA@HWC  
Cc: Lisa MacKay/HC-SC/GC/CA@HWC, Blossom Leung/HC-SC/GC/CA@HWC, Bruna Brands/HC-SC/GC/CA@HWC, Christine Roush/HC-SC/GC/CA@HWC, Collin Pinto/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, Elizabeth Keeping/HC-SC/GC/CA@HWC, Hanan Abramovici/HC-SC/GC/CA@HWC, Maggie Graham/HC-SC/GC/CA@HWC, Mano Murty/HC-SC/GC/CA@HWC, Robert Leitch/HC-SC/GC/CA@HWC, Scott Jordan/HC-SC/GC/CA@HWC, Shahid Perwaiz/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC, Stephanie DiTrapani/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC  
Date: 2011-02-15 05:09 PM  
Subject: Re: Salvia It's Your Health article

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Thank you, Jocelyn. You raise a good point. Classifying Salvia divinorum as an NHP when used as a hallucinogen is a stop-gap measure until the amendment to CDSA has been passed. We all agree that CDSA is the most appropriate regulatory framework for this substance. Therefore, I don't think we don't want to continue drawing the public's attention to a linkage with the NHP world after the new regulatory proposal has been announced.

Robin

---

Jocelyn Kula                      Hi Lisa I don't want to speak for my colleagues i...                      2011-02-15 04:24:18 PM

From: Jocelyn Kula/HC-SC/GC/CA  
To: Lisa MacKay/HC-SC/GC/CA@HWC  
Cc: Blossom Leung/HC-SC/GC/CA@HWC, Bruna Brands/HC-SC/GC/CA@HWC, Christine Roush/HC-SC/GC/CA@HWC, Collin Pinto/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, Elizabeth Keeping/HC-SC/GC/CA@HWC, Hanan Abramovici/HC-SC/GC/CA@HWC, Lisa MacKay/HC-SC/GC/CA@HWC, Maggie Graham/HC-SC/GC/CA@HWC, Mano Murty/HC-SC/GC/CA@HWC, Robert Leitch/HC-SC/GC/CA@HWC, Robin Marles/HC-SC/GC/CA@HWC, Scott Jordan/HC-SC/GC/CA@HWC, Shahid Perwaiz/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC, Stephanie Collins/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC  
Date: 2011-02-15 04:24 PM  
Subject: Re: Salvia It's Your Health article

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Hi Lisa

I don't want to speak for my colleagues in NHPD but am not sure we want to continue drawing strings between salvia and other natural health products that have been approved and are actually being sold legitimately as NHPs?? Happy to defer to whatever HPFB thinks is best though.....

The reference to NADS and parents talking to youth is fine.

Jocelyn

---

Jocelyn Kula

Acting Director/ Directrice par intérim

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs

Health Canada/ Santé Canada

Tel: (613) 952-2177 Fax: (613) 946-4224

Lisa MacKay

Hello all, As I'm sure most of you know the IYH...

2011-02-15 02:03:11 PM

From: Lisa MacKay/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, Hanan Abramovici/HC-SC/GC/CA@HWC, Bruna Brands/HC-SC/GC/CA@HWC, Christine Roush/HC-SC/GC/CA@HWC, Robin Marles/HC-SC/GC/CA@HWC, Maggie Graham/HC-SC/GC/CA@HWC, Stephanie Collins/HC-SC/GC/CA@HWC, Scott Jordan/HC-SC/GC/CA@HWC, Robert Leitch/HC-SC/GC/CA@HWC, Mano Murty/HC-SC/GC/CA@HWC, Shahid Perwaiz/HC-SC/GC/CA@HWC, Elizabeth Keeping/HC-SC/GC/CA@HWC, Blossom Leung/HC-SC/GC/CA@HWC, Collin Pinto/HC-SC/GC/CA@HWC  
Cc: Lisa MacKay/HC-SC/GC/CA@HWC  
Date: 2011-02-15 02:03 PM  
Subject: Salvia It's Your Health article

---

Hello all,

As I'm sure most of you know the IYH article on Salvia will be going live soon. We are still waiting on a final date and time for posting but I wanted to have everything on the servers ready to go live when we get confirmation on the date and time. I have asked that the article also be linked to the web pages below but I wondered if any of you wanted to link it to some of your content pages as well?

For example

Learn about drugs at -

<http://www.nationalantidrugstrategy.gc.ca/parents/drugs-drogues/drugs-drogues.html>

Natural Health Products - <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php>

etc.....please let me know if you would like it linked to any of your sections.

Here is the English and French that will be going on-line

[attachment "IYH Salvia divinorum Final Eng HTML 15Feb2011.doc" deleted by Jocelyn

Kula/HC-SC/GC/CA] [attachment "IYH Salvia divinorum Fr Final HTML 15Feb2011.doc" deleted by  
Jocelyn Kula/HC-SC/GC/CA]

#### **New and Updated Articles**

[http://www.hc-sc.gc.ca/iyh-vsv/index\\_e.html](http://www.hc-sc.gc.ca/iyh-vsv/index_e.html)

Salvia divinorum - Updated

[http://www.hc-sc.gc.ca/iyh-vsv/index\\_f.html](http://www.hc-sc.gc.ca/iyh-vsv/index_f.html)

Salvia divinorum - Mises à jour

#### **IYH - A - Z Section**

S - Salvia divinorum

<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/alpha-eng.php#s>

D - Drugs - Salvia divinorum

**Speech for the Minister**  
**The Honourable Leona Aglukkaq**

**Issue: Proposal to add Salvia Divinorum and Salvinorin  
A to Schedule III to the *Controlled Drugs and  
Substances Act*.**

**Date: Wednesday, February 16, 2011**

**Location Brooke Claxton Bldg, or National  
Press Gallery TBD**

**Time: TBD**

Word Count: 328  
Check Against Delivery

Good Morning/Afternoon: Thank you for being here.

Among today's youth, a substance known as Salvia has been gaining popularity and is being abused by some young people.

Its popularity comes from the fact that it can have some of the same effects as certain illicit drugs, and there is also a false perception that it is safe.

But it isn't safe.

Salvia has the real potential to be harmful.

It can cause hallucinations as well as other serious effects on the brain and body. In addition, very little is known about the long-term effects of these substances.

It presents potential risks to the health and safety of Canadians, particularly our young people.

That is why we are proposing to add Salvia divinorum, and its main active ingredient salvinorin A, to the *Controlled Drugs and Substances Act*.

These substances should be controlled, just like other illicit drugs.

As a first step to controlling these substances, a notice will be published in the *Canada Gazette* in a few days. That will start a process during which Canadians will have an opportunity to comment on our proposal.

Legislation is an important step in further controlling the availability and use of Salvia divinorum and salvinorin A.

It would make activities with these substances, such as possession, trafficking, importing or cultivating illegal.

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It would send a clear message that these substances are dangerous, and that they are illegal in Canada.

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It would also allow law enforcement agencies to take action against illegal activities involving these substances.

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Most importantly, it would protect our young people from the harms associated with Salvia.

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This is why we are taking this step now and why we have also made information about Salvia available on the Health Canada web site.

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We want to eliminate the misconceptions that Salvia is a safe alternative to street drugs.

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It is not.

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In the interim, products containing *Salvia divinorum* would be subject to the *Natural Health Products Regulations*.

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To date, Health Canada has not authorized for sale any natural health products which contain *Salvia divinorum*. Selling products that contain *Salvia divinorum*, could result in compliance and enforcement action by Health Canada.

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All of the steps we are taking are designed to protect the health and safety of Canadians from the potentially harmful effects of this substance.

Deleted: or its active ingredient salvinorin A, may be subject to

To find out more about the risks associated with the use of this plant, Canadians can visit Health Canada's website.

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Thank you.

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**Re: Salvia It's Your Health article**

Elizabeth Keeping to: Robin Marles

2011-02-16 09:36 AM

Jocelyn Kula, Blossom Leung, Bruna Brands, Chris Turner, Christine Roush, Collin Pinto, Denis Arsenault, Hanan Abramovici, Ian Grimwood, Kyra Paterson, Lisa MacKay, Maggie Graham, Mano Murty, MBBNHPB Assistants, MHPD\_MNHPD, "nancy\_richards", Robert Leitch, Scott Jordan, Scott Sawler, Shahid Perwaiz, Stephanie Chandler, Stephanie DiTrapani, Suzanne Desjardins

Apologies for not having been clear about links vs text in the IYH.

Could I ask for confirmation that the language speech is okay with everyone - since HECS is working to finalize this today.

Beth



Min\_Speech\_Salvia\_CSTD HECS-ADMO\_15-02-11\_12h10 bk.doc

Robin Marles

I agree with Jocelyn! No more changes, please....

2011-02-16 09:05:57 AM

From: Robin Marles/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Blossom Leung/HC-SC/GC/CA@HWC, Bruna Brands/HC-SC/GC/CA@HWC, Chris Turner/HC-SC/GC/CA@HWC, Christine Roush/HC-SC/GC/CA@HWC, Collin Pinto/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, Elizabeth Keeping/HC-SC/GC/CA@HWC, Hanan Abramovici/HC-SC/GC/CA@HWC, Ian Grimwood/HC-SC/GC/CA@HWC, Kyra Paterson/HC-SC/GC/CA@HWC, Lisa MacKay/HC-SC/GC/CA@HWC, Maggie Graham/HC-SC/GC/CA@HWC, Mano Murty/HC-SC/GC/CA@HWC, MBBNHPB Assistants, MHPD\_MNHPD, "nancy\_richards" <nancy\_richards@hc-sc.gc.ca>, Robert Leitch/HC-SC/GC/CA@HWC, Scott Jordan/HC-SC/GC/CA@HWC, Scott Sawler/HC-SC/GC/CA@HWC, Shahid Perwaiz/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC, Stephanie DiTrapani/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC  
Date: 2011-02-16 09:05 AM  
Subject: Re: Salvia It's Your Health article

I agree with Jocelyn! No more changes, please.

Robin

Jocelyn Kula

Pls let's not open the language in the doc again....

2011-02-16 09:04:30 AM

Elizabeth Keeping

----- Original Message -----

**From:** Elizabeth Keeping  
**Sent:** 2011-02-16 08:58 AM EST  
**To:** Mano Murty  
**Cc:** Lisa MacKay; MHPD\_MNHPD; MBBNHPB Assistants; Chris Turner; Robin Marles; Jocelyn Kula; Kyra Paterson; nancy\_richards@hc-sc.gc.ca; Scott Sawler; Blossom Leung; Bruna Brands; Christine Roush; Collin Pinto; Denis Arsenault; Hanan Abramovici; Maggie Graham; Robert Leitch; Scott Jordan; Shahid Perwaiz; Stephanie Chandler; Stephanie DiTrapani; Suzanne Desjardins; Ian Grimwood  
**Subject:** Re: Salvia It's Your Health article

Thanks all,

This point had been raised as well with respect to the draft speech - which previously lacked any reference to existing regulations, which could imply that no regulations would presently apply.

I think the solution for the interim (until it becomes scheduled) may be to emphasize that there are current regulations that would apply (NHPR), but that NO products have been approved under these regulations (nor would they) - but drop references to salvia products 'meeting the definition of a natural health product', since I believe that this is the part that leads to confusion.

Words to this effect are included in the revised attached speech.

Please advise if this works for everyone.

Thanks,  
Beth

[attachment "Min\_Speech\_Salvia\_CSTD HECS-ADMO\_15-02-11\_12h10 bk.doc" deleted by Jocelyn Kula/HC-SC/GC/CA]

Mano Murty	Hi Lisa I agree with Jocelyn and Robin.	2011-02-16 08:06:54 AM
Robin Marles	Thank you, Jocelyn. You raise a good point. Cla...	2011-02-15 05:09:50 PM
Jocelyn Kula	Hi Lisa I don't want to speak for my colleagues i...	2011-02-15 04:24:18 PM
Lisa MacKay	Hello all, As I'm sure most of you know the IYH...	2011-02-15 02:03:11 PM

**Speech for the Minister**  
**The Honourable Leona Aglukkaq**

**Issue: Proposal to add Salvia Divinorum and Salvinorin  
A to Schedule III to the *Controlled Drugs and  
Substances Act*.**

**Date: Wednesday, February 16, 2011**

**Location Brooke Claxton Bldg, or National  
Press Gallery TBD**

**Time: TBD**

Word Count: 328  
Check Against Delivery

Good Morning/Afternoon: Thank you for being here.

Among today's youth, a substance known as Salvia has been gaining popularity and is being abused by some young people.

Its popularity comes from the fact that it can have some of the same effects as certain illicit drugs, and there is also a false perception that it is safe.

But it isn't safe.

Salvia has the real potential to be harmful.

It can cause hallucinations as well as other serious effects on the brain and body. In addition, very little is known about the long-term effects of these substances.

It presents potential risks to the health and safety of Canadians, particularly our young people.

That is why we are proposing to add Salvia divinorum, and its main active ingredient salvinorin A, to the *Controlled Drugs and Substances Act*.

These substances should be controlled, just like other illicit drugs.

As a first step to controlling these substances, a notice will be published in the *Canada Gazette* in a few days. That will start a process during which Canadians will have an opportunity to comment on our proposal.

Legislation is an important step in further controlling the availability and use of Salvia divinorum and salvinorin A.

It would make activities with these substances, such as possession, trafficking, importing or cultivating illegal.

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It would send a clear message that these substances are dangerous, and that they are illegal in Canada.

It would also allow law enforcement agencies to take action against illegal activities involving these substances.

Most importantly, it would protect our young people from the harms associated with Salvia.

This is why we are taking this step now and why we have also made information about Salvia available on the Health Canada web site.

We want to eliminate the misconceptions that Salvia is a safe alternative to street drugs.

It is not

In the interim, products containing *Salvia divinorum* would be subject to the *Natural Health Products Regulations*.

To date, Health Canada has not authorized for sale any natural health products which contain *Salvia divinorum*. Selling products that contain *Salvia divinorum*, could result in compliance and enforcement action by Health Canada.

All of the steps we are taking are designed to protect the health and safety of Canadians from the potentially harmful effects of this substance.

To find out more about the risks associated with the use of this plant, Canadians can visit Health Canada's website.

Thank you.

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- Deleted: either
- Deleted: meet the definition of a natural health product under
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- Deleted: of any unauthorized natural health
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**Re: Salvia It's Your Health article** 

Elizabeth Keeping to: Robin Marles

2011-02-16 09:54 AM

Blossom Leung, Bruna Brands, Chris Turner, Christine Roush, Collin Pinto, Denis Arsenault, Hanan Abramovici, Ian Grimwood, Jocelyn Kula, Kyra Paterson, Lisa MacKay, Maggie Graham, Mano Murty, MBBNHPB Assistants, MHPD\_MNHPD, "nancy\_richards", Robert Leitch, Scott Jordan, Scott Sawler, Shahid Perwaiz, Stephanie Chandler, Stephanie DiTrapani, Suzanne Desjardins

Super. Thanks very much.

Beth

Robin Marles

I am fine with the text of the speech. Robin

2011-02-16 09:51:39 AM

From: Robin Marles/HC-SC/GC/CA  
To: Elizabeth Keeping/HC-SC/GC/CA@HWC  
Cc: Jocelyn Kula/HC-SC/GC/CA@HWC, Blossom Leung/HC-SC/GC/CA@HWC, Bruna Brands/HC-SC/GC/CA@HWC, Chris Turner/HC-SC/GC/CA@HWC, Christine Roush/HC-SC/GC/CA@HWC, Collin Pinto/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, Hanan Abramovici/HC-SC/GC/CA@HWC, Ian Grimwood/HC-SC/GC/CA@HWC, Kyra Paterson/HC-SC/GC/CA@HWC, Lisa MacKay/HC-SC/GC/CA@HWC, Maggie Graham/HC-SC/GC/CA@HWC, Mano Murty/HC-SC/GC/CA@HWC, MBBNHPB Assistants, MHPD\_MNHPD, "nancy\_richards" <nancy\_richards@hc-sc.gc.ca>, Robert Leitch/HC-SC/GC/CA@HWC, Scott Jordan/HC-SC/GC/CA@HWC, Scott Sawler/HC-SC/GC/CA@HWC, Shahid Perwaiz/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC, Stephanie DiTrapani/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC  
Date: 2011-02-16 09:51 AM  
Subject: Re: Salvia It's Your Health article

I am fine with the text of the speech.

Robin

-----  
Sent from my BlackBerry Wireless Handheld

Elizabeth Keeping

----- Original Message -----

**From:** Elizabeth Keeping  
**Sent:** 2011-02-16 09:33 AM EST  
**To:** Robin Marles

**Cc:** Jocelyn Kula; Blossom Leung; Bruna Brands; Chris Turner; Christine Roush; Collin Pinto; Denis Arsenault; Hanan Abramovici; Ian Grimwood; Kyra Paterson; Lisa MacKay; Maggie Graham; Mano Murty; MBBNHPB Assistants; MHPD\_MNHPD; "nancy\_richards" <nancy\_richards@hc-sc.gc.ca>; Robert Leitch; Scott Jordan; Scott Sawler; Shahid Perwaiz; Stephanie Chandler; Stephanie DiTrapani; Suzanne Desjardins

**Subject:** Re: Salvia It's Your Health article

Apologies for not having been clear about links vs text in the IYH.

Could I ask for confirmation that the language speech is okay with everyone - since HECS is working to finalize this today.





**Re: Salvia It's Your Health article** 

Lisa MacKay to: Robin Marles, Jocelyn Kula

2011-02-16 10:37 AM

Blossom Leung, Bruna Brands, Chris Turner, Christine Roush, Collin Pinto, Denis Arsenault, Elizabeth Keeping, Hanan Abramovici, Ian Grimwood, Kyra Paterson, Maggie Graham, Mano Murty,  
Cc: "nancy\_richards", Robert Leitch, Scott Jordan, Scott Sawler, Shahid Perwaiz, Stephanie Chandler, Stephanie DiTrapani, Suzanne Desjardins

Thank you all,

I will request that the article be linked to the "Learn about drugs" page when it goes live but not the NHP page.

Lisa Mackay

It's Your Health Project Manager/Gestionnaire du projet Votre santé et vous  
Consumer Information Bureau / Bureau d'information aux consommateurs  
Marketing and Communications Services Directorate/Direction des services de marketing et de communications  
Public Affairs, Consultation and Communications Branch/ Direction générale des affaires publiques, de la consultation et des communications  
Health Canada | Santé Canada  
Tel 613.954.0105  
Lisa\_Mackay@hc-sc.gc.caa

Robin Marles

I agree with Jocelyn! No more changes, please....

2011-02-16 09:09:26 AM

From: Robin Marles/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Blossom Leung/HC-SC/GC/CA@HWC, Bruna Brands/HC-SC/GC/CA@HWC, Chris Turner/HC-SC/GC/CA@HWC, Christine Roush/HC-SC/GC/CA@HWC, Collin Pinto/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, Elizabeth Keeping/HC-SC/GC/CA@HWC, Hanan Abramovici/HC-SC/GC/CA@HWC, Ian Grimwood/HC-SC/GC/CA@HWC, Kyra Paterson/HC-SC/GC/CA@HWC, Lisa MacKay/HC-SC/GC/CA@HWC, Maggie Graham/HC-SC/GC/CA@HWC, Mano Murty/HC-SC/GC/CA@HWC, MBBNHPB Assistants, MHPD\_MNHPD, "nancy\_richards" <nancy\_richards@hc-sc.gc.ca>, Robert Leitch/HC-SC/GC/CA@HWC, Scott Jordan/HC-SC/GC/CA@HWC, Scott Sawler/HC-SC/GC/CA@HWC, Shahid Perwaiz/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC, Stephanie DiTrapani/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC  
Date: 2011-02-16 09:09 AM  
Subject: Re: Salvia It's Your Health article

I agree with Jocelyn! No more changes, please.

Robin

Jocelyn Kula

Pls let's not open the language in the doc again....

2011-02-16 09:04:30 AM

Elizabeth Keeping

----- Original Message -----

**From:** Elizabeth Keeping  
**Sent:** 2011-02-16 08:58 AM EST  
**To:** Mano Murty  
**Cc:** Lisa MacKay; MHPD\_MNHPD; MBBNHPB Assistants; Chris Turner; Robin Marles; Jocelyn Kula; Kyra Paterson; nancy\_richards@hc-sc.gc.ca; Scott Sawler;

**Fw: For tomorrow morning - Salvia products**

Christine Roush to: Jocelyn Kula

2011-02-16 06:15 PM

Cc: "Stephanie Chandler", "Denis Arsenault", "Stephanie Szick"

History: This message has been forwarded.

Hi Jocelyn - can you see question below in email about date by which you will accept comments on the NOI. Is this date still correct? As well, see comment in MLs from the Director of Comms in Min office. I'll need answers to these Qs by tomorrow latest. Thx

Alexis M Tervo

----- Original Message -----

**From:** Alexis M Tervo

**Sent:** 2011-02-16 05:49 PM EST

**To:** Christine Roush

**Cc:** Blossom Leung; Dave Stephens

**Subject:** For tomorrow morning - Salvia products

Hi Christine, a couple questions for you on the Salvia products.

For the news release:

-Can we confirm if interested parties are encouraged to submit any comments regarding the Notice to Interested Parties by March 14, 2011? In the news release, we still have this marked by TBC.

For the media lines (see comments/revisions in attached).



HECS\_ML\_Salvia\_Feb11\_1327.doc

Alexis Tervo  
Communications Advisor  
Public Affairs, Communications and Consultation  
Health Canada  
Ph: (613) 954-4868

**DRAFT**  
11/02/2011

**Media Lines**  
***Salvia divinorum***

**Issue**

There is ongoing media interest regarding the availability of *Salvia divinorum* in Canada as well as Canadian surveillance data suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has concluded that *Salvia divinorum* and its main active ingredient salvinorin A should be scheduled under the *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth. A Notice to Interested Parties outlining Health Canada's proposal to regulate this substance will be published in *Canada Gazette*, Part I, on February 19, 2011 (TBC).

**Key Messages:**

- The Government of Canada is taking these steps in order to protect the health and safety of Canadians, particularly youth, from the potentially harmful effects of these substances.
- Canadians should not use products containing *Salvia divinorum* and/or salvinorin A because they are hallucinogenic and little is known about the long-term effects of these substances on the brain and body.
- After reviewing available information and reports that suggest this substance has the potential for abuse, especially among young people, Health Canada is proposing to schedule both *Salvia divinorum* and its main active ingredient salvinorin A as controlled substances.
- The proposed inclusion of *Salvia divinorum* and salvinorin A in Schedule III to the Controlled Drugs and Substances Act would make possession, trafficking, importation, exportation, production (or cultivation), possession for the purpose of trafficking or possession for the purposes of exporting illegal unless authorized by regulation.

**Comment [h1]:** Tim doesn't like this message. He would like a message on what the risk is. I understand from Dave that it is still unknown. Can we add something about the fact that we are assessing the risk?

**Supplementary Messages:**

- Though it is a hallucinogen, the plant *Salvia divinorum* is not currently scheduled under the CDSA. ~~At the present time, products containing *Salvia divinorum* would meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations*.~~
- To date, Health Canada has not authorized for sale any natural health products which contain *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products containing *Salvia divinorum* or its active ingredient

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**DRAFT**  
11/02/2011

salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act and its associated regulations*.

**Questions and Answers:**

**Q1 – What is involved in scheduling *Salvia divinorum* as a controlled substance and what stage is it at?**

A1 - Health Canada considers several factors in determining whether the scheduling of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- Overall risk to public health and safety posed by the substance.
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- International requirements and trends in international control.

Health Canada recently concluded its assessment of *Salvia divinorum* and salvinorin A against these factors and proposes to include both substances in Schedule III to the CDSA. The first step in the process of scheduling a substance under the CDSA is the publication of a *Notice to Interested Parties* (NOI) in *Canada Gazette*, Part I, which will be published on February 19, 2011 (TBC) for a 30-day comment period. This notice provides interested stakeholders with the opportunity to provide comments on Health Canada's proposal to add *Salvia divinorum* and its main active ingredient salvinorin A to Schedule III to the CDSA. Any comments received are considered during the preparation of a regulatory proposal. There will be additional opportunities for comment as the federal regulatory process progresses, which usually takes about 18 to 24 months to complete.

**Q2. Why has the Government now decided to schedule these substances under the CDSA?**

A2. Scheduling these products will reduce the potential risks to the health and safety of Canadians associated with their ready availability, with their increased use and their unknown effects. The scheduling of *Salvia divinorum* and salvinorin A will also eliminate the current misconception that these substances are a safe alternative to other illegal drugs. Furthermore, the scheduling will also enable law enforcement agencies to take action against suspected illegal activities involving these substances.

**DRAFT**  
11/02/2011

**Q3 – Are *Salvia divinorum* and/or salvinorin A controlled internationally? How are these substances regulated in other countries?**

A3 - Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions; as a result, there is no requirement for them to be scheduled as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

The move to include *Salvia divinorum* and salvinorin A in Schedule III to the CDSA is consistent with actions taken by several countries (e.g., Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden) that have also placed similar controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Some individual U.S. states have implemented similar laws restricting their use, sale and/or distribution.

**Q4 – Is there any research on the use of *Salvia divinorum* in Canada?**

A4 - Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *Salvia divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *Salvia divinorum* in the past year. The 2009 *Ontario Student Drug Use and Health Survey (OSDUHS)* indicated that 5.4% of Ontario students in grades 7-12 reported ever using *Salvia divinorum* and 4.4% of these students reported using this substance in the past year.

**Q5 - What are the risks associated with the use of *Salvia divinorum***

A5 - *S. divinorum* is known to have both physical and mental effects. The effects of *S. divinorum*, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product;
- how much is used;

**DRAFT**

11/02/2011

- the purity of the product (products that contain *S. divinorum* may be mixed with other substances);
- how it is taken, for example, whether the product is chewed, swallowed or smoked; and
- the user's mood and expectations.

While scientists know which brain receptors are targeted by the main active ingredient, salvinorin A, very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or if it can cause permanent damage;
- how it interacts with other substances, including other drugs, natural health products and alcohol;
- the potential of *S. divinorum* to produce physical dependence and/or addiction.

For more information on *Salvia divinorum* and the risks associated with its use, please see *It's Your Health* at: (insert link to the *It's Your Health* article.)

**Q6 – If Health Canada is aware that the use of *Salvia divinorum* can produce negative health effects such as hallucinations, feelings of anxiety, etc., why is it not controlled under the Controlled Drugs and Substances Act?**

A6 – The move to schedule *Salvia divinorum* and salvinorin A as controlled substances is based on surveillance data from surveys such as the *Canadian Alcohol and Drug Use Monitoring Survey* (CADUMS), *Youth Smoking Survey* (YSS) and the *Ontario Student Drug Use and Health Survey* (OSDUHS), some of which only became available in 2010.

In the interim, as *Salvia divinorum* is a plant with hallucinogenic properties, it currently meets the definition of a natural health product under the *Natural Health Products Regulations* (NHPR). The sale of unauthorized natural health products may be subject to compliance and enforcement action in accordance with the *Food and Drugs Act* and its associated regulations.

**Q7 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A7 – Once *Salvia divinorum* and salvinorin A are included in Schedule III to the CDSA, law enforcement will be able to take appropriate action in response to suspected illegal activities with these substances.

**DRAFT**  
11/02/2011

Currently, however, *Salvia divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. For more information on how to submit a consumer complaint about the unauthorized sale of drugs containing *Salvia divinorum* and/or salvinorin A, visit: [www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_44\\_consumer\\_consommateur\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_44_consumer_consommateur_cp-pc-eng.php).

**Q8 - Has Health Canada issued any kind of warning to Canadians about *Salvia divinorum*?**

A8 - Health Canada has developed an *It's Your Health* article about *Salvia divinorum* to help inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at: (link to come). Health Canada also issued a news release on February XX announcing the Government of Canada's intention to schedule *Salvia divinorum* and salvinorin A, as controlled substances. A Notice to Interested Parties, outlining Health Canada's proposal, was published in *Canada Gazette*, Part I, on February 19, 2011 (TBC), giving interested parties a 30-day period to submit their comments. There will be additional opportunities for comment as the federal regulatory process progresses.

**Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff, incense special, and salvia. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

Data from the 2008-2009 Youth Smoking Survey indicates that:

- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;
- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year; and
- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using Salvia in their lifetime (0.2% in the past year); and
- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

**DRAFT**

11/02/2011

Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that:

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;
- 5.4% of students (grades 7-12) ever used *Salvia divinorum*; and
- use of *Salvia divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

**Prepared by:** Stephanie Chandler and Denis Arseneault, OCS, CSTD

Reviewed and revised by: Christine Roush, Senior Communications  
Advisor, HECS, Communications

**Approved by:**

Jocelyn Kula, A/Director, OCS, CSTD, HECS (Jan 19, 2011 and Jan 27, 2011)  
Suzanne Desjardins, Director, ODARS, CSTD, HECS (Approved Jan 20, 2011)  
Cathy Sabiston, DG, CSTD, HECS  
Chris Turner, DG, MHPD  
Scott Sawler, DG, NHPD  
Diana Dowthwaite, DG, HPFB  
Sharon Mullin, Director, Compliance and Enforcement Coordination, HPFB  
Robin Marles, Director, Bureau of Clinical Trials, NHPD  
Chantal Trepanier, Legal Counsel, HECS  
Sherrey Collier, Legal Counsel, HPFB  
David Gotlieb, A/Communications Executive, HPFB  
Judith O'Brien, A/Communications Executive, HECS  
Ken Polk, A/Director, Public Affairs, PACCB  
Charles Mojsej, DG, PACCB  
Paul Glover, ADM, HPFB  
Hillary Geller, A/ADM, HECS  
Anne Lamar, ADM, PACCB  
DMO (pending)  
MO (pending)  
PCO (pending)





Re: Fw: CSS-WG Stakeholders for Salvia NOI   
Lisa M Young to: Stephanie Chandler  
Cc: Sara O'Connor, Denis Arsenault

2011-02-17 10:24 AM

Hi Stephanie,

Thank you. I will review and get back to you with any comments. We will wait your confirmation before sending anything.

Lisa

Stephanie Chandler Hi Lisa, The Salvia divinorum Notice to Interes... 2011-02-16 04:29:35 PM

From: Stephanie Chandler/HC-SC/GC/CA  
To: Lisa M Young/HC-SC/GC/CA@HWC  
Cc: Sara O'Connor/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2011-02-16 04:29 PM  
Subject: Re: Fw: CSS-WG Stakeholders for Salvia NOI

Hi Lisa,

The *Salvia divinorum* Notice to Interested Parties (NOI) has been submitted to Canada Gazette and it will most likely be published this coming Saturday, February 19th.

The Office of Controlled Substances (OCS) has prepared an email which we will be distributing to our stakeholders, likely on the morning of Monday, February 21st. I have attached these proposed emails below, and it would be appreciated if NHPD could also distribute them to its stakeholders. If you would like to revise these emails to suit the needs of NHPD, OCS would appreciate if you could share with us the final version of what you will be sending before it is distributed.

[attachment "Stakeholder notification of NOI Feb 16 2011 FR.wpd" deleted by Lisa M Young/HC-SC/GC/CA] [attachment "Stakeholder notification of NOI Feb 16 2011 EN.wpd" deleted by Lisa M Young/HC-SC/GC/CA]

Please also note that as we have not yet received final confirmation of the publication, **please do not send out this email until you have received confirmation from myself.** At this time, I will also provide you with the appropriate website links.

Please let me know if you have any questions or concerns.

Regards,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada

Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

Lisa M Young      Hi Stephanie, Below is an example of a messag...      2010-12-22 03:41:18 PM

From: Lisa M Young/HC-SC/GC/CA  
To: Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2010-12-22 03:41 PM  
Subject: Fw: CSS-WG Stakeholders for Salvia NOI

Hi Stephanie,

Below is an example of a message we recently issued regarding some changes to the scheduling of certain NHP ingredients. This was sent to NHPD's Stakeholder list, which primarily includes applicants, however also includes industry members, pharmacists who are interested in receiving this type of information.

Please let me know if you need anything else.

Thanks  
Lisa Young  
613-954-2940

\*\*\*\*\*

October 21, 2010

**Re: Update on the Assessment of Naturally-Sourced Medicinal Ingredients found on Schedule F**

Dear Stakeholders,

In March 2009 Health Canada announced that it would be undertaking the scientific assessment of a number of naturally-sourced substances currently listed in Schedule F to the *Food and Drug Regulations*. The purpose of this initiative was to determine which of these substances should remain unchanged, be modified, or removed entirely from the Schedule. Health Canada followed up this announcement with an update in December 2009

(  
[http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/notice-avis\\_schedulef\\_annexef-dec2009-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/notice-avis_schedulef_annexef-dec2009-eng.php)).

This message is to provide *an update on* this initiative:

**1) Four (4) medicinal ingredients proposed for removal from Schedule F: apiol oil, centella asiatica extract and active principles thereof, deanol and its salts and derivatives, and theobromine and its salts.**

Targeting consideration by Treasury Board Ministers for final publication in the *Canada Gazette*, Part II in January/February 2011.

**2) Six (6) medicinal ingredients proposed to remain on Schedule F with qualifiers: dopamine and its salts, gold and its salts, uracil and its salts, dimethyl sulfoxide, levocarnitine, and l-tryptophan.**

Prescription status for specific strengths, uses, routes of administration or dosages.

Targeting consideration by Treasury Board Ministers for final publication in the *Canada Gazette*, Part II in February/March 2011.

**3) Lovastatin**

Moving forward as its own regulatory package.

Health Canada is reviewing comments received further to the Notice of Intent and undertaking further

internal analysis.

Further updates will be provided when appropriate.

Respectfully,

The Natural Health Products Directorate  
Health Canada

\*\*\*\*\*

----- Forwarded by Sara O'Connor/HC-SC/GC/CA on 2010-12-21 06:04 PM -----

From: Stephanie Chandler/HC-SC/GC/CA  
To: Sara O'Connor/HC-SC/GC/CA@HWC  
Date: 2010-12-21 04:57 PM  
Subject: Re: Fw: CSS-WG Stakeholders for Salvia NOI

---

Hi Sara,

The Notice of Intent is published in the Canada Gazette, but we will send a letter to stakeholders indicating that the NOI has been published and include a link to the document. In this Office the majority of our stakeholders will be contacted by email unless we don't have an email on file for them. While email is the preferred method of contact, if this option isn't available we could mail or fax.

Let me know if you have any other questions.

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

Sara O'Connor                      Stephanie, is this notice of intent sent via email?...                      2010-12-21 04:48:05 PM

From: Sara O'Connor/HC-SC/GC/CA  
To: Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2010-12-21 04:48 PM  
Subject: Fw: CSS-WG Stakeholders for Salvia NOI

---

Stephanie, is this notice of intent sent via email?

Sara

----- Forwarded by Sara O'Connor/HC-SC/GC/CA on 2010-12-21 04:45 PM -----

From: Robin Marles/HC-SC/GC/CA  
To: Sara O'Connor/HC-SC/GC/CA@HWC  
Cc: don\_boyer@hc-sc.gc.ca, Carol Toone/HC-SC/GC/CA@HWC  
Date: 2010-12-21 04:37 PM  
Subject: Fw: CSS-WG Stakeholders for Salvia NOI

---

Could you please forward to the Office of Controlled Substances a list of stakeholders (BEEP?) to whom OCS should copy their upcoming Notice of Intent to add Salvia divinorum to Schedule III of the Controlled Drugs and Substances Act?

Robin

----- Forwarded by Robin Marles/HC-SC/GC/CA on 2010-12-21 04:35 PM -----

From: Stephanie Chandler/HC-SC/GC/CA  
To: Robin Marles/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2010-12-21 04:34 PM  
Subject: CSS-WG Stakeholders for Salvia NOI

---

Hi Robin,

I am just wondering if you have any updates with regards to when we will be receiving the HPFB / NHPD list of stakeholders with regard to the Salvia NOI. We are hoping to publish the NOI in January, so we'd like to be able to compile the list of stakeholders ASAP.

Thanks,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca



**URGENT: For review - Revised MLs - Salvia**

Christine Roush to: Jocelyn Kula

2011-02-17 10:51 AM

Cc: Stephanie Chandler, Denis Arsenault, CSTD-OCS-DO

---

History: This message has been replied to.

---

Jocelyn,

Here are my revisions to the MLs. Can you please take a look and let me know if you are OK with them before 11:30.



HECS\_ML\_Salvia\_Feb17\_10h48\_MOrev.doc

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
Health Canada/Santé Canada  
Tel/Tél : (613) 954-0712/Cell: (613) 219-7194  
Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca

----- Forwarded by Christine Roush/HC-SC/GC/CA on 2011-02-17 10:49 AM -----

From: Dave Stephens/HC-SC/GC/CA  
To: Alexis M Tervo/HC-SC/GC/CA@HWC  
Cc: Blossom Leung/HC-SC/GC/CA@HWC, Christine Roush/HC-SC/GC/CA@HWC  
Date: 2011-02-17 08:15 AM  
Subject: Re: For tomorrow morning - Salvia products

---

Alexis, Christine:

I was wrong last night...we are stating publicly what the risks may be. I'd suggest moving some of the material from Q5 up to the key messages.

Dave Stephens  
Senior Communications Executive-Gestionnaire Principal des Communications HECSB/DGSCSE  
Health Canada/Sante Canada  
6th Floor, Room 6-033, 269 Laurier Ave. W., Ottawa, ON  
Tel: (613) 946-8107  
Cell: (613) 859-3581

Alexis M Tervo      Hi Christine, a couple questions for you on the S...      2011-02-16 05:49:23 PM

From: Alexis M Tervo/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Cc: Blossom Leung/HC-SC/GC/CA@HWC, Dave Stephens/HC-SC/GC/CA@HWC  
Date: 2011-02-16 05:49 PM  
Subject: For tomorrow morning - Salvia products

---

Hi Christine, a couple questions for you on the Salvia products.

For the news release:

-Can we confirm if interested parties are encouraged to submit any comments regarding the Notice to Interested Parties by March 14, 2011? In the news release, we still have this marked by TBC.

For the media lines (see comments/revisions in attached).



HECS\_ML\_Salvia\_Feb11\_1327.doc

Alexis Tervo  
Communications Advisor  
Public Affairs, Communications and Consultation  
Health Canada  
Ph: (613) 954-4868

DRAFT  
11/02/2011

**Media Lines**  
**Salvia divinorum**

**Issue**

There is ongoing media interest regarding the availability of *Salvia divinorum* in Canada as well as Canadian surveillance data suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has concluded that *Salvia divinorum* and its main active ingredient salvinorin A should be scheduled under the *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth. A Notice to Interested Parties outlining Health Canada's proposal to regulate this substance will be published in *Canada Gazette*, Part I, on February 19, 2011 (TBC).

**Key Messages:**

- The Government of Canada is taking these steps in order to protect the health and safety of Canadians, particularly youth, from the potentially harmful effects of *Salvia divinorum* and/or salvinorin A.
- Canadians should not use products containing these substances because of the risks associated with their use, which may include hallucinations, loss of consciousness and short-term memory loss. As well, little is known about the long-term effects of these substances on the brain and body.
- Therefore, after reviewing available information and reports that suggest these substances have the potential for abuse, especially among young people, Health Canada is proposing to schedule both *Salvia divinorum* and its main active ingredient salvinorin A as controlled substances.
- The proposed inclusion of *Salvia divinorum* and salvinorin A in Schedule III to the Controlled Drugs and Substances Act would make possession, trafficking, importation, exportation, production (or cultivation), possession for the purpose of trafficking or possession for the purposes of exporting illegal unless authorized by regulation.

**Supplementary Messages:**

- Though it is a hallucinogen, the plant *Salvia divinorum* is not currently scheduled under the CDSA.
- To date, Health Canada has not authorized for sale any natural health products which contain *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products containing *Salvia divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act* and its associated regulations.

**Questions and Answers:**

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**Comment [h1]:** Tim doesn't like this message. He would like a message on what the risk is. I understand from Dave that it is still unknown. Can we add something about the fact that we are assessing the risk?

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**Deleted:** At the present time, products containing *Salvia divinorum* would meet the definition of a natural health product (NHP) under the *Natural Health Products Regulations*.

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11/02/2011

**Q1 - What are the risks associated with the use of *Salvia divinorum***

A1 - *S. divinorum* is known to have both physical and mental effects. The effects of *S. divinorum*, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

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There is no way to predict what effect these substances may have on an individual. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product;
- how much is used;
- the purity of the product (products that contain *S. divinorum* may be mixed with other substances);
- how it is taken, for example, whether the product is chewed, swallowed or smoked; and
- the user's mood and expectations.

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While scientists know which brain receptors are targeted by the main active ingredient, salvinorin A, very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or if it can cause permanent damage;
- how it interacts with other substances, including other drugs, natural health products and alcohol;
- the potential of *S. divinorum* to produce physical dependence and/or addiction.

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For more information on *Salvia divinorum* and the risks associated with its use, please see *It's Your Health* at: (insert link to the *It's Your Health* article.)

**Q2 - What is involved in scheduling *Salvia divinorum* as a controlled substance and what stage is it at?**

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A2 - Health Canada considers several factors in determining whether the scheduling of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

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- Overall risk to public health and safety posed by the substance.



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11/02/2011

- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- International requirements and trends in international control.

Health Canada recently concluded its assessment of *Salvia divinorum* and salvinorin A against these factors and proposes to include both substances in Schedule III to the CDSA. The first step in the process of scheduling a substance under the CDSA is the publication of a *Notice to Interested Parties* (NOI) in *Canada Gazette*, Part I, which will be published on February 19, 2011 (TBC) for a 30-day comment period. This notice provides interested stakeholders with the opportunity to provide comments on Health Canada's proposal to add *Salvia divinorum* and its main active ingredient salvinorin A to Schedule III to the CDSA. Any comments received are considered during the preparation of a regulatory proposal. There will be additional opportunities for comment as the federal regulatory process progresses, which usually takes about 18 to 24 months to complete.

**Q3. Why has the Government now decided to schedule these substances under the CDSA?**

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**A3.** Scheduling these products will reduce the potential risks to the health and safety of Canadians associated with their ready availability, with their increased use and their unknown effects. The scheduling of *Salvia divinorum* and salvinorin A will also eliminate the current misconception that these substances are a safe alternative to other illegal drugs. Furthermore, the scheduling will also enable law enforcement agencies to take action against suspected illegal activities involving these substances.

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**Q4 – Are *Salvia divinorum* and/or salvinorin A controlled internationally? How are these substances regulated in other countries?**

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**A4 -** Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions; as a result, there is no requirement for them to be scheduled as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

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The move to include *Salvia divinorum* and salvinorin A in Schedule III to the CDSA is consistent with actions taken by several countries (e.g., Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden) that have also placed similar controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Some individual U.S. states have implemented similar laws restricting their use, sale and/or distribution.

DRAFT  
11/02/2011

**Q5 – Is there any research on the use of *Salvia divinorum* in Canada?**

**A5** - Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *Salvia divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *Salvia divinorum* in the past year. The 2009 *Ontario Student Drug Use and Health Survey (OSDUHS)* indicated that 5.4% of Ontario students in grades 7-12 reported ever using *Salvia divinorum* and 4.4% of these students reported using this substance in the past year.

**Q6 – If Health Canada is aware that the use of *Salvia divinorum* can produce negative health effects such as hallucinations, feelings of anxiety, etc., why is it not controlled under the Controlled Drugs and Substances Act?**

**A6** – The move to schedule *Salvia divinorum* and salvinorin A as controlled substances is based on surveillance data from surveys such as the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)*, *Youth Smoking Survey (YSS)* and the *Ontario Student Drug Use and Health Survey (OSDUHS)*, some of which only became available in 2010.

In the interim, as *Salvia divinorum* is a plant with hallucinogenic properties, it currently meets the definition of a natural health product under the *Natural Health Products Regulations (NHPR)*. The sale of unauthorized natural health products may be subject to compliance and enforcement action in accordance with the *Food and Drugs Act* and its associated regulations.

**Q7 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

**A7** – Once *Salvia divinorum* and salvinorin A are included in Schedule III to the CDSA, law enforcement will be able to take appropriate action in response to suspected illegal activities with these substances.

Currently, however, *Salvia divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. For more information on how to submit a consumer complaint about the unauthorized sale of drugs containing *Salvia divinorum* and/or salvinorin A, visit: [www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_44\\_consumer\\_consommateur\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_44_consumer_consommateur_cp-pc-eng.php).

**Q8 - Has Health Canada issued any kind of warning to Canadians about *Salvia divinorum*?**

**A8** - Health Canada has developed an *It's Your Health* article about *Salvia divinorum* to help inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at: (link to come). Health Canada also

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Deleted: Q5 - What are the risks associated with the use of *Salvia divinorum*?

A5 - *S. divinorum* is known to have both physical and mental effects. The effects of *S. divinorum*, which vary from person to person, are often described as unpleasant and may include the following:

- <#>hallucinations
- <#>dysphoria (feeling anxious, depressed or restless)
- <#>out-of-body experiences
- <#>uncontrollable laughter
- <#>loss of consciousness
- <#>short-term memory loss
- <#>lack of physical coordination
- <#>slurred speech and awkward sentence patterns

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- <#>the potency of the product;
- <#>how much is used;
- <#>the purity of the product (products that contain *S. divinorum* may be mixed with other substances);
- <#>how it is taken, for example, whether the product is chewed, swallowed or smoked; and
- <#>the user's mood and expectations.

While scientists know which brain receptors are targeted by the main active ingredient, salvinorin A, very little is known about the following:

- <#>how it affects the brain overall, including whether there are any long-term effects or if it can cause permanent damage; ... [1]

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**DRAFT**

11/02/2011

issued a news release on February XX announcing the Government of Canada's intention to schedule *Salvia divinorum* and salvinorin A, as controlled substances. A Notice to Interested Parties, outlining Health Canada's proposal, was published in *Canada Gazette*, Part I, on February 19, 2011 (TBC), giving interested parties a 30-day period to submit their comments. There will be additional opportunities for comment as the federal regulatory process progresses.

**Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff, incense special, and salvia. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

Data from the 2008-2009 Youth Smoking Survey indicates that:

- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;
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- 1.6% of Canadians reported using Salvia in their lifetime (0.2% in the past year); and
- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that:

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;
- 5.4% of students (grades 7-12) ever used *Salvia divinorum*; and
- use of *Salvia divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

**Prepared by:** Stephanie Chandler and Denis Arsenault, OCS, CSTD

Reviewed and revised by: Christine Roush, Senior Communications  
Advisor, HECS, Communications

**Approved by:**

**DRAFT**  
11/02/2011

Jocelyn Kula, A/Director, OCS, CSTD, HECS (Jan 19, 2011 and Jan 27, 2011)  
Suzanne Desjardins, Director, ODARS, CSTD, HECS (Approved Jan 20, 2011)  
Cathy Sabiston, DG, CSTD, HECS  
Chris Turner, DG, MHPD  
Scott Sawler, DG, NHPD  
Diana Dowthwaite, DG, HPFB  
Sharon Mullin, Director, Compliance and Enforcement Coordination, HPFB  
Robin Marles, Director, Bureau of Clinical Trials, NHPD  
Chantal Trepanier, Legal Counsel, HECS  
Sherrey Collier, Legal Counsel, HPFB  
David Gotlieb, A/Communications Executive, HPFB  
Judith O'Brien, A/Communications Executive, HECS  
Ken Polk, A/Director, Public Affairs, PACCB  
Charles Mojsej, DG, PACCB  
Paul Glover, ADM, HPFB  
Hillary Geller, A/ADM, HECS  
Anne Lamar, ADM, PACCB  
DMO (pending)  
MO (pending)  
PCO (pending)

**Q5 - What are the risks associated with the use of *Salvia divinorum***

A5 - *S. divinorum* is known to have both physical and mental effects. The effects of *S. divinorum*, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:


- the potency of the product;
- how much is used;
- the purity of the product (products that contain *S. divinorum* may be mixed with other substances);
- how it is taken, for example, whether the product is chewed, swallowed or smoked; and
- the user's mood and expectations.

While scientists know which brain receptors are targeted by the main active ingredient, salvinorin A, very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or if it can cause permanent damage;
- how it interacts with other substances, including other drugs, natural health products and alcohol;
- the potential of *S. divinorum* to produce physical dependence and/or addiction.

For more information on *Salvia divinorum* and the risks associated with its use, please see *It's Your Health* at: (insert link to the *It's Your Health* article.)



**Re: URGENT: For review - Revised MLs - Salvia**   
Suzanne Desjardins to: Stephanie Chandler  
Cc: Christine Roush, CSTD-OCS-DO, Denis Arsenault, Jocelyn Kula

2011-02-17 11:33 AM

I am fine with the changes.

Suzanne

Stephanie Chandler Hi Christine, Jocelyn and Denis are in a meeti... 2011-02-17 11:14:50 AM

From: Stephanie Chandler/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Cc: CSTD-OCS-DO, Denis Arsenault/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC  
Date: 2011-02-17 11:14 AM  
Subject: Re: URGENT: For review - Revised MLs - Salvia

---

Hi Christine,

Jocelyn and Denis are in a meeting until 12 so I don't think she will be responding to you by 11:30...

As the updated key messages include specific references to potential risks, I am cc'ing Suzanne Desjardins in case she has any comments on the revised media lines.

In response to your earlier question, comments on the NOI should be submitted by March 21, 2011.

Regards,

Stephanie


Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

Christine Roush Jocelyn, Here are my revisions to the MLs. Can... 2011-02-17 10:51:29 AM

From: Christine Roush/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Stephanie Chandler/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, CSTD-OCS-DO  
Date: 2011-02-17 10:51 AM  
Subject: URGENT: For review - Revised MLs - Salvia

---

Jocelyn,  
Here are my revisions to the MLs. Can you please take a look and let me know if you are OK with them before 11:30.

**Re: URGENT: For review - Revised MLs - Salvia** 

Christine Roush to: Jocelyn Kula

2011-02-17 12:32 PM

Cc: Stephanie Chandler, Denis Arsenault, CSTD-OCS-DO, Suzanne Desjardins

Thx Jocelyn - Stephanie C already sent this to Suzanne and she is ok with this.  
Jocelyn Kula

----- Original Message -----

**From:** Jocelyn Kula

**Sent:** 2011-02-17 12:16 PM EST

**To:** Christine Roush

**Cc:** Stephanie Chandler; Denis Arsenault; CSTD-OCS-DO; Suzanne Desjardins

**Subject:** Re: URGENT: For review - Revised MLs - Salvia

Approved for OCS.

Wld appreciate if Suzanne could approve as well (generally just a recast of existing info but she shld review to be sure)

JK

Sent by blackberry

Christine Roush

----- Original Message -----

**From:** Christine Roush

**Sent:** 2011-02-17 10:51 AM EST

**To:** Jocelyn Kula

**Cc:** Stephanie Chandler; Denis Arsenault; CSTD-OCS-DO

**Subject:** URGENT: For review - Revised MLs - Salvia

Jocelyn,

Here are my revisions to the MLs. Can you please take a look and let me know if you are OK with them before 11:30.

[attachment "HECS\_ML\_Salvia\_Feb17\_10h48\_MOrev.doc" deleted by Jocelyn Kula/HC-SC/GC/CA]

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
Health Canada/Santé Canada  
Tel/Tél : (613) 954-0712/Cell: (613) 219-7194  
Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca

----- Forwarded by Christine Roush/HC-SC/GC/CA on 2011-02-17 10:49 AM -----

**From:** Dave Stephens/HC-SC/GC/CA  
**To:** Alexis M Tervo/HC-SC/GC/CA@HWC  
**Cc:** Blossom Leung/HC-SC/GC/CA@HWC, Christine Roush/HC-SC/GC/CA@HWC  
**Date:** 2011-02-17 08:15 AM  
**Subject:** Re: For tomorrow morning - Salvia products

Alexis, Christine:

I was wrong last night...we are stating publicly what the risks may be. I'd suggest moving some of the



**Fw:** [redacted]  
Jocelyn Kula to: stephanie.chandler

2011-02-18 01:33 PM

fyi

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224  
---- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2011-02-18 01:33 PM ----

**From:** Christine Roush/HC-SC/GC/CA  
**To:** Ian De Carufel/HC-SC/GC/CA@HWC  
**Cc:** Lisa MacKay/HC-SC/GC/CA@HWC, Alexis M Tervo/HC-SC/GC/CA@HWC, Elizabeth Keeping/HC-SC/GC/CA@HWC, Jaimie Banks/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC, Jean-Christophe Senosier/HC-SC/GC/CA@HWC, Adele Novak/HC-SC/GC/CA@HWC  
**Date:** 2011-02-18 01:03 PM  
**Subject:** Fw: [redacted]

---

**Ian** - we recommend deleting the marihuana image in the IYH article. We will get back to you shortly about whether you can use the other images.

Christine Roush  
Senior Communications Advisor/

**From:** Chantal Trepanier/HC-SC/GC/CA  
**To:** Christine Roush/HC-SC/GC/CA@HWC  
**Cc:** Richard Johnston/HC-SC/GC/CA@HWC  
**Date:** 2011-02-18 12:50 PM  
**Subject:** Re: Fw: [redacted]

---

Hello Christine,



Chantal  
Tél/Tel: 613 946-5682  
Télé/Fax: 613 954-9485

Solicitor-Client Privilege/Protected



This message is intended for the use of the individual or entity to which it is addressed and may contain information that is privileged or confidential and exempt from disclosure under applicable law. Unauthorized disclosure, copying or re-transmission is prohibited. Modification of the transmission is prohibited. If you have received this transmission in error, please notify me immediately by sending me a return e-mail copy. Then, delete the original message. Thank you.

Secret professionnel de l'avocat/Protégé

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Christine Roush/HC-SC/GC/CA



**Christine Roush/HC-SC/GC/CA**  
18/02/2011 09:54 AM

To Chantal Trepanier/HC-SC/GC/CA@HWC  
cc

Subject Re: Fw: [REDACTED]

Chantal

[REDACTED]

Christine Roush  
Senior Communications Advisor/

Chantal Trepanier      Chrsitine, After performing a cursory review of t...      2011-02-17 05:51:38 PM

From: Chantal Trepanier/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Cc: Jocelyn Kula/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC, Sherrey Collier/HC-SC/GC/CA@HWC, Diane Labelle/HC-SC/GC/CA@HWC  
Date: 2011-02-17 05:51 PM  
Subject: Re: Fw: [REDACTED]

Chrsitine,

[REDACTED]

Chantal  
Tél/Tel: 613 946-5682  
Télé/Fax: 613 954-9485

Solicitor-Client Privilege/Protected

This message is intended for the use of the individual or entity to which it is addressed and may contain

information that is privileged or confidential and exempt from disclosure under applicable law. Unauthorized disclosure, copying or re-transmission is prohibited. Modification of the transmission is prohibited. If you have received this transmission in error, please notify me immediately by sending me a return e-mail copy. Then, delete the original message. Thank you.

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Christine Roush/HC-SC/GC/CA



Christine  
Roush/HC-SC/GC/CA

15/02/2011 02:04 PM

To Chantal Trepanier/HC-SC/GC/CA@HWC

cc Jocelyn Kula/HC-SC/GC/CA@HWC, Stephanie  
Chandler/HC-SC/GC/CA@HWC

Subject Fw: [REDACTED]

Hi Chantal,

[REDACTED]

Thanks,

[REDACTED]

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
Health Canada/Santé Canada  
Tel/Tél : (613) 954-0712/Cell: (613) 219-7194  
Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca

----- Forwarded by Christine Roush/HC-SC/GC/CA on 2011-02-15 02:01 PM -----

From: Lisa MacKay/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Date: 2011-02-14 01:54 PM  
Subject: Re: Fw: [REDACTED]

**Page(s) 002844 to\à 002844**

**Is(Are) exempted pursuant to section(s)  
est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**23**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**

s.23

**Secret professionnel de l'avocat/Protégé**

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----- Forwarded by Chantal Trepanier/HC-SC/GC/CA on 18/02/2011 11:04 AM -----



**Christine Roush/HC-SC/GC/CA**  
18/02/2011 09:54 AM

To Chantal Trepanier/HC-SC/GC/CA@HWC

cc

Subject Re: Fw: [REDACTED]

Chantal

[REDACTED]

**Christine Roush**  
Senior Communications Advisor/

Chantal Trepanier    Chrsitine, [REDACTED]

2011-02-17 05:51:38 PM

From: Chantal Trepanier/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Cc: Jocelyn Kula/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC, Sherrey Collier/HC-SC/GC/CA@HWC, Diane Labelle/HC-SC/GC/CA@HWC  
Date: 2011-02-17 05:51 PM  
Subject: Re: Fw: [REDACTED]

Chrsitine,

[REDACTED]

Chantal  
Tél/Tel: 613 946-5682  
Télé/Fax: 613 954-9485

**Solicitor-Client Privilege/Protected**

This message is intended for the use of the individual or entity to which it is addressed and may contain information that is privileged or confidential and exempt from disclosure under applicable law. Unauthorized disclosure, copying or re-transmission is prohibited. Modification of the transmission is prohibited. If you have received this transmission in error, please notify me immediately by sending me a return e-mail copy. Then, delete the original message. Thank you.

002845



**Fw: Salvia Event**  
Jocelyn Kula to: stephanie.chandler

2011-02-18 05:50 PM

for the file

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224  
----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2011-02-18 05:50 PM -----

From: Louis Proulx/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Cc: Stephanie Szick/HC-SC/GC/CA@HWC, Dave Stephens/HC-SC/GC/CA@HWC, Jesse  
Arnup-Blondin/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Michael  
Assad/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC, SoniaH  
Lindblad1/HC-SC/GC/CA@HWC, Paula Robert/HC-SC/GC/CA@HWC  
Date: 2011-02-18 01:20 PM  
Subject: Re: Salvia Event

Thanks Christine:

As you already know, Suzanne Desjardins will be in Montréal and Jocelyn Kula will be in Winnipeg.

Louis Proulx  
Tel/Tél: (613) 954-5851  
Cell: (613) 447-1762

Christine Roush      Stephanie - as requested, below are the final Sa...      2011-02-18 12:22:30 PM

From: Christine Roush/HC-SC/GC/CA  
To: Stephanie Szick/HC-SC/GC/CA@HWC  
Cc: Dave Stephens/HC-SC/GC/CA@HWC, Jesse Arnup-Blondin/HC-SC/GC/CA@HWC, Jocelyn  
Kula/HC-SC/GC/CA@HWC, Louis Proulx/HC-SC/GC/CA@HWC, Michael  
Assad/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC, SoniaH  
Lindblad1/HC-SC/GC/CA@HWC, Paula Robert/HC-SC/GC/CA@HWC  
Date: 2011-02-18 12:22 PM  
Subject: Re: Salvia Event

**Stephanie** - as requested, below are the final Salvia products, which are currently with PCO for approval. I don't have the final version of the fact sheet below, but will get a copy of it from our DG, Comms and send to you later.

[attachment "HECS\_ML\_Salvia\_Feb18\_10h10\_MOrev.doc" deleted by Louis Proulx/HC-SC/GC/CA]  
[attachment "Salvia NR\_HECS-ADM\_10-02-11\_10h36.doc" deleted by Louis Proulx/HC-SC/GC/CA]

[attachment "Min\_Speech\_Salvia\_HPFB ADMO Comments bk.doc" deleted by Louis  
Proulx/HC-SC/GC/CA] [attachment "DRAFT Salvia NOI\_Feb 10 EN\_clean.wpd" deleted by Louis  
Proulx/HC-SC/GC/CA]

[attachment "IYH Salvia divinatorum\_v27\_HECS-ADM\_10-02-11\_10h33(clean).doc" deleted by Louis

Proulx/HC-SC/GC/CA]

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
Health Canada/Santé Canada  
Tel/Tél : (613) 954-0712/Cell: (613) 219-7194  
Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca

Stephanie Szick      hi Christine Per our conversation - Louis is meet...      2011-02-18 11:45:43 AM

From:            Stephanie Szick/HC-SC/GC/CA  
To:              Christine Roush/HC-SC/GC/CA@HWC  
Cc:              Dave Stephens/HC-SC/GC/CA@HWC, Jesse Arnup-Blondin/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Louis Proulx/HC-SC/GC/CA@HWC, Michael Assad/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC, SoniaH Lindblad1/HC-SC/GC/CA@HWC, Paula Robert/HC-SC/GC/CA@HWC  
Date:            2011-02-18 11:45 AM  
Subject:        Re: Salvia Event

---

hi Christine

Per our conversation - Louis is meeting with Suzanne and Jocelyn at 12:30 today. We will dial you in for this meeting.

Sonia -- please note to have Christine called to patch in to Cathy's office phone.

Thanks, S

Christine Roush      Louis - could we please have a telecon asap to...      2011-02-18 11:39:49 AM

From:            Christine Roush/HC-SC/GC/CA  
To:              Louis Proulx/HC-SC/GC/CA@HWC  
Cc:              Jocelyn Kula/HC-SC/GC/CA@HWC, Suzanne Desilets/HC-SC/GC/CA@HWC, Jesse Arnup-Blondin/HC-SC/GC/CA@HWC, Dave Stephens/HC-SC/GC/CA@HWC, Stephanie Szick/HC-SC/GC/CA@HWC, Michael Assad/HC-SC/GC/CA@HWC  
Date:            2011-02-18 11:39 AM  
Subject:        Salvia Event

---

Louis - could we please have a telecon asap to go over what is expected of you. I have some further information from the regional comms director in Montreal. Minister Verner will expect a full briefing before the announcement.

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
Health Canada/Santé Canada  
Tel/Tél : (613) 954-0712/Cell: (613) 219-7194  
Fax/Facsimile : 948-8085

E-mail / courriel : christine\_roush@hc-sc.gc.ca

s.19(1)

[REDACTED]

Dear [REDACTED]

Thank you for your correspondence of December 14, 2010; concerning the legal status of *Salvia divinorum*.

After reviewing available information and reports that suggest that *Salvia divinorum* has the potential for abuse, Health Canada is proposing to schedule both *Salvia divinorum* and its main active ingredient salvinorin A as controlled substances. A Notice to Interested Parties, outlining Health Canada's proposal, was published in *Canada Gazette*, Part I, on February 19, 2011, giving interested parties a 30-day period to submit their comments.

The proposed inclusion of *Salvia divinorum* and salvinorin A in Schedule III to the *Controlled Drugs and Substances Act* would make possession, trafficking, importation, exportation, production (or cultivation), possession for the purpose of trafficking or possession for the purposes of exporting illegal unless authorized by regulation.

The Government of Canada is taking these steps in order to protect the health and safety of Canadians, particularly youth, from the potentially harmful effects of these substances. In the meantime, Health Canada is cautioning Canadians against the use of products containing *Salvia divinorum* and/or salvinorin A because these products are reportedly hallucinogenic and little is known about the long-term effects of these substances on the brain and body. ~~The limited information available suggests there is also no way to predict how it will affect you with each use. Health Canada does not recommend the use of products containing *Salvia divinorum* and salvinorin A because very little is known about these substances, their potential effects on the brain and body, and their impact on physical and mental functions.~~

This paragraph reflects what legal has recommended we revise the 14H to say

~~The plant *Salvia divinorum* is not regulated under the *Controlled Drugs and Substances Act* and, therefore, is not considered to be banned, nor are activities associated with it illegal in Canada. Health Canada is currently collecting and studying information about *Salvia divinorum* and is assessing whether regulating *Salvia divinorum* and salvinorin A~~



is warranted.

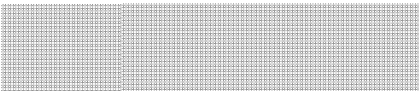
~~When specifically marketed for its hallucinogenic properties, Salvia divinorum meets the definition of a natural health product (NHP) under the Natural Health Products Regulations. However, Health Canada has not authorized any NHPs containing Salvia divinorum as an ingredient for sale. The sale of unauthorized NHPs containing Salvia divinorum or its active ingredient, salvinorin A, may be subject to compliance and enforcement action by the Department under the Food and Drugs Act.~~

Thank you for writing.

Sincerely,

Leona Aglukkaq

s.19(1)



Dear [Redacted]

Thank you for your correspondence of December 14, 2010, concerning the legal status of *Salvia divinorum*.

After reviewing available information and reports that suggest that *Salvia divinorum* has the potential for abuse, ~~especially among young people~~, Health Canada is proposing to schedule both *Salvia divinorum* and its main active ingredient salvinorin A as controlled substances. A Notice to Interested Parties, outlining Health Canada's proposal, was published in *Canada Gazette*, Part I, on February 19, 2011, giving interested parties a 30-day period to submit their comments.

The proposed inclusion of *Salvia divinorum* and salvinorin A in Schedule III to the *Controlled Drugs and Substances Act* <sup>will</sup> ~~will~~ make possession, trafficking, importation, exportation, production (or cultivation), possession for the purpose of trafficking or possession for the purposes of exporting illegal unless authorized by regulation.

The Government of Canada is taking these steps in order to protect the health and safety of Canadians, particularly youth, from the potentially harmful effects of these substances. ~~Canadians should not Health Canada does not recommend the use of products containing *Salvia divinorum* and salvinorin A because they are hallucinogenic and very little is known about the long-term effects of these substances on the brain and body. these substances, their potential effects on the brain and body, and their impact on physical and mental functions.~~

~~The plant *Salvia divinorum* is not regulated under the Controlled Drugs and Substances Act and, therefore, is not considered to be banned, nor are activities associated with it illegal in Canada. Health Canada is currently collecting and studying information about *Salvia divinorum* and is assessing whether regulating *Salvia divinorum* and salvinorin A is warranted.~~

~~When specifically marketed for its hallucinogenic properties, *Salvia divinorum* meets the~~

In the  
summary,  
the  
recommendations  
that  
Controlled  
Substances  
Act

~~definition of a natural health product (NHP) under the Natural Health Products Regulations. However, Health Canada has not authorized any NHPs containing Salvia divinorum as an ingredient for sale. The sale of unauthorized NHPs containing Salvia divinorum or its active ingredient, salvinorin A, may be subject to compliance and enforcement action by the Department under the Food and Drugs Act.~~

Thank you for writing.

Sincerely,

Leona Aglukkaq

DEPARTMENT OF HEALTH

CONTROLLED DRUGS AND SUBSTANCES ACT

Notice to interested parties — Proposal regarding the addition of *Salvia divinorum* and salvinorin A to Schedule III to the Controlled Drugs and Substances Act

This notice provides interested stakeholders with the opportunity to provide comments on Health Canada's proposal to add the plant *Salvia divinorum* (*S. divinorum*) and its main active ingredient salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA). Stakeholders may also identify themselves for inclusion in any future consultation.

The plant *S. divinorum* is a species of sage belonging to the mint family. Its leaves are generally chewed or smoked to obtain psychotropic effects. While uncertainty remains surrounding the health risks of *S. divinorum*, known effects are reported to be short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant. Neither *S. divinorum* nor salvinorin A are currently included in any of the schedules to the CDSA.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. *S. divinorum* is widely touted as a "legal" hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs.<sup>1</sup> Results from the *Canadian Alcohol and Drug Use Monitoring Survey* (CADUMS) reveal that, in 2009, 1.6% of Canadians aged 15 years and older reported having used *S. divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15–24 years. The results from the Canadian 2008–2009 *Youth Smoking Survey* also show that 5% of 15-year-olds have used *S. divinorum* in the past year. Moreover, the 2009 *Ontario Student Drug Use and Health Survey* (OSDUHS) indicated that 5.4% of Ontario students in grades 7–12 reported ever using *S. divinorum* and 4.4% of these students reported using this substance in the past year. Because its psychoactive effects resemble those of other substances included in Schedule III to the CDSA such as lysergic acid diethylamide (LSD) and psilocybin, Health Canada is concerned that the ready availability and use of *S. divinorum* poses a risk to the health and safety of Canadians, particularly youth.

While *S. divinorum* and salvinorin A are not currently included in any of the United Nations drug control conventions, a number of countries have chosen to regulate one or both as controlled substances. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden have all placed controls on the import and/or sale of *S. divinorum* and/or salvinorin A. Some American states have also implemented laws restricting their use, sale and/or distribution.

<sup>1</sup> Dennehy C. E., Tsourounis C., Miller A. E. "Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use." *Annals of Pharmacotherapy* 39, 10 (October 2005):1634–9.

MINISTÈRE DE LA SANTÉ

LOI RÉGLEMENTANT CERTAINES DROGUES ET AUTRES SUBSTANCES

Avis aux parties intéressées — Proposition concernant l'ajout de *Salvia divinorum* et de la salvinorine A à l'annexe III de la Loi réglementant certaines drogues et autres substances

Cet avis informe les parties intéressées de la possibilité de commenter la proposition de Santé Canada d'ajouter la plante *Salvia divinorum* (*S. divinorum*) et son principal ingrédient actif, la salvinorine A, à l'annexe III de la *Loi réglementant certaines drogues et autres substances* (LRCDAS). Les parties intéressées ont aussi l'occasion d'ajouter leur nom pour toute consultation future.

La plante *S. divinorum* est une espèce de sauge appartenant à la famille des menthes. Généralement, ses feuilles sont mâchées ou fumées pour obtenir des effets psychotropes. Alors qu'une incertitude subsiste quant aux risques pour la santé découlant de la consommation de *S. divinorum*, les effets de cette consommation sont connus pour être brefs et comprennent des hallucinations, une dysphorie, des expériences extracorporelles, l'inconscience et une perte de mémoire à court terme. Les effets, qui varient d'une personne à l'autre, sont également souvent décrits comme déplaisants. Ni la *S. divinorum* ni la salvinorine A ne sont actuellement incluses dans les annexes de la LRCDAS.

Des rapports ont récemment été publiés indiquant que des adolescents et des jeunes adultes canadiens consomment de la *S. divinorum* pour sa capacité à produire des hallucinations. La *S. divinorum* est largement vantée comme un hallucinogène « légal » sur Internet et a aussi été signalée comme l'un des produits à base d'herbes médicinales les plus courants utilisés comme solution de rechange aux drogues illicites<sup>1</sup>. Les conclusions tirées de l'*Enquête de surveillance canadienne de la consommation d'alcool et de drogues* (ESCCAD) révèlent que, en 2009, 1,6 % des Canadiens âgés de 15 ans ou plus ont déclaré avoir consommé de la *S. divinorum* au moins une fois dans leur vie, avec un taux de consommation plus important (7,3 %) parmi les jeunes âgés de 15 à 24 ans. Les résultats de l'*Enquête sur le tabagisme chez les jeunes* de 2008-2009 au Canada montrent également que 5 % des jeunes de 15 ans ont consommé de la *S. divinorum* au cours de la dernière année. De plus, le *Sondage sur la consommation de drogues et la santé des élèves de l'Ontario* (SCDSEO) de 2009 indique que 5,4 % des élèves de l'Ontario des classes scolaires 7 à 12 ont déclaré avoir déjà consommé de la *S. divinorum* et que 4,4 % de ces élèves ont indiqué avoir consommé cette substance au cours de la dernière année. Puisque ses effets psychoactifs ressemblent à ceux d'autres substances comprises dans l'annexe III de la LRCDAS, comme l'acide lysergique diéthylamide (LSD) et la psilocybine, Santé Canada craint que la disponibilité immédiate et la consommation de *S. divinorum* ne posent un risque pour la santé et la sécurité des Canadiens, en particulier pour celles des jeunes.

Alors que la *S. divinorum* et la salvinorine A ne sont actuellement comprises dans aucune des conventions de l'Organisation des Nations Unies sur le contrôle des drogues, de nombreux pays ont choisi de réglementer une de ces substances, ou les deux, comme substance désignée. L'Australie, la Belgique, le Danemark, la Finlande, l'Allemagne, l'Italie, le Japon, la Corée du Sud, l'Espagne et la Suède ont tous établi des contrôles sur les importations ou la vente, ou les deux, de *S. divinorum* et/ou de salvinorine A. Certains États américains ont aussi mis en œuvre des lois restreignant son utilisation, sa vente et/ou sa distribution.

<sup>1</sup> Dennehy C. E., C. Tsourounis et A. E. Miller. « Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use ». *Annals of Pharmacotherapy*, vol. 39, n° 10 (octobre 2005), p. 1634-1639.

Including these substances within Schedule III to the CDSA would prohibit possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation). The scheduling of *S. divinorum* and salvinorin A under the CDSA will also enable law enforcement agencies to take action against suspected illegal activities involving these substances.

As this action is not intended to interfere with the use and availability of *S. divinorum* and/or salvinorin A for legitimate medical, scientific or industrial purposes, Health Canada is seeking information from stakeholders on whether there are any such uses in Canada. Information received in response to this notice will be instrumental in determining appropriate regulation under the CDSA.

The publication of this notice begins a 30-day comment period. There will be additional opportunities to provide comments as the federal regulatory process progresses.

If you are interested in this process or have comments on this proposal, please contact Stephanie Chandler, Regulatory Policy Division, Office of Controlled Substances, Address Locator: 3503D, 123 Slater Street, Ottawa, Ontario, Canada K1A 1B9, by fax at 613-946-4224 or by email at OCS.Policy.and.Regulatory.Affairs@hc-sc.gc.ca.

February 4, 2011

CATHY A. SABISTON  
Director General  
Controlled Substances and  
Tobacco Directorate

[8-1-0]

## DEPARTMENT OF HEALTH

### FOOD AND DRUGS ACT

#### Food and Drug Regulations — Amendments

#### Interim Marketing Authorization

The addition of nutrients to foods sold in Canada is regulated under the *Food and Drug Regulations* (the Regulations). The current regulatory provisions list the types of foods that can be fortified, which nutrients can be added and the levels permitted in the particular food. Provision currently exists in the Regulations for the addition of vitamin D to products such as skim milk, partly skimmed milk, margarine and liquid whole eggs.

Health Canada has received a submission to permit the optional addition of vitamin D2-yeast to yeast-leavened bakery products at a level of 90 I.U. (2.25 µg) per 100 g. Health Canada has completed the safety assessment of the proposal to fortify yeast-leavened bread and unstandardized yeast-leavened bakery products such as pizza crust, bread mix, donuts, croissants and bagels. Evaluation of available data has demonstrated that the addition of vitamin D to the foods described above at a level of up to 90 I.U. (2.25 µg) per 100 g of product, as consumed, is safe. The evaluation also concluded that the source of vitamin D need not be limited to a yeast source.

Le fait d'ajouter ces substances à l'annexe III de la LRCDas en interdirait la possession, le commerce, la possession aux fins de commerce, l'importation, l'exportation, la possession aux fins d'exportation et la production (ou la culture). La mise en annexe de la *S. divinorum* et de la salvinorine A sous la LRCDas permettrait également aux organismes d'application de la loi de prendre des mesures contre les activités illicites présumées liées à ces substances.

Étant donné que cette mesure ne vise pas à interférer avec l'utilisation et la disponibilité de la *S. divinorum* et/ou de la salvinorine A à des fins médicales, scientifiques ou industrielles légitimes, Santé Canada sollicite de l'information aux parties intéressées sur les possibilités de ces types d'utilisation au Canada. L'information reçue en réponse à cet avis sera déterminante dans la rédaction d'un règlement approprié conformément à la LRCDas.

La publication de cet avis entame une période de commentaires de 30 jours. Il y aura des occasions supplémentaires de fournir des commentaires au fur et à mesure que progresse le processus de réglementation fédéral.

Si vous êtes intéressé par ce processus ou que vous avez des commentaires sur cette proposition, veuillez communiquer avec Stephanie Chandler, Division de la politique réglementaire, Bureau des substances contrôlées, Indice de l'adresse 3503D, 123, rue Slater, Ottawa (Ontario), Canada K1A 1B9, par télécopieur au 613-946-4224 ou par courriel au OCS.Policy.and.Regulatory.Affairs@hc-sc.gc.ca.

Le 4 février 2011

La directrice générale  
Direction des substances contrôlées et  
de la lutte au tabagisme  
CATHY A. SABISTON

[8-1-0]

## MINISTÈRE DE LA SANTÉ

### LOI SUR LES ALIMENTS ET DROGUES

#### Règlement sur les aliments et drogues — Modifications

#### Autorisation de mise en marché provisoire

L'ajout de nutriments aux aliments vendus au Canada est régi en vertu du *Règlement sur les aliments et drogues* (le Règlement). Les dispositions réglementaires actuelles énumèrent les types d'aliments pouvant être enrichis, les nutriments qui peuvent être ajoutés et la quantité permise dans un aliment donné. Dans le Règlement, il existe actuellement une disposition traitant de l'ajout de vitamine D à des produits tels que le lait écrémé, le lait partiellement écrémé, la margarine et les œufs entiers liquides.

Santé Canada a reçu une demande afin de permettre l'ajout facultatif de levure contenant de la vitamine D2 aux produits de boulangerie levés à l'aide de levure en une quantité de 90 U.I. (2,25 µg) par 100 g. Santé Canada a effectué une évaluation de l'innocuité de la proposition consistant à enrichir les pains levés à l'aide de levure et les produits de boulangerie non normalisés levés à l'aide de levure tels que les croûtes à pizza, les préparations pour pain, les beignets, les croissants et les bagels. L'évaluation des données disponibles a démontré que l'ajout de vitamine D aux aliments décrits ci-dessus en une quantité pouvant atteindre 90 U.I. (2,25 µg) par 100 g de produit, sous leur forme consommable ne comporte aucun danger. L'évaluation a aussi

**Page(s) 002855 to\à 002862**

**Is(Are) exempted pursuant to section(s)  
est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**



## Salvia divinorum

News Release: The Government of Canada Proposes to Schedule Salvia Divinorum and Salvinorin A as Controlled Substances (insert link)

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Certain websites promote the use of *S. divinorum* as a “legal” alternative to street drugs. The products are sold in a number of forms, including fresh or dried leaves, liquids or seeds and plant cuttings for growing purposes.

Canadians should not use products containing *S. divinorum* and/or salvinorin A because they are hallucinogenic and little is known about the long-term effects of these substances on the brain and body; how it interacts with other substances, including other drugs, natural health products and alcohol; and the potential of *S. divinorum* to produce physical dependence and/or addiction.

### Risks Associated with the Use of *Salvia divinorum*

*S. divinorum* is known to have both physical and mental effects, which may include:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

### Legal Status of *Salvia divinorum*

#### In Canada

*S. divinorum* currently meets the definition of a natural health product (NHP) under the *Natural Health Products Regulations*. As of February 2011, Health Canada has not authorized for sale any natural health products which contain *S. divinorum* as an ingredient. The sale of unauthorized natural health products containing *S. divinorum* or its main active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

While *S. divinorum* and salvinorin A are not currently scheduled under the *Controlled Drugs and Substances Act* (CDSA), Health Canada has issued a Notice to Interested Parties which proposes to include *S. divinorum* and salvinorin A as controlled substances under the CDSA. This means that activities such as possession, trafficking, importation, exportation, production (or cultivation), possession for the purpose of trafficking or possession for the purposes of exporting would be illegal unless authorized by regulation.

### In Other Countries

Several countries including but not limited to Australia, Belgium, Germany, Italy and Japan, have placed similar controls on the import and/or sale of *S. divinorum* and/or salvinorin A.

In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed similar restrictions on their sale and/or import.

### **Research on the use of *Salvia divinorum* in Canada?**

Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *S. divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *S. divinorum* in the past year. The 2009 *Ontario Student Drug Use and Health Survey (OSDUHS)* indicated that 5.4% of Ontario students in grades 7-12 reported ever using *S. divinorum* and 4.4% of these students reported using this substance in the past year.

### **Need More Info?**

For information on how to submit a consumer or trade complaint about the unauthorized sale of health products containing *S. divinorum* please consult the following documents:

- Consumers: [http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_44\\_consumer\\_consommateur\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_44_consumer_consommateur_cp-pc-eng.php)
- Trade: [http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_38\\_trade-industrie\\_cp-pc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_38_trade-industrie_cp-pc-eng.php). Or contact the **Health Products and Food Branch Inspectorate** directly by calling toll-free 1-800-267-9675.

To report an adverse reaction or interaction involving any health product, contact Health Canada at 1-866-234-2345 (toll free in Canada), or visit the [MedEffect Canada](http://www.health.gc.ca/medeffect) web section at: [www.health.gc.ca/medeffect](http://www.health.gc.ca/medeffect)

For more information on the risks of using Salvia, please see *It's Your Health* at: (insert link)





Health Canada Santé  
Canada Canada

## NOTICE TO MEDIA

February 19, 2011

MP Shelly Glover (Saint Boniface) will make an announcement on behalf of the Honourable Leona Aglukkaq, Minister of Health, related to the health and safety of Canadians.

### Date

February 21, 2011

### Time

1:45 p.m. (CST)

### Location

YMCA-YWCA - South Y  
5 Fermor Avenue  
Multi-purpose room 2  
Winnipeg, Manitoba

### Media Inquiries

Health Canada  
(613) 957-2983

Jenny Van Alstyne  
Office of the Honourable Leona Aglukkaq  
Federal Minister of Health  
(613) 957-0200

## AVIS AUX MÉDIAS

Le 19 février 2011

La députée Shelly Glover (Saint-Boniface), fera une annonce sur la santé et la sécurité des Canadiens, au nom de l'honorable Leona Aglukkaq, ministre de la Santé.

### Date

Le 21 février 2011

### Heure

13 h 45 (HNC)

### Endroit

YMCA-YWCA - South Y  
5, avenue Fermor  
Salle polyvalente 2  
Winnipeg (Manitoba)

### Renseignements aux médias

Santé Canada  
613-957-2983

Jenny Van Alstyne  
Cabinet de l'honorable Leona Aglukkaq  
Ministre fédéral de la Santé  
613-957-0200



**DRAFT**  
11/02/2011

## **Media Lines** ***Salvia divinorum***

### **Issue**

There is ongoing media interest regarding the availability of *Salvia divinorum* in Canada as well as Canadian surveillance data suggesting that *Salvia divinorum* is being used by adolescents and young adults specifically for its hallucinogenic properties. Health Canada has concluded that *Salvia divinorum* and its main active ingredient salvinorin A should be scheduled under the *Controlled Drugs and Substances Act* (CDSA) in order to protect the health and safety of Canadians, particularly youth. A Notice to Interested Parties outlining Health Canada's proposal to regulate this substance will be published in *Canada Gazette*, Part I, on February 19, 2011 (TBC).

### **Key Messages:**

- The Government of Canada is taking these steps in order to protect the health and safety of Canadians, particularly youth, from the potentially harmful effects of *Salvia divinorum* and/or salvinorin A.
- After reviewing available information and reports that suggest these substances have the potential for abuse, especially among young people, Health Canada is proposing to schedule both *Salvia divinorum* and its main active ingredient salvinorin A as controlled substances.
- Health Canada is continuing to survey the prevalence of salvia use and have based our proposed scheduling on available information and reports that suggest these substances have the potential for abuse, especially among young Canadians. The risks of salvia use include hallucinations, loss of consciousness and short-term memory loss.
- The proposed inclusion of *Salvia divinorum* and salvinorin A in Schedule III to the *Controlled Drugs and Substances Act* would make possession, trafficking, importation, exportation, production (or cultivation), possession for the purpose of trafficking or possession for the purposes of exporting illegal unless authorized by regulation.

### **Supplementary Messages:**

- Though it is a hallucinogen, the plant *Salvia divinorum* is not currently scheduled under the CDSA.
- To date, Health Canada has not authorized for sale any natural health products which contain *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products containing *Salvia divinorum* or its active ingredient

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salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act and its associated regulations*.

**Questions and Answers:**

**Q1 - What are the risks associated with the use of *Salvia divinorum***

A1 - *S. divinorum* is known to have both physical and mental effects. The effects of *S. divinorum*, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

There is no way to predict what effect these substances may have on an individual. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product;
- how much is used;
- the purity of the product (products that contain *S. divinorum* may be mixed with other substances);
- how it is taken, for example, whether the product is chewed, swallowed or smoked; and
- the user's mood and expectations.

While scientists know which brain receptors are targeted by the main active ingredient, salvinorin A, very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or if it can cause permanent damage;
- how it interacts with other substances, including other drugs, natural health products and alcohol;
- the potential of *S. divinorum* to produce physical dependence and/or addiction.

For more information on *Salvia divinorum* and the risks associated with its use, please see *It's Your Health* at: (insert link to the *It's Your Health* article.)

**Q2 – What is involved in scheduling *Salvia divinorum* as a controlled substance and what stage is it at?**

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A2 - Health Canada considers several factors in determining whether the scheduling of a substance under the *Controlled Drugs and Substances Act* (CDSA) is warranted. These include:

- Overall risk to public health and safety posed by the substance.
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- International requirements and trends in international control.

Health Canada recently concluded its assessment of *Salvia divinorum* and salvinorin A against these factors and proposes to include both substances in Schedule III to the CDSA. The first step in the process of scheduling a substance under the CDSA is the publication of a *Notice to Interested Parties* (NOI) in *Canada Gazette*, Part I, which will be published on February 19, 2011 (TBC) for a 30-day comment period. This notice provides interested stakeholders with the opportunity to provide comments on Health Canada's proposal to add *Salvia divinorum* and its main active ingredient salvinorin A to Schedule III to the CDSA. Any comments received are considered during the preparation of a regulatory proposal. There will be additional opportunities for comment as the federal regulatory process progresses, which usually takes about 18 to 24 months to complete.

**Q3. Why has the Government now decided to schedule these substances under the CDSA?**

A3. Scheduling these products will reduce the potential risks to the health and safety of Canadians associated with their ready availability, with their increased use and their unknown effects. The scheduling of *Salvia divinorum* and salvinorin A will also eliminate the current misconception that these substances are a safe alternative to other illegal drugs. Furthermore, the scheduling will also enable law enforcement agencies to take action against suspected illegal activities involving these substances.

**Q4 – Are *Salvia divinorum* and/or salvinorin A controlled internationally? How are these substances regulated in other countries?**

A4 - Neither *Salvia divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions; as a result, there is no requirement for them to be scheduled as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

The move to include *Salvia divinorum* and salvinorin A in Schedule III to the CDSA is consistent with actions taken by several countries (e.g., Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden) that have also placed similar controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A.

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Some individual U.S. states have implemented similar laws restricting their use, sale and/or distribution.

**Q5 – Is there any research on the use of *Salvia divinorum* in Canada?**

A5 - Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *Salvia divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *Salvia divinorum* in the past year. The 2009 *Ontario Student Drug Use and Health Survey (OSDUHS)* indicated that 5.4% of Ontario students in grades 7-12 reported ever using *Salvia divinorum* and 4.4% of these students reported using this substance in the past year.

**Q6 – If Health Canada is aware that the use of *Salvia divinorum* can produce negative health effects such as hallucinations, feelings of anxiety, etc., why is it not controlled under the Controlled Drugs and Substances Act?**

A6 – The move to schedule *Salvia divinorum* and salvinorin A as controlled substances is based on surveillance data from surveys such as the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)*, *Youth Smoking Survey (YSS)* and the *Ontario Student Drug Use and Health Survey (OSDUHS)*, some of which only became available in 2010.

In the interim, as *Salvia divinorum* is a plant with hallucinogenic properties, it currently meets the definition of a natural health product under the *Natural Health Products Regulations (NHPR)*. The sale of unauthorized natural health products may be subject to compliance and enforcement action in accordance with the *Food and Drugs Act* and its associated regulations.

**Q7 – What will Health Canada do if it finds products containing *Salvia divinorum* on the market?**

A7 – Once *Salvia divinorum* and salvinorin A are included in Schedule III to the CDSA, law enforcement will be able to take appropriate action in response to suspected illegal activities with these substances.

Currently, however, *Salvia divinorum* products that are not in compliance with the *Natural Health Products Regulations* may be subject to compliance and enforcement action by Health Canada. For more information on how to submit a consumer complaint about the unauthorized sale of drugs containing *Salvia divinorum* and/or salvinorin A, visit: [www.he-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_44\\_consumer\\_consommateur\\_cp-pc-eng.php](http://www.he-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_44_consumer_consommateur_cp-pc-eng.php).

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**Q8 - Has Health Canada issued any kind of warning to Canadians about *Salvia divinorum*?**

A8 - Health Canada has developed an *It's Your Health* article about *Salvia divinorum* to help inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at: [\(link to come\)](#). Health Canada also issued a news release on February XX announcing the Government of Canada's intention to schedule *Salvia divinorum* and salvinin A, as controlled substances. A Notice to Interested Parties, outlining Health Canada's proposal, was published in *Canada Gazette*, Part I, on February 19, 2011 (TBC), giving interested parties a 30-day period to submit their comments. There will be additional opportunities for comment as the federal regulatory process progresses.

**Background**

*Salvia divinorum* is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff, incense special, and salvia. Its leaves are chewed or smoked to obtain psychotropic effects. These effects are short acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant.

The leaves of this plant have been used traditionally for medicinal and other purposes by the Mazatec people in Mexico.

Data from the 2008-2009 Youth Smoking Survey indicates that:

- 2.6% of students (grades 7-10) reported having used *Salvia divinorum* in the past year;
- 7.0% of students (grades 10-12) reported having used *Salvia divinorum* in the past year; and
- 5.0% of students 15 years of age reported using *Salvia divinorum* in the past year.

Data from the 2009 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that:

- 1.6% of Canadians reported using Salvia in their lifetime (0.2% in the past year); and
- the prevalence of lifetime use among youth (15-24 years of age) was 7.3% while only 0.5% of adults reported having ever used this substance.

Data from the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) published by the Centre for Addiction and Mental Health (CAMH) indicate that:

- 4.4% of students (grades 7-12) used *Salvia divinorum* in the past year;
- 5.4% of students (grades 7-12) ever used *Salvia divinorum*; and
- use of *Salvia divinorum* was significantly higher in males than in females (6.2% vs. 2.3%) in 2009.

002870

**DRAFT**  
11/02/2011

**Prepared by:** Stephanie Chandler and Denis Arsenault, OCS, CSTD  
Reviewed and revised by: Christine Roush, Senior Communications  
Advisor, HECS, Communications

**Approved by:**

Jocelyn Kula, A/Director, OCS, CSTD, HECS (Jan 19, 2011 and Jan 27, 2011)  
Suzanne Desjardins, Director, ODARS, CSTD, HECS (Approved Jan 20, 2011)  
Cathy Sabiston, DG, CSTD, HECS  
Chris Turner, DG, MHPD  
Scott Sawler, DG, NHPD  
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Sharon Mullin, Director, Compliance and Enforcement Coordination, HPFB  
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Paul Glover, ADM, HPFB  
Hillary Geller, A/ADM, HECS  
Anne Lamar, ADM, PACCB  
DMO (pending)  
MO (pending)  
PCO (pending)

**Last updated February 18, 2011 at 7:41 p.m.**

**Scenario Note for  
Shelly Glover, Member of Parliament for Saint-Boniface**

**Announcement of the Government of Canada's intention to regulate *Salvia divinorum* and salvinorin A, also known as Salvia, as controlled substances.**

**Winnipeg, Manitoba  
February 21, 2011  
1:45 p.m.**

**Purpose of Event:** On behalf of the Honourable Leona Aglukkaq, Shelly Glover, Member of Parliament for Saint-Boniface, will announce the Government of Canada's intention to regulate *Salvia divinorum* and salvinorin A, also known as Salvia, as controlled substances.

**Event Address:**

The YMCA-YWCA – South Y  
Multipurpose Room 2  
5 Fermor Avenue  
Winnipeg, Manitoba

**Contacts:**

**MP Glover's Office:**

Myrrhanda Novak  
gloves1@parl.gc.ca  
204.983.3183

**Health Canada**

Jocelyn Kula  
A/Director, Office of Controlled Substances  
Controlled Substances and Tobacco Directorate, HECS

Cell: 613-797-2103

**On-site Health Canada logistics support:**

Adele Novak  
Regional Communications Officer

Office: 204-984-7895  
Cell: 204-791-0240

Karen Christiuk  
Regional Communications Officer

Office: 204-984-7199  
Cell: 204-291-3657



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**YMCA-YWCA – South Y**

Caroline Winston  
Communications Manager

Office: 204-831-2974  
Cell: [REDACTED]

Angela Hildebrand  
General Manager, YMCA, South Y

Office: 204-

**Event Emcee**

Angela Hildebrand  
General Manager, YMCA, South Y

Office: 204-

**Holding Room:**

General Manager's Office (Angela Hildebrand)  
YMCA, South Y  
5 Fermor Avenue

**Photographer (CP photographer booked by Health Canada Media Relations):**

Name David Lipnowski Cell: [REDACTED]

**Media:** Media will be invited to attend by way of a notice to media issued to the news wire by Health Canada (HQ) and posted to Health Canada's Web site. Regional Communications will make follow-up calls to media after the notice to media is issued. At the event, media will have the opportunity to ask questions following the speakers' remarks in the format of a question and answer period.

**Transcript:**

Required: Yes (Media Q booked by Health Canada Media Relations)

**Logistics (sound system, podium, flags):**

Arranged by Health Canada Regional Communications.

**Sound system (arranged by Health Canada Regional Communications)**

Tel Av  
Aaron Jakab/Tom Borsa

Office: 204-775-6198  
Cell:

**Winnipeg, Manitoba**

**Monday, February 21, 2011**

**DETAILED ITINERARY**

1255 hrs MP Glover arrives at the front doors of the YMCA, South Y, 5 Fermor Avenue, and is greeted by Angela Hildebrand, General Manager, YMCA, South Y and event Emcee; and Adele Novak, Regional Communications Officer, Health Canada. Angela Hildebrand and Adele Novak escort MP Glover to the holding room, Angela's Office (behind the front reception).

1300 hrs MP Glover and Angela Hildebrand arrive at the holding room and are joined by Jocelyn Kula, A/Director, Office of Controlled Substances, Health Canada.

A pitcher of water will be available in the briefing room.

1344 hrs MP Glover, Angela Hildebrand, and Jocelyn Kula depart holding room en route to the Multipurpose Room 2 where the announcement will take place.

1345 hrs Event begins. Angela Hildebrand welcomes everyone and introduces MP Glover.

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**Open to media. Media will be set up behind the audience.**

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1347 hrs MP Glover speaks.

1352 hrs Angela Hildebrand thanks MP Glover and introduces **second speaker (TBC)**

1353 hrs **Second speaker** speaks.

1357 hrs Angela Hildebrand thanks **second speaker**, and invites MP Glover and Jocelyn Kula to the podium to answer questions from the audience and media.

1407 hrs Event concludes. Photos may be taken.

1420 hrs MP Glover departs YMCA, South Y and proceeds to board her vehicle.

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**Speech for**  
**Shelly Glover**  
**Parliamentary Secretary to the Minister of Finance**  
**Member of Parliament for Saint Boniface**

**Issue: Proposal to add Salvia Divinorum and Salvinorin  
A to Schedule III to the *Controlled Drugs and  
Substances Act*.**

**Date: February 21, 2011**

Check Against Delivery

Good Morning/Afternoon:

I'd like to thank you for joining me here today for what I consider to be a very important announcement for Canadian families and safer communities.

Une substance connue sous le nom de salvia continue de gagner en popularité chez les jeunes, et certains d'entre eux en abusent. En tant que mère et que policière, je peux vous assurer qu'il s'agit d'une question qui me préoccupe

Its popularity comes from the fact that it can have some of the same effects as certain illicit drugs, and there is also a false perception that it is safe.

But it isn't safe.

Salvia has the real potential to be harmful.

It can cause hallucinations and can have other serious effects on the brain and body. At this point, very little is known about the long-term effect of this substance.

Results from the *Canadian Alcohol and Drug Use Monitoring Survey* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *S. divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24.

And, the results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *S. divinorum* in the past year.

Because of the potential risks to the health of Canadians, particularly young people, we are proposing to add Salvia

divinorum, and its main active ingredient salvinorin A, to the *Controlled Drugs and Substances Act*.

These substances should be controlled, just like other illicit drugs.

As a first step, a notice was published in the *Canada Gazette* on this past weekend. That started a process during which all Canadians will have a 30-day period to comment on our proposal. While we are consulting with Canadians, our position is clear. We want to help parents, families and communities to keep our kids safe.

L'ajout de la *salvia divinorum* à la liste des substances contrôlées rendrait illégales les activités mettant en cause la salvia, comme la possession, le trafic, l'importation et la culture.

And, these measures are in line with other countries, including but not limited to Australia, Belgium, Germany, Italy and Japan. All of these countries have placed similar controls on the import and/or sale of *salvia*.

The bottom line is that our teens face enough pressure already. And with heavily covered stories of young people in Hollywood using Salvia to get high, we have the responsibility to help protect our youth. In a fragile economy like this, Moms and Dads literally can't afford to always keep watch of what's happening. We want to help Mom and Dad.

Nous agissons rapidement dans ce dossier, parce que nous voulons protéger nos jeunes des méfaits associés à la salvia.

**Nous voulons éliminer les idées fausses selon lesquelles la salvia est un substitut sécuritaire aux drogues de la rue.**

**It is not.**

**All of the steps we are taking are designed to protect the health and safety of Canadians from the potentially harmful effects of this substance. We know that parents want their children to be protected from substances like Salvia, particularly when they are in their teenage years.**

**I am happy to take your questions.**

**Thank you**

**Speech for**  
**Shelly Glover**  
**Parliamentary Secretary to the Minister of Finance**  
**Member of Parliament for Saint Boniface**

**Issue: Proposal to add Salvia Divinorum and Salvinorin  
A to Schedule III to the *Controlled Drugs and  
Substances Act*.**

**Date: February 21, 2011**

Check Against Delivery

Good Morning/Afternoon:

I'd like to thank you for joining me here today for what I consider to be a very important announcement for Canadian families and safer communities.

Among today's youth, a substance known as Salvia has been gaining popularity, and is being abused by some young people. As a parent and a police officer, I can tell you that it's something I'm personally concerned about.

Its popularity comes from the fact that it can have some of the same effects as certain illicit drugs, and there is also a false perception that it is safe.

But it isn't safe.

Salvia has the real potential to be harmful.

It can cause hallucinations and can have other serious effects on the brain and body. At this point, very little is known about the long-term effect of this substance.

Results from the *Canadian Alcohol and Drug Use Monitoring Survey* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *S. divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24.

And, the results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *S. divinorum* in the past year.

Because of the potential risks to the health of Canadians, particularly young people, we are proposing to add *Salvia divinorum*, and its main active ingredient salvinorin A, to the *Controlled Drugs and Substances Act*.

These substances should be controlled, just like other illicit drugs.

As a first step, a notice was published in the *Canada Gazette* on this past weekend. That started a process during which all Canadians will



have a 30-day period to comment on our proposal. While we are consulting with Canadians, our position is clear. We want to help parents, families and communities to keep our kids safe.

Adding salvia divinorum to the list of controlled drugs and substances would make activities with salvia, such as possession, trafficking, importing or cultivating illegal.

And, these measures are in line with other countries, including but not limited to Australia, Belgium, Germany, Italy and Japan. All of these countries have placed similar controls on the import and/or sale of *salvia*.

The bottom line is that our teens face enough pressure already. And with heavily covered stories of young people in Hollywood using Salvia to get high, we have the responsibility to help protect our youth. In a fragile economy like this, Moms and Dads literally can't afford to always keep watch of what's happening. We want to help Mom and Dad.

We're acting quickly on this because we want to protect our young people from the harms associated with Salvia.

We want to eliminate the misconceptions that Salvia is a safe alternative to street drugs.

It is not.

All of the steps we are taking are designed to protect the health and safety of Canadians from the potentially harmful effects of this substance. We know that parents want their children to be protected from substances like Salvia, particularly when they are in their teenage years.

I am happy to take your questions.

Thank you.

Health Canada

2011-XX

# News Release

## Harper Government Takes Action to Protect Families

February 21, 2011

For immediate release

Factsheet: *Salvia Divinorum* (insert link)

**OTTAWA** – Today, MP Shelly Glover (Saint Boniface), Parliamentary Secretary to the Minister of Finance, and the Honourable Christian Paradis, Minister of Natural Resources, announced on behalf of the Honourable Leona Aglukkaq, Minister of Health, the Harper Government's proposed intention to include *Salvia divinorum* and salvinorin A, also known as Salvia, as controlled substances. A Notice to Interested Parties outlining Health Canada's proposal was published in *Canada Gazette*, Part I, on February 19, 2011.

"As a mother and police officer, I am pleased to see our Government take action to help parents protect their children from this dangerous substance," said P.S. Glover.

"After reviewing Canadian surveillance data and scientific reports that suggest this substance has the potential for abuse, especially among young people, we are taking these steps to protect the health and safety of Canadians from the harmful effects of this substance," said Minister Paradis.

The Notice to Interested Parties proposes that *Salvia divinorum* and its main active ingredient salvinorin A be added to Schedule III to the *Controlled Drugs and Substances Act*. This means that activities such as possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation) would be illegal unless authorized by regulation. The scheduling of *Salvia divinorum* and salvinorin A as a controlled substance would also enable law enforcement agencies to take action against suspected illegal activities involving these substances.

Interested parties are encouraged to submit any comments regarding the Notice to Interested Parties by March 21, 2011.

For more information on *Salvia divinorum* and the risks associated with its use, please see *It's Your Health* at: (insert link to the *It's Your Health* article.)

-30-

**Media Enquiries:**  
Health Canada  
(613) 957-2983

*Également disponible en français*

Jenny Van Alstyne  
Office of the Honourable Leona Aglukkaq  
Federal Minister of Health  
(613) 957-0200

**Public Enquiries:**  
(613) 957-2991  
1-866 225-0709

Health Canada news releases are available on the Internet at  
[www.healthcanada.gc.ca/media](http://www.healthcanada.gc.ca/media)



Health Santé  
Canada Canada

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## Fiche de renseignements Février 2011

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### ***Salvia divinorum***

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Communiqué de presse : Le gouvernement du Canada propose d'ajouter la salvia et la salvinorine A à la liste des substances contrôlées (insérer le lien)

La *salvia divinorum* (la salvia) est une espèce de sauge de la famille des labiacées. Certains sites Web encouragent la consommation de salvia comme substitut légal aux drogues de la rue. Les produits se vendent sous plusieurs formes, notamment en feuilles fraîches ou séchées, en liquides ou en graines et en boutures pour la culture.

Les Canadiens doivent éviter de consommer des produits contenant de la salvia, car il s'agit d'une substance hallucinogène dont on connaît mal les effets à long terme sur le cerveau et l'organisme, la façon dont elle interagit avec d'autres substances, comme d'autres drogues, des produits de santé naturel et l'alcool, et le risque de dépendance physique ou de toxicomanie associé à la consommation de la salvia.

#### **Risques associés à la consommation de salvia**

La salvia a des effets physiques et mentaux connus qui peuvent comprendre les suivants :

- hallucinations
- dysphorie (sentiment d'angoisse, de dépression ou d'agitation)
- expériences extracorporelles
- rire incontrôlable
- évanouissement
- perte de mémoire immédiate
- manque de coordination des mouvements
- trouble de l'élocution et phrases maladroites

#### **Statut juridique de la *salvia***

##### Au Canada

La salvia correspond présentement à la définition d'un produit de santé naturel que donne le *Règlement sur les produits de santé naturels*. En février 2011, Santé Canada n'avait toujours pas homologué de produit de santé naturel contenant de la salvia. Conformément à la *Loi sur les aliments et drogues*, Santé Canada peut prendre des mesures coercitives à l'égard de quiconque vend des produits de santé naturels non homologués contenant de la salvia ou son principal ingrédient actif, la salvinorine A.

Si la salvia et la salvinorine A ne sont pas, à l'heure actuelle, considérées comme des substances contrôlées en vertu de la *Loi réglementant certaines drogues et autres substances*, Santé Canada a toutefois émis un avis aux parties intéressées dans lequel il propose de les ajouter à l'annexe III de la *Loi*. Cela signifie que les activités comme la possession, le trafic, l'importation, l'exportation, la production (ou la culture), la

possession en vue du trafic ou la possession en vue de l'exportation seraient illégales à moins d'être autorisées par réglementation.

#### À l'étranger

Plusieurs pays, notamment l'Australie, la Belgique, l'Allemagne, l'Italie et le Japon, réglementent l'importation et la vente de la salvia et de la salvinorine A.

Aux États-Unis, la salvia et la salvinorine A ne sont pas réglementées en vertu de la *Loi sur les substances contrôlées*, mais certains États ont adopté des mesures visant à en restreindre la vente et l'importation.

#### **Recherche sur l'utilisation de la *Salvia divinorum* au Canada**

L'Enquête de surveillance canadienne de la consommation d'alcool et de drogues révèle qu'en 2009, 1,6 % des Canadiens ont déclaré avoir consommé de la salvia au moins une fois et que la consommation est beaucoup plus élevée (7,3 %) chez les jeunes de 15 à 24 ans. L'Enquête canadienne 2008-2009 sur le tabagisme chez les jeunes montre que 5 % des jeunes de 15 ans avaient consommé de la salvia au cours de l'année précédente. Selon le Sondage 2009 sur la consommation de drogues et la santé des étudiants de l'Ontario, 5,4 % des étudiants ontariens de la 7<sup>e</sup> à la 12<sup>e</sup> année ont déclaré avoir déjà consommé de la salvia, et 4,4 % d'entre eux ont affirmé en avoir consommée au cours au cours de l'année précédente.

#### **Pour en savoir plus**

Pour savoir comment présenter une plainte concernant la vente non autorisée de produits de santé contenant de la salvia, veuillez consulter le document pertinent ci-dessous :

- Consommateurs : [http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_44\\_consumer\\_consommateur\\_cp-pc-fra.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_44_consumer_consommateur_cp-pc-fra.php)
- Industrie : [http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui\\_38\\_trade-industrie\\_cp-pc-fra.php](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_38_trade-industrie_cp-pc-fra.php)

ou communiquer directement avec l'**Inspectorat de la Direction générale des produits de santé et des aliments**, en composant sans frais le 1-800-267-9675.

Pour signaler un effet indésirable ou une interaction mettant en cause un produit de santé, communiquez avec Santé Canada, au 1-866-234-2345 (sans frais au Canada), ou consultez la section *MedEffet Canada* dans le site [www.sante.gc.ca/medeffet](http://www.sante.gc.ca/medeffet)

Pour de plus amples informations sur le risque associé à l'utilisation de la salvia, veuillez consulter *Votre santé et vous* à (insérer le lien)



## NOTICE TO MEDIA

**February 19, 2011**

The Honourable Christian Paradis, Minister of Natural Resources make an announcement on behalf of the Honourable Leona Aglukkaq, Minister of Health, related to the health and safety of Canadians.

## AVIS AUX MÉDIAS

**Le 19 février 2011**

L'honorable Christian Paradis, ministre des Ressources naturelles, fera une annonce sur la santé et la sécurité des Canadiens, au nom de l'honorable Leona Aglukkaq, ministre de la Santé.

**Date**

February 21, 2011

**Date**

Le 21 février 2011

**Time**

TBC

**Heure**

TBC

**Location**

TBC

**Endroit**

TBC

**Media Inquiries**

Health Canada  
(613) 957-2983

Jenny Van Alstyne  
Office of the Honourable Leona Aglukkaq  
Federal Minister of Health  
(613) 957-0200

**Renseignements aux médias**

Santé Canada  
613-957-2983

Jenny Van Alstyne  
Cabinet de l'honorable Leona Aglukkaq  
Ministre fédéral de la Santé  
613-957-0200



Santé Canada

2011-XX

# News Release

## Le gouvernement Harper prend des mesures pour protéger les familles

Le 21 février 2011

Pour diffusion immédiate

Fiche de renseignements : *Salvia divinorum* ([insert link](#))

OTTAWA – Aujourd'hui, la députée Shelly Glover (Saint-Boniface), Secrétaire parlementaire du ministre des Finances, et l'honorable Christian Paradis, ministre des Ressources naturelles, ont annoncé, au nom de l'honorable Leona Aglukkaq, ministre de la Santé, que le gouvernement Harper avait l'intention d'ajouter la *salvia divinorum* et la salvinorine A à la liste des substances contrôlées. Un Avis aux intéressés décrivant la proposition de Santé Canada a été publié dans la *Gazette du Canada*, Partie I, le 19 février 2011.

« En tant que mère et que policière, je suis heureuse que le gouvernement intervienne pour aider les parents à protéger leurs enfants contre cette substance dangereuse », a indiqué M<sup>me</sup> Glover.

« Après avoir pris connaissance des données de surveillance et des rapports scientifiques canadiens indiquant que certaines personnes, surtout les jeunes, pourraient abuser de la salvia, nous entendons protéger les Canadiens contre les effets dangereux de cette substance », a déclaré la ministre Paradis.

L'Avis aux intéressés propose d'ajouter la *salvia divinorum* et son principal ingrédient actif, la salvinorine A, à l'annexe III de la *Loi réglementant certaines drogues et autres substances*. Cela signifie que les activités comme la possession, le trafic, la possession en vue du trafic, l'importation, l'exportation, la possession en vue de l'exportation et la production (ou la culture) seraient illégales à moins d'être autorisées par réglementation. L'ajout de la *salvia divinorum* et de la salvinorine A à la liste des substances contrôlées permettrait aux organismes d'application de la loi de lutter contre les activités présumées illégales impliquant ces substances.

Les intervenants sont invités à faire parvenir leurs commentaires sur l'Avis aux intéressés d'ici le 14 mars 2011.

Pour de plus amples renseignements sur la salvia et les risques associés à son utilisation,  
veuillez consulter l'article de *Votre santé et vous* à : (insert link to the *It's Your Health*  
article.)

-30-

**Renseignements aux médias**

Santé Canada  
613-957-2983

*Also available in English*

Jenny Van Alstyne  
Cabinet de l'honorable Leona Aglukkaq  
Ministre fédérale de la Santé  
613-957-0200

**Renseignements au public**

613-957-2991  
1-866-225-0709

On peut consulter les communiqués de Santé Canada dans le site  
[www.santecanada.gc.ca/media](http://www.santecanada.gc.ca/media)



**Discours de  
l'honorable Christian Paradis,  
ministre des Ressources naturelles**

**Question : Proposition d'ajouter la *salvia divinorum* et la  
salvinorine A à l'annexe III de la *Loi réglementant  
certaines drogues et autres substances***

**Date : le 21 février 2011**

Seul le texte prononcé fait foi

Bonjour,

Je tiens à vous remercier de vous être joints à moi aujourd'hui pour ce que je considère une annonce très importante pour les familles canadiennes, annonce qui contribuera à la sécurité des collectivités.

Une substance connue sous le nom de salvia continue de gagner en popularité chez les jeunes, et certains d'entre eux en abusent.

Cette substance est populaire, car elle peut avoir les mêmes effets que certaines drogues illicites. Il y a aussi une fausse impression selon laquelle elle est sans danger.

Mais ce n'est pas le cas.

La salvia peut être très dangereuse.

Elle cause parfois des hallucinations et peut avoir d'autres effets néfastes sur le cerveau et l'organisme. À l'heure actuelle, les effets à long terme de cette substance sont peu connus.

L'Enquête de surveillance canadienne de la consommation d'alcool et de drogues de 2009 révèle qu'en 2009, 1,6 % des Canadiens de 15 ans et plus ont consommé de la *salvia divinorum* au moins une fois dans leur vie et que la consommation est beaucoup plus élevée (7,3 %) chez les jeunes de 15 à 24 ans.

De plus, les résultats de l'Enquête sur le tabagisme chez les jeunes 2008-2009, menée au Canada, révèlent que 5 % des jeunes de 15 ans ont consommé de la *salvia divinorum* au cours de l'année précédent l'enquête.

En raison des risques possibles pour la santé des Canadiens, en particulier celle des jeunes, nous proposons d'ajouter la *salvia divinorum*, et son principal ingrédient actif, la salvinorine A, à la *Loi réglementant certaines drogues et autres substances*.

Ces substances doivent être réglementées, tout comme les autres drogues illicites.

Dans un premier temps, un avis a été publié dans la *Gazette du Canada* au cours de la fin de semaine dernière, de sorte que tous les Canadiens disposent de 30 jours pour émettre leurs commentaires au sujet de notre proposition. Alors que nous consultons les Canadiens, notre position est claire. Nous voulons aider les parents, les familles et les collectivités à assurer la sécurité de nos enfants.

L'ajout de la *salvia divinorum* à la liste des substances contrôlées rendrait illégales les activités mettant en cause la salvia, comme la possession, le trafic, l'importation et la culture.

Ces mesures vont dans le sens de celles adoptés par d'autres pays, notamment l'Australie, la Belgique, l'Allemagne, l'Italie et le Japon, qui ont tous mis en place des contrôles semblables qui s'appliquent à l'importation ou à la vente de la *salvia*.

Le fait est que nos adolescents subissent déjà suffisamment de pression. Et, avec des histoires dans les médias de jeunes gens à Hollywood qui utilisent la salvia pour son effet euphorique, nous avons la responsabilité de faire ce qu'il faut pour protéger nos jeunes. Dans une économie aussi fragile que celle que nous connaissons présentement, les mères et les pères ne peuvent tout simplement pas se permettre de toujours surveiller ce que leurs jeunes font.

Ce que nous voulons, c'est aider ces parents.

Nous agissons rapidement dans ce dossier, parce que nous voulons protéger nos jeunes des méfaits associés à la salvia.

Nous voulons éliminer les idées fausses selon lesquelles la salvia est un substitut sécuritaire aux drogues de la rue.

Ce n'est pas le cas.

Toutes les mesures que nous prenons visent à protéger la santé et la sécurité des Canadiens des effets néfastes que peut avoir cette substance. Nous savons que les parents veulent que leurs enfants soient protégés contre les substances comme la salvia, surtout pendant leur adolescence.

C'est avec plaisir que je répondrai maintenant à vos questions.

Merci.

**Speech for  
The Honourable Christian Paradis,  
Minister of Natural Resources**

**Issue: Proposal to add Salvia Divinorum and Salvinorin  
A to Schedule III to the *Controlled Drugs and  
Substances Act*.**

**Date: February 21, 2011**

Check Against Delivery

Good Morning/Afternoon:

I'd like to thank you for joining me here today for what I consider to be a very important announcement for Canadian families and safer communities.

Among today's youth, a substance known as Salvia has been gaining popularity, and is being abused by some young people.

Its popularity comes from the fact that it can have some of the same effects as certain illicit drugs, and there is also a false perception that it is safe.

But it isn't safe.

Salvia has the real potential to be harmful.

It can cause hallucinations and can have other serious effects on the brain and body. At this point, very little is known about the long-term effect of this substance.

Results from the *Canadian Alcohol and Drug Use Monitoring Survey* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *S. divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24.

And, the results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *S. divinorum* in the past year.

Because of the potential risks to the health of Canadians, particularly young people, we are proposing to add *Salvia divinorum*, and its main active ingredient salvinorin A, to the *Controlled Drugs and Substances Act*.

These substances should be controlled, just like other illicit drugs.

As a first step, a notice was published in the *Canada Gazette* on this past weekend. That started a process during which all Canadians will have a 30-day period to comment on our proposal. While we are

consulting with Canadians, our position is clear. We want to help parents, families and communities to keep our kids safe.

Adding salvia divinorum to the list of controlled drugs and substances would make activities with salvia, such as possession, trafficking, importing or cultivating illegal.

And, these measures are in line with other countries, including but not limited to Australia, Belgium, Germany, Italy and Japan. All of these countries have placed similar controls on the import and/or sale of *salvia*.

The bottom line is that our teens face enough pressure already. And with heavily covered stories of young Hollywood using this salvia to get high, we have the responsibility to help protect our youth. In a fragile economy like this, Moms and Dads literally can't afford to always keep watch of what's happening.

We want to help Mom and Dad.

We're acting quickly on this because we want to protect our young people from the harms associated with Salvia.

We want to eliminate the misconceptions that Salvia is a safe alternative to street drugs.

It is not.

All of the steps we are taking are designed to protect the health and safety of Canadians from the potentially harmful effects of this substance. We know that parents want their children to be protected from substances like Salvia, particularly when they are in their teenage years.

I would now be happy to take your questions.

Thank you.

**Page(s) 002896 to\à 002900**

**Is(Are) exempted pursuant to section(s)  
est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**



Bernard  
Lerhe  
President JF

Stakeholder List – Salvia Announcement

Stakeholder	Positive or Negative?	Interested in Event?	Willing to Issue News Release	Willing to have Media Availability
Centre of Excellence for Youth Engagement Stoney McCart 416-597-8297 stoney@tgmag.ca	Expected to be positive	Unknown	Unknown	Unknown
Canadian Association for School Health Doug McCall Executive Director 604-575-3199 or 250-483-6988 dmcall@cash-aces.ca	Expected to be positive	Unknown	Unknown	Unknown
Media Awareness Network Cathy Wing 613-224-7721 x227 cwing@media-awareness.ca	Expected to be positive	Unknown	Unknown	Unknown
Canadian Association of Family Resource Programs Janice MacAulay macaulay@frp.ca 613-237-7667 Ext # 222	Expected to be positive	Unknown No	Unknown No	Unknown No

left message  
left message  
left message  
left message

peripheral to the mandate - not specifically interested in this proposal

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s.19(1)

Stakeholder	Positive or Negative?	Interested in Event?	Willing to Issue News Release	Willing to have Media Availability
Drug Prevention Network of Canada (past President) Randy White 250-752-5816	Expected to be positive	Unknown	Unknown	Unknown
Royal Canadian Mounted Police (RCMP) Eric Slinn, Superintendent 613-949-4265 <a href="mailto:Eric.slinn@rcmp-grc.gc.ca">Eric.slinn@rcmp-grc.gc.ca</a>	Expected to be positive	Unknown	Unknown	Unknown
Canadian Centre on Substance Abuse (CCSA) Michel Peron, CEO 613-235-4048 ext 232	Expected to be positive	Unknown	Unknown	Unknown
Canada Border Services Agency (CBSA) Bente Baklid Director, Program Evaluation Division 613-954-7280 <a href="mailto:Bente.baklid@cbsa-asfc.gc.ca">Bente.baklid@cbsa-asfc.gc.ca</a>	Expected to be positive	Unknown	Unknown	Unknown



Re: Fw: URGENT AR 11-103679-138 Ministerial Announcements on Salvia - February 21

Anna Roberts to: Stephanie Chandler

2011-02-21 09:39 AM

History: This message has been replied to.

Thanks Stephanie,

We didn't have much luck either.

Anna Roberts  
Policy Analyst  
Healthy Environments and Consumer Safety Branch,  
Controlled Substances and Tobacco Directorate  
9th Fl. Rm. A903, MacDonald Building  
123 Slater St. Ottawa, ON. K1A 0K9  
anna.roberts@hc-sc.gc.ca  
(613) 948-8960

Stephanie Chandler Hi Anna, I have called the first four stakeholder...

2011-02-21 09:27:44 AM

From: Stephanie Chandler/HC-SC/GC/CA  
To: Anna Roberts/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC, Frank Cesa/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC  
Date: 2011-02-21 09:27 AM  
Subject: Fw: URGENT AR 11-103679-138 Ministerial Announcements on Salvia - February 21

Hi Anna,

I have called the first four stakeholders and have left a message with all of them. I will try again in a few minutes to see if I can get a hold of anyone in person. I'll let you know the result, but I think all of these associations are closed for Family Day.

[attachment "EDMS - 80653 - 1 - SALVIA ANNOUNCEMENT - STAKEHOLDER LIST\_OCS.DOC" deleted by Anna Roberts/HC-SC/GC/CA]

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca  
----- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2011-02-21 09:23 AM -----

From: Denis Arsenault/HC-SC/GC/CA  
To: Frank Cesa/HC-SC/GC/CA@HWC  
Cc: Stephanie Szick/HC-SC/GC/CA@HWC, Anna Roberts/HC-SC/GC/CA@HWC, Brenda

Paine/HC-SC/GC/CA@HWC, Gisele Osta/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Michael Assad/HC-SC/GC/CA@HWC, Paula Robert/HC-SC/GC/CA@HWC, SoniaH Lindblad1/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC, Matthieu Winter/HC-SC/GC/CA@HWC, Jacqueline DaSilva/HC-SC/GC/CA@HWC, Lyse Champagne/HC-SC/GC/CA@HWC, Cesare Spadaccini/HC-SC/GC/CA@HWC

Date: 2011-02-21 08:58 AM  
Subject: Re: URGENT AR 11-103679-138 Ministerial Announcements on Salvia - February 21

---

Hi Frank,

O.K. Our group will call the first four stakeholder groups and provide Anna our feedback.

Denis

---

Denis Arsenault, A/Manager / Gestionnaire p.i.  
Regulatory Policy Division /  
Division des politiques réglementaires,  
Office of Controlled Substances /  
Bureau des substances contrôlées,  
Health Canada / Santé Canada  
Tel/Tél: (613) 957-6828  
Fax / Télécopieur : (613) 946-4224  
E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca

Frank Cesa	We will take the last four on the list if Denis take...	2011-02-21 07:30:56 AM
Stephanie Szick	hi all, Further to my earlier emails of today regar...	2011-02-20 08:47:04 PM



**Salvia Stakeholder List**

Anna Roberts to: Frank Cesa

2011-02-21 11:13 AM

Cc: Cesare Spadaccini, Jacqueline DaSilva, Lyse Champagne, Matthieu  
Winter, Denis Arsenault, Stephanie Chandler

Hi Frank,

Here is the coordinated response.

Unfortunately I do not think this will be much help. Very few connections were made.



Salvia Stakeholder List.DOC

Anna Roberts  
Policy Analyst  
Healthy Environments and Consumer Safety Branch,  
Controlled Substances and Tobacco Directorate  
9th Fl. Rm. A903, MacDonald Building  
123 Slater St. Ottawa, ON. K1A 0K9  
anna.roberts@hc-sc.gc.ca  
(613) 948-8960



**Salvia revised**

Anna Roberts to: Frank Cesa

2011-02-21 11:25 AM

Cc: Cesare Spadaccini, Jacqueline DaSilva, Matthieu Winter, Lyse  
Champagne, Denis Arsenault, Stephanie Chandler

---

History: This message has been replied to.

---



Salvia Stakeholder List.DOC

Anna Roberts  
Policy Analyst  
Healthy Environments and Consumer Safety Branch,  
Controlled Substances and Tobacco Directorate  
9th Fl. Rm. A903, MacDonald Building  
123 Slater St. Ottawa, ON. K1A 0K9  
anna.roberts@hc-sc.gc.ca  
(613) 948-8960

**Stakeholder List – Salvia Announcement**

<b>Stakeholder</b>	<b>Positive or Negative?</b>	<b>Interested in Event?</b>	<b>Willing to Issue News Release</b>	<b>Willing to have Media Availability</b>
Centre of Excellence for Youth Engagement Stoney McCart 416-597-8297 stoney@tgmag.ca	Expected to be positive. <i>A message has been left.</i>	Unknown	Unknown	Unknown
Canadian Association for School Health Doug McCall Executive Director 604-575-3199 or 250-483-6988 dmcall@cash-aces.ca	Expected to be positive. <i>A message has been left.</i>	Unknown	Unknown	Unknown
Media Awareness Network Cathy Wing 613-224-7721 x227 cwing@media-awareness.ca	Expected to be positive. <i>A message has been left.</i>	Unknown	Unknown	Unknown
Canadian Association of Family Resource Programs Janice MacAulay macaulay@frp.ca	Expected to be positive. <i>A message has been left.</i>	Unknown	Unknown	Unknown

Stakeholder	Positive or Negative?	Interested in Event?	Willing to Issue News Release	Willing to have Media Availability
Drug Prevention Network of Canada (past President) Randy White 250-752-5816 randywhitehome@yahoo.ca	<i>Unknown. Will have to speak with president of the group.</i>	<i>Unknown</i>	<i>Unknown</i>	<i>Unknown</i>
Royal Canadian Mounted Police (RCMP) Eric Slinn, Superintendent 613-949-4265 Eric.slinn@rcmp-grc.gc.ca	<i>Positive</i>	<i>Unknown</i>	<i>No</i>	<i>No</i>
Canadian Centre on Substance Abuse (CCSA) Michel Peron, CEO 613-235-4048 ext 232	<i>Expected to be positive Call made to Michel Perron – left voicemail with EA at 8:50am Feb. 21 (expected to be off for provincial holiday)</i>	<i>Unknown</i>	<i>Unknown</i>	<i>Unknown</i>
Canada Border Services Agency (CBSA) Bente Baklid Director, Program Evaluation Division 613-954-7280 Bente.baklid@cbsa-asfc.gc.ca	<i>Bente Baklid was unsure whether CBSA would be supportive. CBSA has recently undergone a re-organization.</i>	<i>Unknown</i>	<i>Unknown</i>	<i>Unknown</i>



Stakeholder	Positive or Negative?	Interested in Event?	Willing to Issue News Release	Willing to have Media Availability
Jean Beaudoin (president of Qc City police association) cell: 418-952-8201	<i>To be determined. M. Lerhe had not previously heard of Salvia and therefore will need time to look into this substance before drawing any conclusions about it.</i>	N/A	N/A	N/A
Jean-Guy Dagenais (president of Qc (province) police association). cell: [REDACTED]	Unkown. A message has been left.	Unknown	Unknown	Unknown

s.19(1)



**Fw: Salvia revised**

Anna Roberts to: Stephanie Szick  
Cc: Stephanie Chandler, Frank Cesa

2011-02-21 01:56 PM

Hi Stephanie,

Please see below for a correction concerning one of the contacts re: salvia.

Anna Roberts  
Policy Analyst  
Healthy Environments and Consumer Safety Branch,  
Controlled Substances and Tobacco Directorate  
9th Fl. Rm. A903, MacDonald Building  
123 Slater St. Ottawa, ON. K1A 0K9  
anna.roberts@hc-sc.gc.ca  
(613) 948-8960

----- Forwarded by Anna Roberts/HC-SC/GC/CA on 2011-02-21 01:55 PM -----

From: Stephanie Chandler/HC-SC/GC/CA  
To: Anna Roberts/HC-SC/GC/CA@HWC  
Cc: Cesare Spadaccini/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, Frank Cesa/HC-SC/GC/CA@HWC, Jacqueline DaSilva/HC-SC/GC/CA@HWC, Lyse Champagne/HC-SC/GC/CA@HWC, Matthieu Winter/HC-SC/GC/CA@HWC  
Date: 2011-02-21 11:54 AM  
Subject: Re: Salvia revised

---

Hi Anna,

Just for the sake of clarity, we did not contact Jean Beaudoin (no longer President of the police association). The contact information for his successor is as follows:

Fraternité des policiers et policières de la Ville de Québec  
Bernard Lerhe, président  
418-683-8558

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

Anna Roberts

Anna Roberts Policy Analyst

2011-02-21 11:25:02 AM

From: Anna Roberts/HC-SC/GC/CA  
To: Frank Cesa/HC-SC/GC/CA  
Cc: Cesare Spadaccini/HC-SC/GC/CA@HWC, Jacqueline DaSilva/HC-SC/GC/CA@HWC, Matthieu Winter/HC-SC/GC/CA@HWC, Lyse Champagne/HC-SC/GC/CA@HWC, Denis

Date: Arsenault/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC  
2011-02-21 11:25 AM  
Subject: Salvia revised

---

[attachment "Salvia Stakeholder List.DOC" deleted by Stephanie Chandler/HC-SC/GC/CA]

Anna Roberts  
Policy Analyst  
Healthy Environments and Consumer Safety Branch,  
Controlled Substances and Tobacco Directorate  
9th Fl. Rm. A903, MacDonald Building  
123 Slater St. Ottawa, ON. K1A 0K9  
anna.roberts@hc-sc.gc.ca  
(613) 948-8960

Re: Notice to Stakeholders on Salvia   
Jocelyn Kula to: Stephanie Chandler

2011-02-21 02:38 PM

Ok by me. Today is a holiday for most non feds anyways.  
Can you send me a few so I can see the types of things that people are saying..

JK

Sent by blackberry

Stephanie Chandler

----- Original Message -----

From: Stephanie Chandler

Sent: 2011-02-21 02:34 PM EST

To: Jocelyn Kula

Subject: Fw: Notice to Stakeholders on Salvia

Hi Jocelyn,

In preparing to send the Salvia NOI notification through the SIMS database, Isabel has indicated that she is not familiar with the database itself and isn't comfortable sending out the notification particularly given the number of stakeholders involved. Catherine has indicated that while she is too busy to help Isabel send out the notification today, she can help us tomorrow morning. Therefore, we will be sending the notification of the NOI at that time.

FYI - As of noon today we had already received approx. 15 emails with regard to the NOI, all of which were critical of the proposal.

Regards,

Stephanie

Stephanie Chandler

Junior Regulatory Project Officer

Regulatory Policy Division/ Division de la politique réglementaire

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs

Health Canada/ Santé Canada

Tel: (613) 946-0124, Fax: (613) 946-4224

E-Mail: stephanie.chandler@hc-sc.gc.ca

----- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2011-02-21 02:15 PM -----

From: Denis Arsenault/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2011-02-21 01:31 PM  
Subject: Notice to Stakeholders on Salvia

Hi Jocelyn,

FYI - We will be sending out later this afternoon the notice to stakeholders (which you approved earlier) regarding the publication of the NOI on salvia.

Denis

Denis Arsenault, A/Manager / Gestionnaire p.i.  
Regulatory Policy Division /  
Division des politiques réglementaires,  
Office of Controlled Substances /  
Bureau des substances contrôlées,  
Health Canada / Santé Canada  
Tel/Tél: (613) 957-6828  
Fax / Télécopieur : (613) 946-4224  
E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca



**Re: Salvia NOI Stakeholders**  
Stephanie Chandler to: Lisa M Young  
Cc: Denis Arsenault

2011-02-21 03:14 PM

Thanks Lisa.

As discussed, there is no issue with your deletion of the last paragraph for the purposes of sending this email to NHPD stakeholders.

I have included the NOI link and page numbers below (in red ink).

I will confirm with you once OCS has sent out the email from our end (anticipated for tomorrow morning).

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

Lisa M Young

Hi Stephanie, This is how our message will app...

2011-02-21 03:09:17 PM

From: Lisa M Young/HC-SC/GC/CA  
To: Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2011-02-21 03:09 PM  
Subject: Salvia NOI Stakeholders

Hi Stephanie,

This is how our message will appear. I am proposing that the last statement be removed as discussed.

Lisa

This email is being provided for information purposes only. Please do not respond to this email as it will not be answered.

You are receiving this email because you are a contact for an application or licence with the Natural Health Products Directorate. If you want to update your status as an application contact, please send a request to [PLA.info.DLMM@hc-sc.gc.ca](mailto:PLA.info.DLMM@hc-sc.gc.ca) for Product Licence Applications or [SLA.info.DLE@hc-sc.gc.ca](mailto:SLA.info.DLE@hc-sc.gc.ca) for Site Licence Applications.

-----  
Ce message vous est transmis à titre d'information seulement. SVP ne pas répondre à ce courriel puisqu'aucune réponse ne vous sera envoyée.

Vous avez reçu ce courriel parce que vous étiez une personne-ressource pour une demande ou licence avec la Direction des produits de santé naturels. Si vous souhaitez mettre à jour votre statut en tant que personne-ressource, veuillez envoyer une demande par courriel à [PLA.info.DLMM@hc-sc.gc.ca](mailto:PLA.info.DLMM@hc-sc.gc.ca) pour les Demandes de licence de mise en marché ou à [SLA.info.DLE@hc-sc.gc.ca](mailto:SLA.info.DLE@hc-sc.gc.ca) pour les Demandes

de licence d'exploitation.

Dear Sir/Madam:

The purpose of this email is to advise you that a *Notice of Intent to Interested Parties* (NOI) regarding the following substances was published in the *Canada Gazette*, Part I on February 19, 2011:

- *Salvia divinorum*
- Salvinorin A

The electronic version of the NOI is available at the following website:

<http://www.gazette.gc.ca/rp-pr/p1/2011/2011-02-19/pdf/g1-14508.pdf>, pages 8-9 in PDF format (pages 438-439 in *Canada Gazette*, Part I).

This NOI outlines Health Canada's proposal to include *Salvia divinorum* and salvinorin A in Schedule III to the *Controlled Drugs and Substances Act* (CDSA). In particular, Health Canada is seeking further information from stakeholders as to whether these substances have any legitimate industrial, scientific or medical uses in Canada. Information received in response to this notice will be instrumental in determining appropriate regulatory controls.

If you are interested in this process or wish to provide us with information for our consideration, please do so by March 21, 2011. You may send your comments to Stephanie Chandler, Regulatory Policy Division, Office of Controlled Substances, Address Locator: 3503D, 123 Slater St., Ottawa, Ontario, Canada K1A 1B9, by fax at (613) 946-4224 or by email to [OCS.Policy.and.Regulatory.Affairs@hc-sc.gc.ca](mailto:OCS.Policy.and.Regulatory.Affairs@hc-sc.gc.ca).

PLEASE FORWARD THIS EMAIL TO OTHERS WHO MAY BE INTERESTED.

~~Should this notification have reached you in error, it would be appreciated if you could please forward it to the appropriate person in your organization and ask that person to inform us of this by sending an e-mail to:-~~

Thank you,

Regulatory Policy Division  
Office of Controlled Substances  
Controlled Substances and Tobacco Directorate  
Healthy Environments and Consumer Safety Branch

\*\*\*\*\*

Madame, Monsieur,

Le présent courriel a pour but de vous informer qu'un Avis d'intention aux parties intéressées concernant les substances ci-dessous a été publié dans la Partie I de la Gazette du Canada, le 19 février 2011:

- Salvia divinorum (sauge des devins)
- Salvinatorine A

La version électronique de l'Avis d'intention est disponible à l'adresse Internet <http://www.gazette.gc.ca/rp-pr/p1/2011/2011-02-19/pdf/g1-14508.pdf>, pages 8-9, en format PDF (pages 438-439 dans la Partie I de la *Gazette du Canada* ).

Cet avis d'intention décrit la proposition de Santé Canada qui consiste à inclure la Salvia divinorum (sauge des devins) et la salvinatorine A dans l'annexe III de la Loi réglementant certaines drogues et autres substances. Santé Canada cherche précisément à obtenir plus d'information de la part des intervenants afin de déterminer si ces substances ont une utilité légitime sur les plans industriel, scientifique ou médical au Canada. Les renseignements qui seront obtenus permettront de prendre des mesures réglementaires appropriées.

Si vous désirez participer à ce processus ou tout simplement nous fournir de l'information, veuillez communiquer avec nous d'ici le 21 mars 2011. Vous pouvez envoyer vos commentaires par la poste à Stephanie Chandler, Division de la politique réglementaire, Bureau des substances contrôlées, indice de l'adresse : 3503D, 123 rue Slater, Ottawa, Ontario, Canada K1A 1B9, par télécopieur, au 613-946-4224, ou par courriel à [OCS.Policy.and.Regulatory.Affairs@hc-sc.gc.ca](mailto:OCS.Policy.and.Regulatory.Affairs@hc-sc.gc.ca).


**VEUILLEZ TRANSFÉRER LE PRÉSENT COURRIEL AUX PERSONNES QUI POURRAIENT ÊTRE INTÉRESSÉES.**

~~Si vous avez reçu cet avis par erreur, nous vous saurions gré de le transférer à la personne concernée de votre organisation et de lui demander de nous en informer par courriel à : [OCS.Policy.and.Regulatory.Affairs@hc-sc.gc.ca](mailto:OCS.Policy.and.Regulatory.Affairs@hc-sc.gc.ca).~~

Merci.

Division de la politique réglementaire  
Bureau des substances contrôlées  
Direction des substances contrôlées et de la lutte au tabagisme  
Direction générale de la santé environnementale et de la sécurité des consommateurs



Re: Salvia Debrief 

Jocelyn Kula to: Stephanie Szick

2011-02-21 04:31 PM

Cc: Brenda Paine, CSTD-DGO, Denis Arsenault, Stephanie Chandler, Michael Assad

Local and national. Not sure if that means 6 or 10. Could be both.

JK

Sent by blackberry  
Stephanie Szick

----- Original Message -----

From: Stephanie Szick

Sent: 2011-02-21 04:27 PM EST

To: Jocelyn Kula

Cc: Brenda Paine; CSTD-DGO; Denis Arsenault; Stephanie Chandler; Michael Assad

Subject: Re: Salvia Debrief

Thanks for this Jocelyn,

Glad to hear it went well, and also that there was such a turn out.

Will we see you on TV?? or is it Winnipeg CTV local?

Jocelyn Kula

So it all went off OK. Full briefing for Shelley Glo...

2011-02-21 04:21:14 PM

From: Jocelyn Kula/HC-SC/GC/CA

To: "Brenda Paine" <brenda.paine@hc-sc.gc.ca>, "Stephanie Szick" <stephanie.szick@hc-sc.gc.ca>

Cc: CSTD-DGO, "Denis Arsenault" <denis.arsenault@hc-sc.gc.ca>, "Stephanie Chandler" <stephanie.chandler@hc-sc.gc.ca>

Date: 2011-02-21 04:21 PM

Subject: Salvia Debrief

---

So it all went off OK. Full briefing for Shelley Glover (the MP) beforehand but then I had a very backseat role during the announcement itself. Lots of media attendance- all major outlets were represented and Ms Glover took questions for over 10 mins afterwards (which is apparently unusual for out here). I did a short interview for CTV afterwards and that went fine I guess (I am no media star).

Apparently the RPD email has already had quite a few hits in response to the NOI; all from harm reduction advocates/ users who are not in favour....

JK

Sent by blackberry

s.19(1)



**Fw: Media query - CBC Sask - [REDACTED] - Salvia**

Christine Roush to: Louis Proulx

2011-02-21 04:35 PM

Cc: Denis Arsenault, Stephanie Chandler, CSTD-DGO, Brenda Paine, Jesse Arnup-Blondin, Linsey Hollett

Louis - we responded to this CBC media inquiry using the already approved text below.

Christine Roush  
Senior Communications Advisor/

From: Dave Stephens/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC, Gary Holub/HC-SC/GC/CA@HWC  
Cc: Alastair Sinclair/HC-SC/GC/CA@HWC, Nicole Prentice/HC-SC/GC/CA@HWC  
Date: 2011-02-21 04:25 PM  
Subject: Re: Media query - CBC Sask - [REDACTED] - Salvia

Looks good.  
Christine Roush

----- Original Message -----

**From:** Christine Roush  
**Sent:** 2011-02-21 04:24 PM EST  
**To:** Gary Holub  
**Cc:** Alastair Sinclair; Dave Stephens; Nicole Prentice  
**Subject:** Re: Media query - CBC Sask - [REDACTED] - Salvia

Dave - this response is taken directly from the NOI and the last para from the MLs. We can drop the last para if you like and just go with para 1 & 2. Please advise.

**Q - What is the intention of the federal government; to ban this substance completely or to tighten control of access through a regulatory change?**

A; Including these substances within Schedule III to the CDSA would prohibit possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation). The scheduling of *S. divinorum* and salvinorin A under the CDSA will also enable law enforcement agencies to take action against suspected illegal activities involving these substances.

As this action is not intended to interfere with the use and availability of *S. divinorum* and/or salvinorin A for legitimate medical, scientific or industrial purposes, Health Canada is seeking information from stakeholders on whether there are any such uses in Canada. Information received in response to this notice will be instrumental in determining appropriate regulation under the CDSA.

Scheduling these products will reduce the potential risks to the health and safety of Canadians associated with their ready availability, with their increased use and their unknown effects. The scheduling of *Salvia divinorum* and salvinorin A will also eliminate the current misconception that these substances are a safe alternative to other illegal drugs. Furthermore, the scheduling will also enable law enforcement agencies to take action against suspected illegal activities involving these substances.

Christine Roush  
Senior Communications Advisor/

Gary Holub Hi Christine, Nicole, Not sure whether our MLs h...

2011-02-21 04:13:29 PM

From: Gary Holub/HC-SC/GC/CA

002918

To: Christine Roush/HC-SC/GC/CA@HWC, Nicole Prentice/HC-SC/GC/CA@HWC  
Cc: Dave Stephens/HC-SC/GC/CA@HWC, Alastair Sinclair/HC-SC/GC/CA@HWC  
Date: 2011-02-21 04:13 PM  
Subject: Media query - CBC Sask - [redacted] Salvia

Hi Christine, Nicole,

Not sure whether our MLs have anything to specifically address this Q - the deadline is rather tight...

Citing the statement (italics added for reference) in the news release:

<< The Notice to Interested Parties proposes that Salvia divinorum and its main active ingredient salvinorin A be added to Schedule III to the Controlled Drugs and Substances Act. This means that activities such as possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation) *would be illegal unless authorized by regulation.*

Q - What is the intention of the federal government; to ban this substance completely or to tighten control of access through a regulatory change?

Deadline: 6pm (EST)

\*\*\*

Thanks,  
Gray

Gary Scott Holub  
Media Relations Officer | Agent des relations avec les médias  
Regulatory Communications and Media Relations Division | Division des communications réglementaires et des relations avec les médias  
Health Canada | Santé Canada  
(t) 613.954.4807  
(e) gary.holub@hc-sc.gc.ca  
Government of Canada | Gouvernement du Canada  
---- Forwarded by Gary Holub/HC-SC/GC/CA on 2011-02-21 04:12 PM ----



### Media Enquiry - Demande médiatique

Name/Nom : [redacted]	Media/Média : CBC Radio Saskatchewan
Telephone/Téléphone : [redacted]	Language/Langue : English-anglais
Cell Telephone/Téléphone cellulaire : [redacted]	Fax/Télocopieur :
Email/Courriel : [redacted]	

Date and Time Received Date et Heure de réception : 2011-02-21 04:03:23 PM	Date Completed Date d'achèvement :
---	---------------------------------------

Subject/Objet :

Question:

Add to the Question/ajouter a la question  
2011-02-21 4:03:24 PM (Gary Holub)

[redacted]  
CBC, Saskatoon

What are the Government's intentions re: salvia?

Citing the statement (italics added for reference) in the news release:

<< The Notice to Interested Parties proposes that Salvia divinorum and its main active ingredient salvinin A be added to Schedule III to the Controlled Drugs and Substances Act. This means that activities such as possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation) *would be illegal unless authorized by regulation.*

Q - What is the intention of the federal government; to ban this substance completely or to tighten control of access through a regulatory change?

Deadline: 6pm (EST)

\*\*\*

**Response/Réponse :**

Add to the Response/ajouter a la réponse

**Action Taken/Mesures prises :**

Add to the Action Taken/ajouter au mesures prises

2011-02-21 4:11:38 PM (Gary Holub)

Sent to Christine, Nicole, Dave Ste, Alast

Interview with spokesperson granted/Entrevue avec porte-parole accordé:  Yes-Oui  No-Non

Branch/Direction générale :

Spokesperson/Porte-parole :

Reporter's Deadline

Heure de tombée du journaliste :

Priority/Priorité : Regular

Telephone/Téléphone :

Story Run Date

Date de parution de l'article :

Status/Rapport de situation : Follow-up

**Comment/Commentaire :**

**Attachments/Pièces jointes :**

**Related Clippings/Coupures connexes :**

Media Relations Officer/Agente de relations avec les médias : Gary Holub

**Edit History / Historique des révisions**

Send To / Transmettre à : ; Tim Vail/HC-SC/GC/CA; Jenny VanAlstyne/HC-SC/GC/CA; Warren Braun/HC-SC/GC/CA  
Branch Recipient:

Mail Recipients:

CN=Tim Vail/OU=HC-SC/O=GC/C=CA, CN=Jenny VanAlstyne/OU=HC-SC/O=GC/C=CA, CN=Warren Braun/OU=HC-SC/O=GC/C=CA

s.19(1)

Re: Fw: URGENT MEDIA ENQUIRY - Salvia [REDACTED] (La Presse) - COB DEADLINE

Louis Proulx to: Christine Roush, Brenda Paine 2011-02-21 04:42 PM

Cc: CSTD-DGO, Denis Arsenault, Jesse Arnup-Blondin, Jocelyn Kula, Linsey Hollett, Stephanie Chandler

Thanks Christine:

Please note that Brenda is A/DG today. Cheers.

Louis Proulx  
Tel/Tél: (613) 954-5851  
Cell: (613) 447-1762

Christine Roush FYI only - we provided the following response to... 2011-02-21 04:40:40 PM

From: Christine Roush/HC-SC/GC/CA  
To: Louis Proulx/HC-SC/GC/CA@HWC  
Cc: CSTD-DGO, Denis Arsenault/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC, Jesse Arnup-Blondin/HC-SC/GC/CA@HWC, Linsey Hollett/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC  
Date: 2011-02-21 04:40 PM  
Subject: Fw: URGENT MEDIA ENQUIRY - Salvia - [REDACTED] (La Presse) - COB DEADLINE

FYI only - we provided the following response to this media inquiry from approved text:

**Q1A - What is the legal status of salvia? If I have this substance right now, can I be arrested or fined?**

A1A - Though it is a hallucinogen, the plant *Salvia divinorum* is not currently scheduled under the CDSA. To date, Health Canada has not authorized for sale any natural health products which contain *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products containing *Salvia divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act and its associated regulations*. The Natural Health Products Regulations do not apply to the possession of natural health products and/or ingredients for personal use.

**Q2 - Is the addition of salvia to the list of controlled substances effective as of today?**

A2 - No. The first step in the process of scheduling a substance under the CDSA is the publication of a *Notice to Interested Parties (NOI)* in *Canada Gazette, Part I*, which was published on February 19, 2011 for a 30-day comment period, ending March 21, 2011. This Notice provides interested stakeholders with the opportunity to provide comments on Health Canada's proposal to add *Salvia divinorum* and its main active ingredient salvinorin A to Schedule III to the CDSA. Any comments received are considered during the preparation of a regulatory proposal. There will be additional opportunities for comment as the federal regulatory process progresses, which usually takes about 18 to 24 months to complete.

**Q3 - What is salvia?**

Health Canada has developed an *It's Your Health* article about *Salvia divinorum* to help inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at:

<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/life-vie/salvia-eng.php>

s.19(1)

<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/life-vie/salvia-fra.php>

Christine Roush  
Senior Communications Advisor/

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
Health Canada/Santé Canada  
Tel/Tél : (613) 954-0712/Cell: (613) 219-7194  
Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca

----- Forwarded by Christine Roush/HC-SC/GC/CA on 2011-02-21 04:38 PM -----

From: Leslie Meerburg/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC, Nicole Prentice/HC-SC/GC/CA@HWC  
Cc: Dave Stephens/HC-SC/GC/CA@HWC  
Date: 2011-02-21 03:13 PM  
Subject: URGENT MEDIA ENQUIRY - Salvia - [REDACTED] (La Presse) - COB DEADLINE

Good afternoon,

We've received a media enquiry from [REDACTED] with La Presse. Her deadline is COB. The questions look to be relatively straightforward. I don't have an approved version of the media lines yet, but I suspect the answer will lie within.

I've enclosed the questions in both French and English.

Q1 - Quel est le statut juridique de la salvia? Par exemple, si je possède présentement cette substance, puis-je être arrêtée ou être passible d'amende?

Q2 - Est-ce que l'ajout de cette substance à la liste des substances contrôlées est en vigueur à partir d'aujourd'hui?

Q3 - Qu'est-ce que la salvia?

Q1 - What is the legal status of salvia? i.e., if I have this substance right now, can I be arrested or fined?

Q2 - Is the addition of salvia to the list of controlled substances effective as of today?

Q3 - What is salvia?

Please advise if we will have responses before COB.

Thanks,

Leslie.

Leslie Meerburg  
Media Relations Officer | Agente des relations avec les médias  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la  
consultation et des communications  
Health Canada | Santé Canada  
(t) 613.957.1803

002922

(e) [leslie.meerburg@hc-sc.gc.ca](mailto:leslie.meerburg@hc-sc.gc.ca)  
Government of Canada | Gouvernement du Canada



## About Health Canada

### **Salvia divinorum**

#### **Fact Sheet**

February 2011

#### **News Release: Harper Government Takes Action to Protect Families**

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Certain websites promote the use of *S. divinorum* as a "legal" alternative to street drugs. The products are sold in a number of forms, including fresh or dried leaves, liquids or seeds and plant cuttings for growing purposes.

Canadians should not use products containing *S. divinorum* and/or salvinorin A because they are hallucinogenic and little is known about the long-term effects of these substances on the brain and body; how it interacts with other substances, including other drugs, natural health products and alcohol; and the potential of *S. divinorum* to produce physical dependence and/or addiction.

#### **Risks Associated with the Use of *Salvia divinorum***

*S. divinorum* is known to have both physical and mental effects, which may include:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

#### **Legal Status of *Salvia divinorum***

##### **In Canada**

*S. divinorum* currently meets the definition of a natural health product (NHP) under the *Natural Health Products Regulations*. As of February 2011, Health Canada has not authorized for sale any natural health products which contain *S. divinorum* as an ingredient. The sale of unauthorized natural health products containing *S. divinorum* or its main active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

While *S. divinorum* and salvinorin A are not currently scheduled under the *Controlled Drugs and Substances Act* (CDSA), Health Canada has issued a Notice to Interested Parties which proposes to include *S. divinorum* and salvinorin A as controlled substances under the CDSA. This means that activities such as possession, trafficking, importation, exportation, production (or cultivation), possession for the purpose of trafficking or possession for the purposes of exporting would be illegal unless authorized by regulation



## In Other Countries

Several countries including but not limited to Australia, Belgium, Germany, Italy and Japan, have placed similar controls on the import and/or sale of *S. divinorum* and/or salvinorin A.

In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed similar restrictions on their sale and/or import.

## Research on the use of *Salvia divinorum* in Canada?

Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *S. divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *S. divinorum* in the past year. The *2009 Ontario Student Drug Use and Health Survey (OSDUHS)* indicated that 5.4% of Ontario students in grades 7-12 reported ever using *S. divinorum* and 4.4% of these students reported using this substance in the past year.

## Need More Info?

For information on how to submit a consumer or trade complaint about the unauthorized sale of health products containing *S. divinorum* please consult the following documents:

- [Consumers](#)
- [Trade](#) Or contact the **Health Products and Food Branch Inspectorate** directly by calling toll-free 1-800-267-9675.

To report an adverse reaction or interaction involving any health product, contact Health Canada at 1-866-234-2345 (toll free in Canada), or visit the [MedEffect Canada](http://www.health.gc.ca/medeffect) web section at: [www.health.gc.ca/medeffect](http://www.health.gc.ca/medeffect)

For more information on the risks of using Salvia, please see [It's Your Health](#).

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Date Modified: 2011-02-21



Home > Healthy Living > It's Your Health > Lifestyles

## Healthy Living

### Salvia divinorum

#### It's Your Health

##### On this page:

- [The Issue](#)
- [Risks Associated with the Use of Salvia divinorum](#)
- [Minimizing Your Risk](#)
- [Legal Status of Salvia divinorum](#)
- [Background](#)
- [Health Canada's Role](#)
- [Need More Info?](#)

#### The Issue

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, ska Maria pastora, ska pastora, diviner's sage, magic mint, puff, incense special, and salvia.

Certain websites promote the use of *S. divinorum* as a "legal" alternative to street drugs. Recent Canadian surveillance data indicates that Canadian teens and young adults are using *S. divinorum* for its ability to produce [hallucinations](#). Scientific reports also suggest that it has the potential for abuse.

Canadians should not use products containing *S. divinorum* and/or salvinorin A because they are hallucinogenic and little is known about the long-term effects of these substances on the brain and body. There is also no way to predict how it will affect you with each use.

In light of this information, Health Canada is proposing to schedule both *S. divinorum* and its main active ingredient salvinorin A under Schedule III to the [Controlled Drugs and Substances Act \(CDSA\)](#) in order to protect the health and safety of Canadians, particularly youth.

#### Risks Associated with the Use of Salvia divinorum

*S. divinorum* is known to have both physical and mental effects. The effects of *S. divinorum*, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

There is no way to predict what effect this substance may have on you. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product
- how much is used
- the purity of the product (products that contain *S. divinorum* may be mixed with other substances)
- how it is taken, for example, whether the product is chewed, swallowed or smoked
- the user's mood and expectations

While scientists know which brain receptors are targeted by the main active ingredient, salvinorin A, very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or if it can cause permanent damage
- how it interacts with other substances, including other drugs, natural health products and alcohol
- the potential of *S. divinorum* to produce physical dependence and/or addiction

## Minimizing Your Risk

Hallucinogens like *S. divinorum* work by modifying functions in the brain. Health Canada recommends that you should not use *S. divinorum* because little is known about the long-term effects it may have on your body and/or brain functions. There is also no way to predict how it will affect you with each use. Just because a drug is plant-based or "natural", does not mean that it is safe.

Also, if you have children, talk to them about peer pressure and the risks of using [illegal drugs](#), such as [marijuana](#), [cocaine](#), [ecstasy](#), [LSD](#) and [other substances](#) that distort reality. See the [Need More Info](#) section below for links to resources that can help you with this.

## Legal Status of Salvia divinorum

### In Canada

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As *S. divinorum* is a plant with hallucinogenic properties when consumed by humans, it currently meets the definition of a natural health product (NHP) under the [Natural Health Products Regulations](#). As of February 2011, Health Canada has not authorized for sale any natural health products which contain *S. divinorum* as an ingredient. The sale of unauthorized natural health products containing *S. divinorum* or its main active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the [Food and Drugs Act](#).

While *S. divinorum* and salvinorin A are not currently scheduled under the [Controlled Drugs and Substances Act \(CDSA\)](#), Health Canada has issued a Notice to Interested Parties which proposes to include *S. divinorum* and salvinorin A as controlled substances to the CDSA. This means that activities such as possession, trafficking, importation, exportation, production (or cultivation), possession for the purpose of trafficking or possession for the purposes of exporting would be illegal unless authorized by regulation.

### In Other Countries

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Several countries including but not limited to Australia, Belgium, Germany, Italy and Japan, have placed similar controls on the import and/or sale of *S. divinorum* and/or salvinorin A.

In the United States, *S. divinorum* and salvinorin A are not regulated under the *Controlled Substances Act*, but a number of individual states have placed similar restrictions on their sale and/or import. For example, several states have made it illegal to manufacture, distribute, import/export, possess, use, buy and/or sell *S. divinorum* and/or salvinorin A to various degrees, while others have placed restrictions on distribution. In some states, for example, it is illegal for *S. divinorum* to be sold to anyone under the age of 18.

## Background

The leaves of this plant have been used traditionally by the Mazatec people for medicinal and mystical purposes.

The products are sold in a number of forms, including fresh or dried leaves, liquids or seeds and plant cuttings for growing purposes.

Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *S. divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *S. divinorum* in the past year. The *2009 Ontario Student Drug Use and Health Survey (OSDUHS)* indicated that 5.4% of Ontario students in grades 7-12 reported ever using *S. divinorum* and 4.4% of these students reported using this substance in the past year. For more information on these surveys, see the *Need More Info* section below.

## Health Canada's Role

As noted above, in light of the health and safety risks associated with the use of *S. divinorum* and particularly the risks to youth, [Health Canada](#) is taking steps to schedule *S. divinorum* and salvinorin A under the Controlled Drugs and Substances Act.

## Need More Info?

For information on how to submit a consumer or trade complaint about the unauthorized sale of health products containing *S. divinorum* please consult the following documents:

- [How to Submit a Consumer Complaint](#)
- [How to Submit a Trade Complaint](#)

Or contact the [Health Products and Food Branch Inspectorate](#) directly by calling toll-free 1-800-267-9675.

To report an adverse reaction or interaction involving any health product, contact Health Canada at 1-866-234-2345 (toll free in Canada), or visit the [MedEffect Canada](#) web section

For information about the Government of Canada's *National Anti-Drug Strategy* The Prevention section on this site has a number of helpful resources for parents, including:

- [Tips on Talking to Your Teenager](#)
- [What to Do if Your Teen is Using Drugs](#)
- Health Canada's [Not4Me](#) youth drug prevention section

Information on natural health products and the [Natural Health Products Regulations](#)

## It's Your Health - Salvia divinorum

For more on the surveys that have collected information about *Salvia divinorum* use in Canada, see:

- [The 2008-2009 Youth Smoking Survey](#)
- [The 2009 Canadian Alcohol and Drug Use Monitoring Survey](#)
- [The 2009 Ontario Student Drug Use and Health Survey](#)

### Additional Resources:

- U.S. Drug Enforcement Administration: Drugs and Chemicals of Concern: [Salvia divinorum and Salvinorin A](#)
- U.S. Department of Health & Human Services, [National Survey on Drug Use and Health: Use of Specific Hallucinogens: 2006](#)

For additional articles on health and safety issues go to the [It's Your Health](#) web section at.

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245\*

Original : February 2011

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Date Modified: 2011-02-18



Health  
Canada Santé  
Canada

Canada

Home > About Health Canada > Media Room > News Releases

## About Health Canada

### Harper Government Takes Action to Protect Families

#### News Release

2011-29

February 21, 2011

For immediate release

#### Factsheet: *Salvia Divinorum*

**OTTAWA** - Today, the Honourable Christian Paradis, Minister of Natural Resources, and MP Shelly Glover (Saint Boniface), Parliamentary Secretary to the Minister of Finance, announced on behalf of the Honourable Leona Aglukkaq, Minister of Health, the Harper Government's proposed intention to include *Salvia divinorum* and salvinorin A, also known as *Salvia*, as controlled substances. A Notice to Interested Parties outlining Health Canada's proposal was published in *Canada Gazette*, Part I, on February 19, 2011.

"After reviewing Canadian surveillance data and scientific reports that suggest this substance has the potential for abuse, especially among young people, we are taking these steps to protect the health and safety of Canadians from the harmful effects of this substance," said Minister Paradis.

"As a mother and police officer, I am pleased to see our Government take action to help parents protect their children from this dangerous substance," said P.S. Glover.

The Notice to Interested Parties proposes that *Salvia divinorum* and its main active ingredient salvinorin A be added to Schedule III to the *Controlled Drugs and Substances Act*. This means that activities such as possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production (or cultivation) would be illegal unless authorized by regulation. The scheduling of *Salvia divinorum* and salvinorin A as a controlled substance would also enable law enforcement agencies to take action against suspected illegal activities involving these substances.

Interested parties are encouraged to submit any comments regarding the Notice to Interested Parties by March 21, 2011.

For more information on *Salvia divinorum* and the risks associated with its use, please see [It's Your Health](#).

-30-

#### Media Enquiries:

Health Canada  
(613) 957-2983

Jenny Van Alstyne  
Office of the Honourable Leona Aglukkaq

002930

## Harper Government Takes Action to Protect Families

Federal Minister of Health  
(613) 957-0200

**Public Enquiries:**

(613) 957-2991  
1-866 225-0709

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Date Modified: 2011-02-21



## Health Canada proposes ban on hallucinogen salvia

*The Canadian Press*

*Updated: Sat. Feb. 19 2011 8:18 AM ET*

OTTAWA — The federal government is proposing to ground "psychonauts" from taking any more psychedelic trips on salvia divinorum.

Health Canada has posted notice of its intention to ban the potent hallucinogenic herb and its active ingredient, salvinorin A.

It is proposing to add both to the Controlled Drugs and Substances Act, making it illegal to produce, possess, traffic, import or export the substances.

The notice, posted Feb. 4 on the Canada Gazette, gives stakeholders 30 days in which to comment.

Currently, salvia --also known as magic mint and diviner's sage -- is considered a natural health product. As such, it is supposedly illegal to sell it without authorization from Health Canada.

Health Canada has given no such authorization but the agency appears to have done little to enforce its regulations.

Salvia is readily available at head shops across the country and through the Internet, touted as a perfectly legal hallucinogen. As recently as last fall, head shops within a stone's throw of Parliament Hill were openly selling vials of salvia extract for \$20 to \$80 per gram, depending on the potency.

Users of salvia have sometimes referred to themselves as psychonauts on YouTube videos of their trips

Police have long complained they're powerless to halt the sale of salvia, which has been known to produce some adverse reactions, including one case reported by Health Canada in 2006 in which an incoherent, suicidal teenage boy threatened to kill police officers. Police have no jurisdiction to enforce natural health product regulations.

Adding salvia divinorum and salvinorin A to the Controlled Drugs and Substances Act would finally "enable law enforcement agencies to take action against suspected illegal activities involving these substances," Health Canada says in the notice.

It adds that salvia has been "reported to be one of the most prevalent herbal products used as an alternative to illicit drugs."

The Canadian Alcohol and Drug Use Monitoring Survey in 2009 found 7.3 per cent of youths aged 15-24 reported having used salvia at least once.

Because the effects of salvia are similar to those of LSD and other controlled hallucinogenic drugs, "Health Canada is concerned that the ready availability and use of *S. divinorum* poses a risk to the health and safety of Canadians, particularly youth," the notice says.

Other countries, including Australia, Belgium, Denmark, Finland, Germany, Italy, Spain and Sweden, have already regulated or banned salvia, as have some dozen states in the U.S.





**Fw: CTV National News - Government mulls ban of drug "salvia" - February  
21 2011 - 23:00**

Christine Roush to: Suzanne Desjardins, Jocelyn Kula  
Cc: Denis Arsenault, Stephanie Chandler, Michael Assad, Nicole  
Prentice

2011-02-22 09:24 AM

I don't know where the reporter got the following statistics: STUDIES SHOW 17% OF 15 TO 24 YEAR OLDS USED SALVIA IN 2009. THAT'S LITTLE COMPARED TO CANADA BUST AT -- CANNABIS AT 26%.

These are the revised stats we are using from Suzanne last night:

A5 - Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *Salvia divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of students grades 7-12 have used *Salvia divinorum* in the past year. This represents about 123,000 Canadian high-school students. The *2009 Ontario Student Drug Use and Health Survey (OSDUHS)* indicated that 5.4% of Ontario students in grades 7-12 reported ever using *Salvia divinorum* and 4.4% of these students reported using this substance in the past year.

Christine Roush  
Senior Communications Advisor/

From: HC\_Media\_SC/HC-SC/GC/CA  
To:  
Date: 2011-02-22 07:06 AM  
Subject: CTV National News - Government mulls ban of drug "salvia"  
- February 21 2011 - 23:00  
Sent by: Hisham Kelati

Distribution group/Groupe de distribution: Natural Health Products -  
Produits de santé naturels - HPFB/DGPSA, Controlled Substances -  
Substances contrôlées - HECSB/DGSESC, Health Care - Soins de santé,

CTV National News  
February 21 2011  
23:00  
Government mulls ban of drug "salvia"

TO HEALTH NEWS NOW AND NEW CONCERNS ABOUT A PLANT MANY CANADIANS HAVE NOT HEARD ABOUT. IT'S CALLED SALVIA. AS GENEVIEVE BEAUCHEMIN REPORTS, OTTAWA SAYS IT'S TIME SALVIA WENT FROM NATURAL HERB TO ILLEGAL SUBSTANCE.  
Reporter: ALONG SIDE HEMP CLOSING AND BOUTIQUE UTOPIA, A PSYCHEDELIC HERB THAT THE GOVERNMENT NOW WANTS TO BAN.  
OR YOU MIGHT JUST BE LAUGHING OR YOU MIGHT FEEL LIKE YOU WANT TO -- YOU KNOW, YOU FEEL ENERGIZED.  
Reporter: SALVIA CAUSES HALLUCINATIONS AND WHAT SOME USERS DESCRIBE AS AN OUT-OF-BODY EXPERIENCE.  
BUT IT HAS GARNERED MUCH ATTENTION BECAUSE OF THE HOLLYWOOD STORIES.  
Reporter: STORIES LIKE TEEN STAR MILEY CYRUS WHO INHALED ON A VIDEO LAST YEAR. THE SALE  
ISN'T LICENSED BY CANADA, BUT IT'S ALSO NOT ILLEGAL. THE GOVERNMENT SAYS THERE HAS BEEN ADVERSE REACTIONS AND IT IS TIME TO INCLUDE IT IN THE CONTROLLED DRUGS AND SUBSTANCES ACT LIKE MARIJUANA, COCAINE.

WE'RE TAKING PRO-ACTIVE MEASURES TO ENSURE THAT WE ADDRESS SALVIA RIGHT NOW. BECAUSE WE WANT TO MAKE SURE THAT OUR KIDS ARE SAFE.

Reporter: SAFE FROM MEMORY LOSS, HALLUCINATIONS, ANXIETY, AND POTENTIAL LONG-TERM EFFECTS SAYS HEALTH CANADA.

VERY LITTLE CONTROLLED STUDIES HAVE BEEN DONE ON THE EFFECTS OF SALVIA ON THE BODY.

Reporter: BUT AT UTOPIA, ALEX SAYS THAT LACK OF EVIDENCE IS ACTUALLY PART OF THE REASON HE'LL BE PUSHING BACK AGAINST THE BAN. HE SAYS THERE'S MORE.

IT WOULD BE THE WORST OF ALL WORLDS. IF WE BAN IT, WE GIVE A NEW INCOME SOURCE TO ALL CRIMINAL ORGANIZATIONS.

Reporter: BUT HE DOES SAY HE'LL BE SUGGESTING IT BE RESTRICTED AS IT IS IN SOME STATES SOUTH OF THE BORDER WHERE IT IS ILLEGAL TO SELL SALVIA TO THOSE UNDER 21, JUST LIKE ALCOHOL. BEFORE FINALIZING ITS DECISION TO INCLUDE SALVIA AS A CONTROLLED SUBSTANCE,

-END-

---

You are receiving this e-mail because you are subscribed to the distribution group identified at the top of this e-mail message. If you wish to unsubscribe from this group, please reply to this message or send a request to [HC\\_Media\\_SC@hc-sc.gc.ca](mailto:HC_Media_SC@hc-sc.gc.ca)

Thank you.

Media Monitoring Team

Health Canada

Vous recevez ce courriel parce que vous faites partie du groupe de distribution qui apparaît en haut du présent courriel. Si vous désirez que votre nom soit retiré de ce groupe, veuillez répondre à ce courriel et demander que votre nom soit retiré ou envoyer une demande à

[HC\\_Media\\_SC@hc-sc.gc.ca](mailto:HC_Media_SC@hc-sc.gc.ca)

Merci.

L'Équipe de surveillance des médias

Santé Canada

**QUESTION PERIOD NOTE**  
**NOTE POUR LA PÉRIODE DE QUESTIONS**

Date:	February 14, 2011
Classification :	<b>HECS PROTECTED - SESC PROTÉGÉ</b>

**SUBJECT - SUJET**

English:

**DRUGS - SALVIA DIVINORUM**

Français:

**DROGUES - SALVIA DIVINORUM**

**SYNOPSIS - SOMMAIRE**

English:

EMBARGOED UNTIL FEBRUARY 19, 2011.

Media interest in Salvia divinorum is recurrent. Questions around this substance generally focus on its legality. Recently, a number of media reports have commented on a YouTube video which reportedly shows a young celebrity smoking Salvia divinorum. Canadian surveillance data indicates that this substance is being used by adolescents and young adults for its hallucinogenic properties, and there have also been several reports from scientific sources indicating that Salvia divinorum has a potential for abuse.

**ANTICIPATED QUESTION - QUESTION PRÉVUE**

English:

What is Health Canada doing to protect young Canadians from the potential adverse effects associated with the use of Salvia divinorum?

Français:

Quelles mesures Santé Canada prend-il pour protéger les jeunes Canadiens contre les effets indésirables possibles liés à l'utilisation de la Salvia divinorum?

---

English:

- Health Canada is proposing to regulate Salvia as a controlled substance in order to protect the health and safety of Canadians, particularly youth.
- Health Canada has published a *Notice to Interested Parties* in *Canada Gazette*, Part I, to give Canadians the opportunity to provide comments on its proposal to regulate Salvia as a controlled substance.
- The regulation of Salvia would make possession, trafficking, importation, exportation, and production illegal unless authorized by regulation.

Français:

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## BACKGROUND - CONTEXTE

English:

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, diviner's sage, magic mint, and puff. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs.

Both the plant *S. divinorum* and its main active ingredient salvinorin A are known to have physical and mental effects which are often described as unpleasant, including:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

Recent surveys indicate that Canadian youth are trying this substance which could be dangerous to their health. Results from the *Canadian Alcohol and Drug Use Monitoring Survey* (CADUMS) reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *Salvia divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24 years. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15 year olds have used *Salvia divinorum* in the past year. The 2009 *Ontario Student Drug Use and Health Survey* (OSDUHS) indicated that 5.4% of Ontario students in grades 7-12 reported ever using *Salvia divinorum* and 4.4% of these students reported using this substance in the past year.

Current Situation in Canada

As *Salvia divinorum* is a plant with hallucinogenic properties when consumed by humans, it currently meets the definition of a natural health product (NHP) under the *Natural Health Products Regulations*. To date, Health Canada has not licensed for sale any natural health product which contains *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products containing *Salvia divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act*.

Health Canada is proposing that *S. divinorum* and Salvinorin A be included in Schedule III to the CDSA. This would mean that the possession, trafficking, importation, exportation and production of *Salvia divinorum* and salvinorin A would be illegal unless authorized by regulation. The regulation of *Salvia divinorum* and Salvinorin A as controlled substances would allow law enforcement to take action against illegal activities involving this substance.

International Control of *S. divinorum*

Neither *Salvia divinorum* nor its main active ingredient salvinorin A are listed under the United Nations Drug Control Conventions; as a result, they do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions. The proposal to include *Salvia divinorum* and salvinorin A in Schedule III to the (CDSA) is consistent with actions taken by several countries (e.g. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Some individual U.S. states have also implemented laws restricting their use, sale and/or distribution.

**ATTACHMENTS / PIÈCE(S)-JOINTE(S)**

Contact/Personne ressource : Denis Arsenault/HC-SC/GC/CA	Tel. no./No de tél. 613-957-6828	Approved by/ Approuvé par Paul Glover, ADM (HECS/SESC)	Tel. no./No. de tél. 946-6701
	Mobile/ Cellulaire: 613-296-4239	Title/ Titre:	Mobile/ Cellulaire:
Alternate/ Secondaire: Jocelyn Kula	Telephone/ Téléphone: 613-952-2177		
	Mobile/ Cellulaire: 613-797-2103		

**Date Prepared/Préparé le :** 2010-09-07

**Prepared by/Préparé par :** Stephanie Chandler **Phone/ No de tél. :** 613-946-0124

**Office/Bureau :** CSTD - Office of Controlled Substances

**Date Contact Signed/** 2011-02-14

Contact Signed - Signé

**Signature de la personne  
ressource :**

**D.G. Verification/  
Vérification par le D.E. :**

Cathy Sabiston

D.G. Approved / Approuvé D.E.

**Date D.G. Verified/  
Date vérifié par le D.E. :**

2011-02-14

**Programme :**

Controlled Substances and Tobacco Directorate

**ADM Approved/ Approbation  
par le SMA :**

Paul Glover  
(946-6701)

**Branch/ Direction générale :**

HECS/SESC

**Department/ Ministère :**

Health Canada / Santé Canada



**RE: Salvia divinorum - Notice to Interested Parties / Avis d'intention aux parties intéressées**

OCS Policy and Regulatory Affairs to: [REDACTED] 2011-02-22 01:46 PM

OCS Policy and Regulatory Affa	Dear [REDACTED]	<i>I apologize for this inconvenience.</i>
OCS Policy and Regulatory Affl		<i>Thank you and I apologize again for the inconvenience</i>

Dear [REDACTED]

I apologize for this inconvenience.

Could you send the email I sent back to me so I can investigate where this error occurred.

Thank you

Isabel Shanahan

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada

John Brocklebank Dear Sir/ Madam, You have sent 15 notices in s... 2011-02-22 12:31:01 PM

From: [REDACTED]  
To: OCS Policy and Regulatory Affairs <ocs.policy.and.regulatory.affairs@hc-sc.gc.ca>  
Date: 2011-02-22 12:31 PM  
Subject: RE: Salvia divinorum - Notice to Interested Parties / Avis d'intention aux parties intéressées

Dear Sir/ Madam,

You have sent 15 notices in succession of this same message to me.

Yours truly,

[REDACTED]

**From:** HC-R\_AGENT-SC [mailto:hc-r\_agent-sc@hc-sc.gc.ca] **On Behalf Of** OCS Policy and Regulatory Affairs  
**Sent:** Tuesday, February 22, 2011 7:58 AM  
**To:** Isabel Shanahan  
**Subject:** Salvia divinorum - Notice to Interested Parties / Avis d'intention aux parties intéressées

[le français suit]

Dear Sir/Madam:

The purpose of this email is to advise you that a *Notice of Intent to Interested Parties* (NOI) regarding the following substances was published in the *Canada Gazette* , Part I on February 19, 2011:

- *Salvia divinorum*
- Salvinorin A

The electronic version of the NOI is available at the following website:

<http://www.gazette.gc.ca/rp-pr/p1/2011/2011-02-19/pdf/g1-14508.pdf> , pages 8-9 in PDF format (pages 438-439 in *Canada Gazette* , Part I).

This NOI outlines Health Canada's proposal to include *Salvia divinorum* and salvinorin A in Schedule III to the *Controlled Drugs and Substances Act* (CDSA). In particular, Health Canada is seeking further information from stakeholders as to whether these substances have any legitimate industrial, scientific or medical uses in Canada. Information received in response to this notice will be instrumental in determining appropriate regulatory controls.

If you are interested in this process or wish to provide us with information for our consideration please do so by March 21, 2011. You may send your comments to Stephanie Chandler, Regulatory Policy Division, Office of Controlled Substances, Address Locator: 3503D, 123 Slater St., Ottawa, Ontario, Canada K1A 1B9, by fax at (613) 946-4224 or by email to [OCS.Policy.and.Regulatory.Affairs@hc-sc.gc.ca](mailto:OCS.Policy.and.Regulatory.Affairs@hc-sc.gc.ca)

PLEASE FORWARD THIS EMAIL TO OTHERS WHO MAY BE INTERESTED.

Should this notification have reached you in error, it would be appreciated if you could please forward it to the appropriate person in your organization and ask that person to inform us of this by sending an e-mail to: [OCS.Policy.and.Regulatory.Affairs@hc-sc.gc.ca](mailto:OCS.Policy.and.Regulatory.Affairs@hc-sc.gc.ca)

Thank you,

Regulatory Policy Division  
Office of Controlled Substances  
Controlled Substances and Tobacco Directorate  
Healthy Environments and Consumer Safety Branch

\*\*\*\*\*

Madame, Monsieur,

Le présent courriel a pour but de vous informer qu'un *Avis d'intention aux parties intéressées*



concernant les substances ci-dessous a été publié dans la Partie I de la *Gazette du Canada* , le 19 février 2011:

- *Salvia divinorum* (sauge des devins)
- Salvinorine A

La version électronique de l'Avis d'intention est disponible à l'adresse Internet <http://www.gazette.gc.ca/rp-pr/p1/2011/2011-02-19/pdf/g1-14508.pdf> , pages 8-9 ,en format PDF (pages 438-439 dans la Partie I de la *Gazette du Canada* ).

Cet avis d'intention décrit la proposition de Santé Canada qui consiste à inclure la *Salvia divinorum* (sauge des devins) et la salvinorine A dans l'annexe III de la *Loi réglementant certaines drogues et autres substances* . Santé Canada cherche précisément à obtenir plus d'information de la part des intervenants afin de déterminer si ces substances ont une utilité légitime sur les plans industriel, scientifique ou médical au Canada. Les renseignements qui seront obtenus permettront de prendre des mesures réglementaires appropriées.

Si vous désirez participer à ce processus ou tout simplement nous fournir de l'information, veuillez communiquer avec nous d'ici le 21 mars 2011. Vous pouvez envoyer vos commentaires par la poste à Stephanie Chandler, Division de la politique réglementaire, Bureau des substances contrôlées, indice de l'adresse : 3503D, 123 rue Slater, Ottawa, Ontario, Canada K1A 1B9, par télécopieur, au 613-946-4224, ou par courriel à [OCS.Policy.and.Regulatory.Affairs@hc-sc.gc.ca](mailto:OCS.Policy.and.Regulatory.Affairs@hc-sc.gc.ca)

**VEUILLEZ TRANSFÉRER LE PRÉSENT COURRIEL AUX PERSONNES QUI POURRAIENT ÊTRE INTÉRESSÉES.**

Si vous avez reçu cet avis par erreur, nous vous saurions gré de le transférer à la personne concernée de votre organisation et de lui demander de nous en informer par courriel à : [OCS.Policy.and.Regulatory.Affairs@hc-sc.gc.ca](mailto:OCS.Policy.and.Regulatory.Affairs@hc-sc.gc.ca)

Merci.

Division de la politique réglementaire  
Bureau des substances contrôlées  
Direction des substances contrôlées et de la lutte au tabagisme  
Direction générale de la santé environnementale et de la sécurité des consommateurs



**RE: Salvia divinorum - Notice to Interested Parties / Avis d'intention aux parties intéressées**

OCS Policy and Regulatory Affairs to: [redacted] 2011-02-22 02:43 PM

OCS Policy and Regulatory Affa	Dear [redacted]	I apologize for this inconvenience.
OCS Policy and Regulatory Affa		Thank you and I apologize again for the inconvenience

Thank you and I apologize again for the inconvenience

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada

John Brocklebank Here is an example of the repetitive emails with... 2011-02-22 02:19:57 PM

From: [redacted]  
To: OCS Policy and Regulatory Affairs <ocs.policy.and.regulatory.affairs@hc-sc.gc.ca>  
Date: 2011-02-22 02:19 PM  
Subject: RE: Salvia divinorum - Notice to Interested Parties / Avis d'intention aux parties intéressées

Here is an example of the repetitive emails with this same message.

**From:** HC-R\_AGENT-SC [mailto:hc-r\_agent-sc@hc-sc.gc.ca] **On Behalf Of** OCS Policy and Regulatory Affairs  
**Sent:** Tuesday, February 22, 2011 7:30 AM  
**To:** Isabel Shanahan  
**Subject:** Salvia divinorum - Notice to Interested Parties / Avis d'intention aux parties intéressées

*[le français suit]*

Dear Sir/Madam:

The purpose of this email is to advise you that a *Notice of Intent to Interested Parties* (NOI) regarding the following substances was published in the *Canada Gazette*, Part I on February 19, 2011:

- *Salvia divinorum*
- Salvinorin A

The electronic version of the NOI is available at the following website:

<http://www.gazette.gc.ca/rp-pr/p1/2011/2011-02-19/pdf/g1-14508.pdf> , pages 8-9 in PDF format (pages 438-439 in *Canada Gazette* , Part I).

This NOI outlines Health Canada's proposal to include *Salvia divinorum* and salvinorin A in Schedule III to the *Controlled Drugs and Substances Act* (CDSA). In particular, Health Canada is seeking further information from stakeholders as to whether these substances have any legitimate industrial, scientific or medical uses in Canada. Information received in response to this notice will be instrumental in determining appropriate regulatory controls.

If you are interested in this process or wish to provide us with information for our consideration please do so by March 21, 2011. You may send your comments to Stephanie Chandler, Regulatory Policy Division, Office of Controlled Substances, Address Locator: 3503D, 123 Slater St., Ottawa, Ontario, Canada K1A 1B9, by fax at (613) 946-4224 or by email to [OCS.Policy.and.Regulatory.Affairs@hc-sc.gc.ca](mailto:OCS.Policy.and.Regulatory.Affairs@hc-sc.gc.ca)

PLEASE FORWARD THIS EMAIL TO OTHERS WHO MAY BE INTERESTED.

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Thank you,

Regulatory Policy Division  
Office of Controlled Substances  
Controlled Substances and Tobacco Directorate  
Healthy Environments and Consumer Safety Branch

\*\*\*\*\*

Madame, Monsieur,

Le présent courriel a pour but de vous informer qu'un *Avis d'intention aux parties intéressées* concernant les substances ci-dessous a été publié dans la Partie I de la *Gazette du Canada* , le 19 février 2011:

- *Salvia divinorum* (sauge des devins)
- Salvinorine A

La version électronique de l'Avis d'intention est disponible à l'adresse Internet <http://www.gazette.gc.ca/rp-pr/p1/2011/2011-02-19/pdf/g1-14508.pdf> , pages 8-9 ,en format PDF (pages 438-439 dans la Partie I de la *Gazette du Canada* ).

Cet avis d'intention décrit la proposition de Santé Canada qui consiste à inclure la *Salvia divinorum* (sauge des devins) et la salvinorine A dans l'annexe III de la *Loi réglementant*

*certaines drogues et autres substances* . Santé Canada cherche précisément à obtenir plus d'information de la part des intervenants afin de déterminer si ces substances ont une utilité légitime sur les plans industriel, scientifique ou médical au Canada. Les renseignements qui seront obtenus permettront de prendre des mesures réglementaires appropriées.

Si vous désirez participer à ce processus ou tout simplement nous fournir de l'information, veuillez communiquer avec nous d'ici le 21 mars 2011. Vous pouvez envoyer vos commentaires par la poste à Stephanie Chandler, Division de la politique réglementaire, Bureau des substances contrôlées, indice de l'adresse : 3503D, 123 rue Slater, Ottawa, Ontario, Canada K1A 1B9, par télécopieur, au 613-946-4224, ou par courriel à [OCS.Policy.and.Regulatory.Affairs@hc-sc.gc.ca](mailto:OCS.Policy.and.Regulatory.Affairs@hc-sc.gc.ca)

**VEUILLEZ TRANSFÉRER LE PRÉSENT COURRIEL AUX PERSONNES QUI  
POURRAIENT ÊTRE INTÉRESSÉES.**

Si vous avez reçu cet avis par erreur, nous vous saurions gré de le transférer à la personne concernée de votre organisation et de lui demander de nous en informer par courriel à :  
[OCS.Policy.and.Regulatory.Affairs@hc-sc.gc.ca](mailto:OCS.Policy.and.Regulatory.Affairs@hc-sc.gc.ca)

Merci.

Division de la politique réglementaire  
Bureau des substances contrôlées  
Direction des substances contrôlées et de la lutte au tabagisme  
Direction générale de la santé environnementale et de la sécurité des consommateurs

Subject Re: Fw: Letter to the editor requested for today  
:  
From: Christine Roush  
To: Suzanne Desjardins, Jocelyn Kula, "Suzanne Desjardins", "Brenda Paine", Dave Stephens, Michael Assad,  
Jesse Arnup-Blondin  
Date: 2011-02-23 10:56 AM

---

Suzanne - I have drafted the letter to the editor. Can you please review and provide input where appropriate. I will need your approval and that of Jocelyn's no later than 11:30 today. In the meantime, I'll work on a suitable ending to the letter.



Response to Editorial in today.doc

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
Health Canada/Santé Canada  
Tel/Tél : (613) 954-0712/Cell: (613) 219-7194  
Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca

---

Suzanne Desjardins Hanan and I are working on this and we shoul... 2011-02-23 10:32:29 AM

From: Suzanne Desjardins/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Cc: Jocelyn Kula/HC-SC/GC/CA@HWC, "Suzanne Desjardins" <Suzanne.Desjardins@hc-sc.gc.ca>, "Brenda Paine" <brenda.paine@hc-sc.gc.ca>, Dave Stephens/HC-SC/GC/CA@HWC, Michael Assad/HC-SC/GC/CA@HWC  
Date: 2011-02-23 10:32 AM  
Subject: Re: Fw: Letter to the editor requested for today

---

Hanan and I are working on this and we should have a draft shortly. We could go from there.  
Suzanne

---

Christine Roush Jocelyn - I spoke with Suzanne by phone and sh... 2011-02-23 10:18:09 AM

From: Christine Roush/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: "Suzanne Desjardins" <Suzanne.Desjardins@hc-sc.gc.ca>, "Brenda Paine" <brenda.paine@hc-sc.gc.ca>, Dave Stephens/HC-SC/GC/CA@HWC, Michael Assad/HC-SC/GC/CA@HWC  
Date: 2011-02-23 10:18 AM  
Subject: Re: Fw: Letter to the editor requested for today

---

Jocelyn - I spoke with Suzanne by phone and she will be sending me shortly some points I can make in the editorial re: the scientific evidence that it is harmful. For the rest of the letter, I will use info from the Salvia comms products. Please make yourselves available to review and approve the letter this morning. thanks.

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
Health Canada/Santé Canada  
Tel/Tél : (613) 954-0712/Cell: (613) 219-7194  
Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca

Jocelyn Kula Brenda and Michael are on their way to ADMO r... 2011-02-23 10:10:10 AM

From: Jocelyn Kula/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC  
Cc: "Suzanne Desjardins" <Suzanne.Desjardins@hc-sc.gc.ca>, "Brenda Paine"  
<brenda.paine@hc-sc.gc.ca>, Dave Stephens/HC-SC/GC/CA@HWC, Michael  
Assad/HC-SC/GC/CA@HWC  
Date: 2011-02-23 10:10 AM  
Subject: Re: Fw: Letter to the editor requested for today

Brenda and Michael are on their way to ADMO right now for a briefing with Hilary on another matter. Suzanne and I can probably make ourselves this morning, although I have a 15 min meeting at 11:00 that cannot be rescheduled. Just send an invite and we can go from there.

JK

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

Christine Roush Can we please have a conference call ASAP to... 2011-02-23 09:38:24 AM

From: Christine Roush/HC-SC/GC/CA  
To: "Jocelyn Kula" <jocelyn.kula@hc-sc.gc.ca>, "Suzanne Desjardins"  
<Suzanne.Desjardins@hc-sc.gc.ca>  
Cc: "Brenda Paine" <brenda.paine@hc-sc.gc.ca>, Dave Stephens/HC-SC/GC/CA@HWC, Michael  
Assad/HC-SC/GC/CA@HWC, Dave Stephens/HC-SC/GC/CA@HWC  
Date: 2011-02-23 09:38 AM  
Subject: Re: Fw: Letter to the editor requested for today

Can we please have a conference call ASAP to discuss content of this Letter to the Editor that needs to be drafted and signed by both our Minister and Public Safety Minister by noon today.

Christine Roush  
Senior Communications Advisor/

Dave Stephens Head\*'s up. Christine will be in touch very soon.... 2011-02-23 09:29:58 AM

From: Dave Stephens/HC-SC/GC/CA  
To: "Suzanne Desjardins" <Suzanne.Desjardins@hc-sc.gc.ca>, "Jocelyn Kula"  
<jocelyn.kula@hc-sc.gc.ca>, "Brenda Paine" <brenda.paine@hc-sc.gc.ca>  
Cc: "Christine Roush" <christine.roush@hc-sc.gc.ca>  
Date: 2011-02-23 09:29 AM  
Subject: Fw: Letter to the editor requested for today

---

Head\*'s up. Christine will be in touch very soon.  
Charles Mojsej

----- Original Message -----

From: Charles Mojsej  
Sent: 2011-02-23 09:26 AM EST  
To: stephanie.durand@ps-sp.gc.ca  
Cc: Ken Polk; Dave Stephens; Alexis M Tervo; Alastair Sinclair; Anne  
Lamar; Karen Robertson  
Subject: Letter to the editor requested for today

To be signed by both our Ministers.  
We will draft and share before noon

Attached is the editorial from today's Winipeg Free Press  
No need to ban salvia -

Editorial St. Boniface MP Shelly Glover may well be -- along with all the other parents she insists share her fears -- "very worried about the long-term effects" of salvia divinorum, but until that or some other evil of smoking this herb is established by scientific evidence, the hallucinogen ought not be banned. There is little science that says it is dangerous to human health and safety.

Salvia, regulated in Canada as a natural health product, has been compared to marijuana, except that it produces more often a wild psychedelic trip rather than a cosy high. Those who smoke, inhale or chew it can experience an out-of-body sensation or the sense that they become inanimate objects, such as a table leg. Others collapse into laughing fits. Infamously, Miley Cyrus was sure that a guy at her party looked exactly like her boyfriend. Ms. Cyrus' mini-trip wrote salvia onto the parental watch lists -- who would want their newly minted 18-year-old to indelibly imprint their own "this is your brain on salvia" on YouTube? Ms. Glover and fellow MPs in the Harper government seem to be taking their drug-watch cues from YouTube and the alarmist anecdotes of legislators in other countries who have acted rashly to ban salvia, a member of the mint family used traditionally by Mexico's Mazatec natives to produce spiritual visions. The hallucinations can be intense, but are short-lived.

There is no evidence salvia is addictive or toxic. Ms. Glover is probably right on the money when she says most parents would not want their children smoking salvia. It should probably be regulated, like alcohol. Making an herb's sale, cultivation or possession punishable as a criminal offence, simply because it makes people see weird things or act funny, is hammering up a solution to a non-problem.

---

Charles Mojsej  
Director General - Directeur général  
Strategic Communications, Communications stratégiques  
ph. 613 948-8916 Cell. 613 558-0792 Fax 613 957-1729

**Response to Editorial in today's Winnipeg Free Press  
No need to ban salvia -**

We would like to respond to the February 23 editorial on the Government's recent proposal to control *Salvia divinorum* and salvinorin A.

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We want to eliminate the misconception that salvia is a safer alternative to street drugs.

It is not.

*Salvia divinorum*, and its active ingredient salvinorin A, produce powerful hallucinations similar to those associated with the use of the well-known hallucinogen LSD, which is a controlled substance. Other effects include confusion, disorientation, and anxiety.

In Canada, about 7% of youth aged 15-24 have tried salvia. This represents about 300,000 young people - a rate that is similar to that of cocaine and ecstasy, and a rate much higher than that of LSD.

The move to control these substances is also consistent with actions taken by several other countries such as Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden, who have all placed similar controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Some U.S. states have taken action to restrict their use, sale and/or distribution.

A situation where an increasing number of Canadians, and particularly youth, are using a potent hallucinogen, which has no demonstrated benefits but known toxic effects, calls for controls to reduce access to these substances. This is what the Government of Canada is doing by proposing to regulate them under the *Controlled Drugs and Substances Act*.

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**Response to Editorial in today's Winnipeg Free Press  
No need to ban salvia -**

We would like to respond to the February 23 editorial in the *Winnipeg Free Press* commenting on the Government's recent proposal to control *Salvia divinorum* and salvinorin A, like other-illicit drugs.

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These substances present potential risks to the health and safety of Canadians, particularly our young people, and that is why we are taking this step now.

We want to eliminate the misconceptions that *Salvia* is a "safe" alternative to street drugs.

It is not.

*Salvia divinorum*, and its active ingredient salvinorin A, produce powerful hallucinations similar to those associated with the use of the well-known hallucinogen LSD, which is regulated as a controlled substance. Other effects include further alterations in mental state such as confusion, disorientation, and anxiety.

Comment [JK1]: We all commented on the use of this language in the speech so do we really want to perpetuate it here? Maybe we could say "safer alternative to ~~street drugs like marijuana or~~ any

*nicot drug*

In addition, the risk of experiencing more severe adverse mental and physical reactions may increase when *Salvia* is consumed along with other psychoactive substances.

Taken together, these findings strongly suggest that *Salvia* does in fact pose a danger to the health and safety of Canadians because it can profoundly alter a person's mental and potentially physical well-being.

In Canada, about 7% of youth age 15-24 have tried *Salvia*. This represents about 423,000 young people - a rate that is similar to that of cocaine and ecstasy, and a rate much higher than that of LSD.

While less information is available regarding the long-term health effects of using *Salvia* compared to other drugs like cocaine, this in no way implies that *Salvia* is safe or that it does not have long-term effects on health.

The move to control these substances is also consistent with actions taken by several other countries such as Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden, who have all placed similar controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Some U.S. states have also taken action to restrict their use, sale and/or distribution.

A situation where an increasing number of Canadians, and particularly youth, are using a potent hallucinogen, which has no demonstrated benefits but known toxic effects, calls for controls to reduce access to these substances and this is what the Government of Canada is doing by proposing to schedule *Salvia divinorum* and salvinorin A regulate it under the *Controlled Drugs and Substances Act*.

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Editorial St. Boniface MP Shelly Glover may well be -- along with all the other parents she insists share her fears -- "very worried about the long-term effects" of salvia divinorum, but until that or some other evil of smoking this herb is established by scientific evidence, the hallucinogen ought not be banned. There is little science that says it is dangerous to human health and safety.

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There is no evidence salvia is addictive or toxic. Ms. Glover is probably right on the money when she says most parents would not want their children smoking salvia. It should probably be regulated, like alcohol. Making an herb's sale, cultivation or possession punishable as a criminal offence, simply because it makes people see weird things or act funny, is hammering up a solution to a non-problem.

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Other effects associated with the use of salvia include further alterations in mental state such as confusion, disorientation, and anxiety.

In addition, the risk of experiencing more severe adverse mental and physical reactions increases when salvia is consumed along with other psychoactive substances.

Taken together, these findings strongly suggest that salvia does in fact pose a danger to human health and safety because it can profoundly alter a person's mental and physical well-being.

In Canada, about 7% of youth age 15-24 have tried salvia, a rate that is similar to that of cocaine and ecstasy and a rate much higher than that of LSD. Easy availability and the false perception that it is safe are likely factors to explain such a rate of use for a substance that is not as well known as cocaine and ecstasy.

While less information is available regarding the long-term health effects of using salvia compared to other drugs like cocaine, this in no way implies that salvia is safe or that it does not have long-term effects on health. Rather, because this is an emerging substance further studies are required to establish with more certainty what those effects may be. What is known is that no beneficial health effects have been reported.

A situation where an increasing number of Canadians, and particularly youth, are using a potent hallucinogen, which has no demonstrated benefits but known toxic effects, calls for controls to reduce access to this substances and this is what the Government of Canada is doing by proposing to regulate it under the *Controlled Drugs and Substances Act*.

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**Re: Fw: DUE COB WEDNESDAY, FEB. 23: Hot Issues Notes - Minister's Appearance on Supp C Estimates and Main Estimates 2011-12** 

Patricia Rapold to: Jocelyn Kula

2011-02-23 10:01 AM

Bcc: Stephanie Chandler

This message is digitally signed.

Here's a draft for your review. Note that Stephanie was a great help, giving me the latest media lines. I also changed the info Suzanne requested.



hot issues notes - salvia.doc

Patricia Rapold  
Senior Policy Advisor/Conseillère principale des politiques  
Office of Controlled Substances CSTD  
Bureau des substances contrôlées DSCLT  
HECSB / DGSESC  
Health Canada / Santé Canada  
A.L. 3503D - Ottawa, Ontario K1A 0K9  
Phone: (613) 948-9404  
Fax: (613) 946-4224

Jocelyn Kula

thanks for taking on the salvia note note attache...

2011-02-22 04:08:40 PM

From: Jocelyn Kula/HC-SC/GC/CA  
To: Patricia Rapold/HC-SC/GC/CA@HWC  
Date: 2011-02-22 04:08 PM  
Subject: Fw: DUE COB WEDNESDAY, FEB. 23: Hot Issues Notes - Minister's Appearance on Supp C Estimates and Main Estimates 2011-12

thanks for taking on the salvia note  
note attached tips sheet

JK

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2011-02-22 04:08 PM -----

From: Michael Assad/HC-SC/GC/CA  
To: CSTD-Directors, CSTD-QP-Notes  
Cc: CSTD-Support Staff  
Date: 2011-02-22 01:25 PM  
Subject: Re: DUE COB WEDNESDAY, FEB. 23: Hot Issues Notes - Minister's Appearance on Supp C Estimates and Main Estimates 2011-12

Attached is the list of tips/reminders.



Tips For Prep of Supps-Mains Notes.doc

Michael Assad, B.Sc., Cert.BA  
Senior Advisor | Conseiller principal  
Office of Policy and Strategic Planning | Bureau des politiques et de la planification stratégique  
Controlled Substances and Tobacco Directorate | Direction des substances contrôlées et de la lutte au  
tabagisme  
Health Canada | Santé Canada  
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Fax | Télécopieur: (613) 948-7977

Michael Assad

Hi everyone, The Minister has been invited to a...

2011-02-22 12:30:04 PM

## ADVICE TO THE MINISTER

### SUBJECT / SUJET

**Salvia Divinorum**

### SYNOPSIS / SOMMAIRE

On February 19, 2011, Health Canada published a Notice to Interested Parties proposing to schedule both *Salvia divinorum* and its main active ingredient salvinorin A under Schedule III to the Controlled Drugs and Substances Act (CDSA) in order to protect the health and safety of Canadians, particularly youth.

### ANTICIPATED QUESTION/QUESTION PRÉVUE

What is Health Canada doing to protect young Canadians from the potential adverse effects associated with the use of *Salvia divinorum*?

- This Government is proposing to regulate *Salvia* as a controlled substance in order to protect the health and safety of Canadians, particularly youth.
- This Government has published a *Notice to Interested Parties* in *Canada Gazette*, Part I, to give Canadians the opportunity to provide comments on its proposal to regulate *Salvia* as a controlled substance.
- The regulation of *Salvia* would make possession, trafficking, importation, exportation, and production illegal unless authorized by regulation.
- This Government has also published an *It's Your Health* article warning the population about the risks associated with the use of this plant.
- This Government is taking these steps in order to protect the health and safety of Canadians, particularly youth, from the potentially harmful effects of *Salvia divinorum* and/or salvinorin A.

### FINANCIAL INFORMATION (IF APPLICABLE) / INFORMATION FINANCIÈRE (SI APPLICABLE) : N/A

### BACKGROUND/CONTEXTE:

Media interest in *Salvia divinorum* is recurrent. Questions around this substance generally focus on its legality. Recently, a number of media reports have commented on a YouTube video which reportedly shows a young celebrity smoking *Salvia divinorum*. Canadian surveillance data indicates that this substance is being used by adolescents and young adults for its hallucinogenic properties, and there have been several reports from scientific sources indicating that *Salvia divinorum* has a potential for abuse.

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, diviner's sage, magic mint, and puff. Certain websites are also promoting the use of *S. divinorum* as a "legal" alternative to street drugs.

Both the plant *S. divinorum* and its main active ingredient salvinorin A are known to have physical and mental



effects which are often described as unpleasant, including:  
hallucinations  
dysphoria (feeling anxious, depressed or restless)  
out-of-body experiences  
uncontrollable laughter  
loss of consciousness  
short-term memory loss  
lack of physical coordination  
slurred speech and awkward sentence patterns

Recent surveys indicate that Canadian youth are trying this substance which could be dangerous to their health. Results from the Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using Salvia divinorum at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24 years. The results from the Canadian 2008-2009 Youth Smoking Survey also show that 5% of students grades 7-12 have used Salvia divinorum in the past year. The 2009 Ontario Student Drug Use and Health Survey (OSDUHS) indicated that 5.4% of Ontario students in grades 7-12 reported ever using Salvia divinorum and 4.4% of these students reported using this substance in the past year.

Current Situation in Canada

As Salvia divinorum is a plant with hallucinogenic properties when consumed by humans, it currently meets the definition of a natural health product (NHP) under the Natural Health Products Regulations. To date, Health Canada has not licensed for sale any natural health product which contains Salvia divinorum as an ingredient. The sale of unauthorized natural health products containing Salvia divinorum or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the Food and Drugs Act. Health Canada is proposing that S. divinorum and Salvinorin A be included in Schedule III to the CDSA. This would mean that the possession, trafficking, importation, exportation and production of Salvia divinorum and salvinorin A would be illegal unless authorized by regulation. The regulation of Salvia divinorum and Salvinorin A as controlled substances would allow law enforcement to take action against illegal activities involving this substance.

International Control of S. divinorum

Neither Salvia divinorum nor its main active ingredient salvinorin A are listed under the United Nations Drug Control Conventions; as a result, they do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions. The proposal to include Salvia divinorum and salvinorin A in Schedule III to the (CDSA) is consistent with actions taken by several countries (e.g. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of Salvia divinorum and/or salvinorin A. Some individual U.S. states have also implemented laws restricting their use, sale and/or distribution.

CONTACT INFORMATION	
Primary:	Telephone:
Alternate:	Telephone:
Approved by:	Telephone:



Revised version - : Fw: DUE COB WEDNESDAY, FEB. 23: Hot Issues Notes - Minister's Appearance on Supp C Estimates and Main Estimates 2011-12

Patricia Rapold to: Jocelyn Kula

2011-02-23 11:47 AM

Bcc: Stephanie Chandler

This message is digitally signed.

Here's the revised version based on your comments. May I suggest to break bullet 2 in 2 since it is quite long (I haven't done it in this version), We may want to have a bullet on the effects only.



hot issues notes - salvia.doc

Patricia Rapold

Senior Policy Advisor/Conseillère principale des politiques

Office of Controlled Substances CSTD

Bureau des substances contrôlées DSCLT

HECSB / DGSESC

Health Canada / Santé Canada

A.L. 3503D - Ottawa, Ontario K1A 0K9

Phone: (613) 948-9404

Fax: (613) 946-4224

Patricia Rapold

Here's a draft for your review. Note that Stepha...

2011-02-23 10:01:48 AM

From: Patricia Rapold/HC-SC/GC/CA

To: Jocelyn Kula/HC-SC/GC/CA@HWC

Date: 2011-02-23 10:01 AM

Subject: Re: Fw: DUE COB WEDNESDAY, FEB. 23: Hot Issues Notes - Minister's Appearance on Supp C Estimates and Main Estimates 2011-12

Here's a draft for your review. Note that Stephanie was a great help, giving me the latest media lines. I also changed the info Suzanne requested.



hot issues notes - salvia.doc

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2011-02-22 04:08:40 PM

Michael Assad

Hi everyone, The Minister has been invited to a...

2011-02-22 12:30:04 PM

## ADVICE TO THE MINISTER

### SUBJECT / SUJET

**Salvia Divinorum**

### SYNOPSIS / SOMMAIRE

On February 19, 2011, Health Canada published a Notice to Interested Parties proposing to include both *Salvia divinorum* and its main active ingredient salvinorin A in Schedule III to the Controlled Drugs and Substances Act (CDSA). This action is being taken in order to protect the health and safety of Canadians, particularly youth.

### ANTICIPATED QUESTION/QUESTION PRÉVUE

What is Health Canada doing to protect young Canadians from the potential adverse effects associated with the use of *Salvia divinorum*?

- This Government is proposing to regulate *Salvia divinorum* and Salvinorin A as controlled substances.
- This Government is taking these steps in order to protect the health and safety of Canadians, particularly youth, from the potentially harmful effects of *Salvia divinorum* and/or salvinorin A. These effects include hallucination, short term memory loss, loss of consciousness, anxiety, etc.
- This Government has published a *Notice to Interested Parties* in *Canada Gazette*, Part I, to give Canadians the opportunity to provide comments on its proposal to regulate *Salvia* as a controlled substance.
- The regulation of *Salvia* would make possession, trafficking, importation, exportation, and production illegal unless authorized by regulation.
- This Government has also published an *It's Your Health* article warning the population about the risks associated with the use of this plant.

FINANCIAL INFORMATION (IF APPLICABLE) / INFORMATION FINANCIÈRE (SI APPLICABLE) :  
N/A

### BACKGROUND/CONTEXTE:

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family. Some street names for *S. divinorum* include: Sally D, Lady Sally, Maria pastora, diviner's sage, magic mint, and puff. Certain websites also promote the use of *S. divinorum* as a "legal" alternative to street drugs.

Media interest in *Salvia divinorum* is ongoing, and questions around this substance generally focus on its legality.

Both the plant *S. divinorum* and its main active ingredient salvinorin A are known to have physical and mental effects, including:

hallucinations  
dysphoria (feeling anxious, depressed or restless)  
out-of-body experiences  
uncontrollable laughter  
loss of consciousness  
short-term memory loss  
lack of physical coordination  
slurred speech and awkward sentence patterns

These effects are often described as unpleasant. Canadian surveillance data indicates that adolescents and young adults are using this plant for its hallucinogenic properties.

Results from the Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *Salvia divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24 years. The results from the Canadian 2008-2009 Youth Smoking Survey also show that 5% of students grades 7-12 have used *Salvia divinorum* in the past year. The 2009 Ontario Student Drug Use and Health Survey (OSDUHS) indicated that 5.4% of Ontario students in grades 7-12 reported ever using *Salvia divinorum* and 4.4% of these students reported using this substance in the past year.

Current Situation in Canada

*Salvia* products being sold as hallucinogens are subject to the *Natural Health Products Regulations*, and the sale of unauthorized natural health products may be subject to compliance and enforcement actions under the *Food and Drugs Act*. The inclusion of *Salvia divinorum* and Salvinorin A in Schedule III to the CDSA would mean that the possession, trafficking, importation, exportation and production of these substances would be illegal unless authorized by regulation. This action would also allow law enforcement to take action against illegal activities involving this substance.

International Control of *S. divinorum*

The proposal to regulate *Salvia divinorum* and salvinorin A as controlled substances is consistent with actions taken by several countries (e.g. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Some individual U.S. states have also implemented laws restricting their use, sale and/or distribution.

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Alternate:

Telephone:

Approved by:

Telephone:

**Fw: Snapshot - salvia**

**Christine Roush** to: Suzanne Desjardins, Jocelyn Kula

2011-02-23 12:00 PM

Cc: Denis Arsenault, Stephanie Chandler, Michael Assad, Brenda Paine

Hello all - here is a media snapshot of comments in relation to the salvia announcement this week. Please let me know if you have any questions or need additional information.

Christine Roush  
Senior Communications Advisor/

Caroline Quinn

---

Public Environment Intelligence and Analysis, Salvia Snapshot, 23 February 2011

1

## *Salvia – Snapshot*

Presented by Public Environment Intelligence and Analysis, Health Canada

Contact Caroline Quinn, Tel 613-960-6074, PEIA.AREP@hc-sc.gc.ca

Coverage Date February 22, 2011

### *Media and Comments Review*

Five articles appeared online on February 22<sup>nd</sup>. The CBC article generated the most comments at a count of 150.

Government moves to criminalize hallucinogenic salvia, CBC , 55 tweets, 129 comments,  
<http://www.cbc.ca/news/health/story/2011/02/21/man-salvia-glover-crime.html?ref=rss>

A sample of the 50 highest rated comments was reviewed. None of the comments support the ban on Salvia.

Comment with the highest "agreed" at 187 agree and 22 disagree:

*Health Canada knows very little about the long term effects. SO BAN IT, QUICK!! Don't bother studying it first. why is it that our masters always believe that if it feels good, then it must be bad. the exception being good old taxable liquor. good thing it never hurts anyone. those weeds and herbs though, ooh, ooh , better lock up anyone partaking is such evilness.*

Health Canada appeared 8 times in the comments. Only one was in support of the ban, one undecided and six were against the ban.

**Positive:** *And when it kills someone as a result of the adverse affects the same people advocating testing with no public warnings will be the first to cry how incompetant the Conservatives and Health Canada have been. Same old, damned if they do and damned if they don't.*

**Negative:** *If its not sold through a drug company so that government can make millions off it they want it against the law, sounds more like Health Canada protecting big drug companies once again.*

Alcohol or "booze" was mentioned in approximately 30 comments. Several commentators referenced how alcohol was harmful, yet it was legal. Some commentators were suggesting to treat Salvia like Alcohol and sell it in a controlled environment (like LCBO).

*I have never understood how such harmful things such as alcohol and tobacco are perfectly fine and legal for people to use and buy, while other much less harmful things that can be found growing naturally on this planet that can bring about 'out of body' experiences and altered states of reality are illegal?*

Government, Harper or Conservatives were mentioned in almost 50 of the comments. Comment examples:

*Police have long complained they're powerless to halt the sale of salvia, which has been known to produce some adverse reactions, including one case reported by Health Canada in 2006 in which an incoherent, suicidal teenage boy threatened to kill police officers." CBC This Article*

*I have to ask Health Canada how many times a week some drunk threatens to kill police officers but alcohol is still perfectly legal. One reported adverse salvia incident is hardly an epidemic. This is just one more Conservative measure to whittle*

*away at the freedom of Canadians. However, I fully expect Harper's usual gang of sycophants to jump on this bandwagon because it is getting tough on crime. What nonsense; it is getting tough on individual rights.*



**OCS Input - DUE COB WEDNESDAY, FEB. 23: Hot Issues Notes - Minister's Appearance on Supp C Estimates and Main Estimates 2011-12** 

Patricia Rapold to: Michael Assad

2011-02-23 12:55 PM

Cc: Jocelyn Kula, Denis Arsenault, Stephanie Chandler

This message is digitally signed.

Bonjour Michael,

Here's the Director approved hot issue on salvia. Merci.



hot issues notes - salvia.doc

Patricia Rapold  
Senior Policy Advisor/Conseillère principale des politiques  
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Bureau des substances contrôlées DSCLT  
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Michael Assad

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2011-02-22 12:30:04 PM

From: Michael Assad/HC-SC/GC/CA  
To: CSTD-Directors, CSTD-QP-Notes  
Cc: CSTD-DGO, CSTD-Support Staff  
Date: 2011-02-22 12:30 PM  
Subject: DUE COB WEDNESDAY, FEB. 23: Hot Issues Notes - Minister's Appearance on Supp C Estimates and Main Estimates 2011-12

Hi everyone,

The Minister has been invited to appear before the Standing Committee on Health (HESA) on Supplementary Estimates C and Main Estimates, scheduled for March 10th. Hot Issues Notes have been requested on a number of topics by ADMO. Please submit your notes to DGO by 3 p.m. tomorrow, Wednesday, February 23, 2011 in order to get the notes approved and sent to ADMO by the deadline.

Below you will find:

- a list of notes that CSTD has been asked to prepare
- where they exist, notes prepared for the Minister's appearance at Supps B last fall and recent ADM-approved QP notes to assist you
- a list of tips and reminders to help with your preparations

Please note that during this process we will also be making use of the permanent briefing binder notes (for the DM) that we've worked on last week.

The template for the Mains notes is the same as the one that was used for Supps B (attached below).

[attachment "hot issues notes - template hecs.doc" deleted by Patricia Rapold/HC-SC/GC/CA]

Since the Minister will have a longer period of time to respond to questions than in Question Period, Hot Issues Notes are not limited to 3 or 4 key bullet messages. Therefore, you are asked to prepare key


messages that will provide clear and sometimes detailed responses to questions. The recommended response portion of the Note could include up to 6 bullets. Please remember that as for QP Cards, the background should only include public-friendly factual information.

Please be sure to include bullets or background for financial/budget information, especially significant changes. For those of you preparing notes on sunseting programs, ADMO is waiting on approved wording from central agencies with respect to funding. ADMO will add the line to affected notes.

Please send the completed notes by February 23 at 3 p.m. to DGO. Where notes are being updated, please use track changes or red text and strike-out.


CSTD

Salvia 

Tobacco - FTCS[attachment "EDMS-#77051-v1-TOBACCO\_CONTROL\_STRATEGY.DOC" deleted by Patricia Rapold/HC-SC/GC/CA] 

Tobacco - Flavoured Cigars and Cigarillos[attachment "EDMS-#76345-v1-TOBACCO\_-\_FLAVOURED\_CIGARS.DOC" deleted by Patricia Rapold/HC-SC/GC/CA] 

Tobacco Health Warning Messages 

Tobacco - Contraband[attachment "EDMS-#76251-v1-CONTRABAND.DOC" deleted by Patricia Rapold/HC-SC/GC/CA] 

Thanks,

Michael Assad, B.Sc., Cert.BA

Senior Advisor | Conseiller principal

Office of Policy and Strategic Planning | Bureau des politiques et de la planification stratégique

Controlled Substances and Tobacco Directorate | Direction des substances contrôlées et de la lutte au tabagisme

Health Canada | Santé Canada

Phone | Téléphone: (613) 948-8958

Fax | Télécopieur: (613) 948-7977



NOTE FOR MAIN ESTIMATES  
NOTE POUR LE BUDGET SUPPLÉMENTAIRE DES DÉPENSES (B)

Date: March 10, 2011  
Classification: HECSB PROTECTED

**ADVICE TO THE MINISTER**

Director  
Approved

SUBJECT / SUJET

**Salvia Divinorum**

**SYNOPSIS / SOMMAIRE**

On February 19, 2011, Health Canada published a Notice to Interested Parties proposing to include both *Salvia divinorum* and its main active ingredient salvinorin A in Schedule III to the Controlled Drugs and Substances Act (CDSA). This action is being taken in order to protect the health and safety of Canadians, particularly youth.

**ANTICIPATED QUESTION/QUESTION PRÉVUE**

What is Health Canada doing to protect young Canadians from the potential adverse effects associated with the use of *Salvia divinorum*?

- This Government is proposing to regulate *Salvia divinorum* and salvinorin A as controlled substances.
- This Government is taking these steps in order to protect the health and safety of Canadians, particularly youth, from the potentially harmful effects of *Salvia divinorum* and/or salvinorin A. These effects include powerful hallucinations, confusion, disorientation and anxiety.
- This Government has published a *Notice to Interested Parties* in *Canada Gazette*, Part I, to give Canadians the opportunity to provide comments on its proposal to regulate salvia as a controlled substance.
- The regulation of salvia would make possession, trafficking, importation, exportation, and production illegal unless authorized by regulation.
- This Government has also published an *It's Your Health* article warning the population about the risks associated with the use of this plant.

**FINANCIAL INFORMATION (IF APPLICABLE) / INFORMATION FINANCIÈRE (SI APPLICABLE) :**  
N/A

**BACKGROUND/CONTEXTE:**

*Salvia divinorum* is a species of sage belonging to the mint family. Some street names for *Salvia divinorum* include: Sally D, Lady Sally, Maria pastora, diviner's sage, magic mint, and puff. Certain websites also promote the use of *Salvia divinorum* as a "legal" alternative to street drugs.

Media interest in *Salvia divinorum* is ongoing, and questions around this substance generally focus on its legality.

Both the plant *Salvia divinorum* and its main active ingredient salvinorin A are known to have physical and mental effects, including:  
hallucinations

dysphoria (feeling anxious, depressed or restless)  
out-of-body experiences  
uncontrollable laughter  
loss of consciousness  
short-term memory loss  
lack of physical coordination  
slurred speech and awkward sentence patterns

These effects are often described as unpleasant. Canadian surveillance data indicates that adolescents and young adults are using this plant for its hallucinogenic properties.

Results from the Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *Salvia divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24 years. The results from the Canadian 2008-2009 Youth Smoking Survey also show that 5% of students grades 7-12 have used *Salvia divinorum* in the past year. The 2009 Ontario Student Drug Use and Health Survey (OSDUHS) indicated that 5.4% of Ontario students in grades 7-12 reported ever using *Salvia divinorum* and 4.4% of these students reported using this substance in the past year.

Current Situation in Canada

*Salvia* products being sold as hallucinogens for consumption by humans are subject to the *Natural Health Products Regulations*, and the sale of unauthorized natural health products may be subject to compliance and enforcement actions under the *Food and Drugs Act*. The inclusion of *Salvia divinorum* and Salvinorin A in Schedule III to the CDSA would mean that the possession, trafficking, importation, exportation and production of these substances would be illegal unless authorized by regulation. This action would also allow law enforcement to take action against illegal activities involving this substance.

International Control of *Salvia divinorum*

The proposal to regulate *Salvia divinorum* and salvinorin A as controlled substances is consistent with actions taken by several countries (e.g. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, Norway, South Korea, Spain and Sweden) that have also placed controls on the import and/or sale of *Salvia divinorum* and/or salvinorin A. Some individual U.S. states have also implemented laws restricting their use, sale and/or distribution.

Primary:	Telephone:
Alternate:	Telephone:
Approved by:	Telephone:



**Re: Salvia NOI Stakeholders**   
Stephanie Chandler to: Lisa M Young

2011-02-23 04:53 PM

**Salvia divinorum - Notice to Interested Parties / Avis d'intention aux parties intéressées**

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

Lisa M Young      Hi Stephanie, We will be sending out tomorrow...      2011-02-23 04:31:01 PM

From: Lisa M Young/HC-SC/GC/CA  
To: Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2011-02-23 04:31 PM  
Subject: Re: Salvia NOI Stakeholders

---

Hi Stephanie,

We will be sending out tomorrow morning. What did you put as your subject line? (translated)

Thanks  
Lisa

Stephanie Chandler      Hi Lisa, Our notification has been sent, so NH...      2011-02-22 01:27:15 PM

From: Stephanie Chandler/HC-SC/GC/CA  
To: Lisa M Young/HC-SC/GC/CA@HWC  
Date: 2011-02-22 01:27 PM  
Subject: Re: Salvia NOI Stakeholders

---

Hi Lisa,

Our notification has been sent, so NHPD can go ahead whenever you are ready.

Regards,

Stephanie

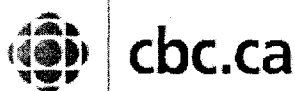
Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224

E-Mail: stephanie.chandler@hc-sc.gc.ca

Lisa M Young

Hi Stephanie, This is how our message will app...

2011-02-21 03:09:17 PM



February 22, 2011

## DJ pleased with federal salvia proposals

By CBC News  
CBC News

*A Saskatoon disc jockey who tried to make a point by trying salvia on the air says Ottawa is on the right track clamping down on the hallucinogenic plant.*

A Saskatoon disc jockey who tried to make a point by trying salvia on the air says Ottawa is on the right track clamping down on the hallucinogenic plant.

"I would say that 99 per cent of people that are getting into it think it's going to be a fun, fun time," said DJ Ryder, who's with Mix 96.3. "And it's not."

Earlier this month, Health Canada posted notice of its intention to ban the potent herb and its active ingredient, salvinorin A. It is proposing to add both to the Controlled Drugs and Substances Act, making it illegal to produce, possess, traffic, import or export the substances.

Ryder said it's a good idea.

Last December, in a video that got more than 50,000 hits on YouTube, he was seen taking a puff of salvia while on the air.

What followed was several minutes of an alarmed and disoriented Ryder talking about the experience.

"I'm totally frigged up," he said at one point on the video.

Ryder said he did it to make the point that the drug is powerful, easily obtained and comes with side-effects more unpleasant than is generally known by the public.

He said he's happy the politicians are paying attention.

"We just wanted to make sure that they knew that a lot of young people were getting in over their heads with this," he said.

Other countries, including Australia, Belgium, Denmark, Finland, Germany, Italy, Spain and Sweden, have

CBC: DJ pleased with federal salvia proposals

already regulated or banned salvia, as have some dozen states in the U.S.

Canadian Broadcasting Corporation



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s.19(1)



**Re: Submissions on Salvia**  
OCS Policy and Regulatory Affairs to: Kirk Tousaw

2011-02-24 09:23 AM

**Submissions on Salvia**

OCS Policy and Regulatory Affairs      *Good morning The deadline is March 21st.*

Good morning

The deadline is March 21st.

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada

Hello: Is the submission deadline March 4 or Ma...

2011-02-23 06:34:04 PM

From: [Redacted]  
To: OCS.Policy.and.Regulatory.Affairs@hc-sc.gc.ca  
Date: 2011-02-23 06:34 PM  
Subject: Submissions on Salvia

Hello:

Is the submission deadline March 4 or March 19?

Best,

[Redacted]  
Beyond Prohibition Foundation  
142-757 West Hastings, Suite 211  
Vancouver, British Columbia V6C1A1  
(c) 604.836.1420  
(f) 1.866.310.3342

[Redacted]  
[www.whyperprohibition.ca](http://www.whyperprohibition.ca)

s.19(1)



**Fw: Salvia divinorum and salvinorin A**  
OCS Policy and Regulatory Affairs to: Stephanie Chandler

2011-02-24 10:23 AM

OCS Policy and Regulatory Affairs Fw: Salvia divinorum and salvinorin A

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada  
----- Forwarded by OCS Policy and Regulatory Affairs/HC-SC/GC/CA on 2011-02-24 10:23 AM -----

From: [REDACTED]  
To: OCS.Policy.and.Regulatory.Affairs@hc-sc.gc.ca  
Date: 2011-02-22 05:05 PM  
Subject: Salvia divinorum and salvinorin A

Attention:  
CATHY A. SABISTON  
Director General  
Controlled Substances and  
Tobacco Directorate

This is in response to the Notice to interested parties — Proposal regarding the addition of Salvia divinorum and salvinorin A to Schedule III to the Controlled Drugs and Substances Act.

My name is [REDACTED]

Currently at our shops we prohibit the sale of these products to anyone under 18. We are able to ensure the quality of the product and, most importantly, we are able to **fully educate** the interested customer regarding the substance's effect.

Salvia has no toxicity, and it is completely safe as long as the user is prepared for its effects. It has been widely available **in Canada since the early '80s and has been attributed to ZERO fatalities**. Like Alcohol or skydiving or many other potentially dangerous things, Salvia can be a pleasant and interesting experience as long as it is done responsibly.

I urge you instead to create a licensing program, similar to tobacco, where recognized retailers are licensed by Health Canada to carry the extract.

Ensuring that:

A) licensed retailers prohibit sales to minors under 18

B) quality and potency of extracts is consistent

C) packaging includes clear warnings regarding Salvia's effects. For example: "This package contains .25g of 18x Salvia Extract - **BE ADVISED**, when smoked, the onset is quick. **Sit in a comfortable place**. The effects will last for less than 15 minutes."

This is a much more reasonable and cost-effective way to mitigate any potential risk when using Salvia.

I understand the need to react to the public concern. It may seem easier to simply classify these products. But, let's be realistic, **scheduling it will not make it unavailable**. Like marijuana it will become an illicit, black market product, left to the hands of criminals to regulate and control. This solution would cause far more harm and cost millions of dollars to enforce. Scheduling Salvia will only stop me, a responsible, tax-paying retailer, from carrying Salvia. It will stop me from responsibly selling it to adults, who



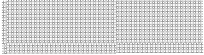
will be informed how to use it in a safe environment.

I don't care about any financial loss that I would incur from the scheduling of this plant. The fact that its regulation will be left to criminals if scheduled is of grave importance and the utmost concern to me.

I am willing to pay more tax, or pay an annual fee for a licence, if that would allow me to carry this product. My shops would responsibly sell safe products to adults. Salvia quality and potency **could be regulated just like tobacco**. Save Canadian citizens from the violence and financial burden of adding more benign substances and plants to our already failed drug policy.

**Please feel free to contact me if I can be of any assistance at all.** I would be more than happy to help facilitate a responsible approach to regulating Salvia in manner that would both appease the legitimate concerns of the Canadian public and allow adults to use Salvia without criminal charges.

Thank you for your time, I hope to hear from you!





**Re: Fw: Salvia interview**  
Jocelyn Kula to: Dave Stephens  
Cc: Denis Arsenault, stephanie.chandler

2011-02-24 10:14 AM

Yep, that's it exactly. Words of truth from someone who runs a store that sells "seeds"..... :)  
Denis/ Stephanie, please note and i think we should start thinking about our response to the whole call for an age limit and licensed retailers arguments.....

Jocelyn

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

---

Dave Stephens "It comes down to a Miley Cyrus video dictating... 2011-02-24 07:51:27 AM

---

From: Dave Stephens/HC-SC/GC/CA  
To: christine.roush@hc-sc.gc.ca, ken.polk@hc-sc.gc.ca, Jesse Arnup-Blondin/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC  
Date: 2011-02-24 07:51 AM  
Subject: Fw: Salvia interview

---

"It comes down to a Miley Cyrus video dictating our laws".

Dave Stephens  
Senior Communications Executive-Gestionnaire Principal des Communications HECSB/DGSCSE  
Health Canada/Sante Canada  
6th Floor, Room 6-033, 269 Laurier Ave. W., Ottawa, ON  
Tel: (613) 946-8107  
Cell: (613) 859-3581  
----- Forwarded by Dave Stephens/HC-SC/GC/CA on 2011-02-24 07:41 AM -----

---

From: Blair Parkhurst/HC-SC/GC/CA  
To: Dave Stephens/HC-SC/GC/CA@HWC, Jennifer Peddle/HC-SC/GC/CA@HWC, Brian Mori, Henry Ip, Dennis Shelley, Richard Laing/HC-SC/GC/CA@HWC  
Cc: Catherine Atyeo, Erik Bruns, Christiane Cote  
Date: 2011-02-23 04:48 PM  
Subject: Salvia interview

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Interview with the owner of the Vancouver Seed Bank on salvia yesterday on CBC BC Radio's 'On the Coast' at 5:25 pm.

<http://www.cbc.ca/onthecoast/episodes/2011/02/22/salvia-divinorum/>

----- Forwarded by Blair Parkhurst/HC-SC/GC/CA on 2011-02-23 01:44 PM -----

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From: Cynthia Khoo/HC-SC/GC/CA  
To: Blair Parkhurst/HC-SC/GC/CA@HWC  
Date: 2011-02-23 12:28 PM  
Subject: Re: Fw: Snapshot - salvia

002974

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Hi Blair,

Here's the link for now:

<http://www.cbc.ca/onthecoast/episodes/2011/02/22/salvia-divinorum/>

I'll record it as well in case they archive or take the link down in the future.

Cynthia

--

Cynthia Khoo | Communications Intern  
Public Affairs, Consultation and Communications  
BC Region | Health Canada  
Suite 410, 757 West Hastings St., V6C 3E6  
(t) 604.666.1685  
(f) 604.666.2258  
cynthia.khoo@hc-sc.gc.ca

Blair Parkhurst

Can you see if you can get the interview on salvi...

2011-02-23 07:02:41 AM

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From: Blair Parkhurst/HC-SC/GC/CA  
To: Cynthia Khoo  
Cc: Christiane Cote, Catherine Atyeo  
Date: 2011-02-23 07:02 AM  
Subject: Fw: Snapshot - salvia

---

Can you see if you can get the interview on salvia which aired yesterday on CBC Radio's 'On the Coast' at around 5:25 pm?

Blair Parkhurst  
Regional Director - Public Affairs, Consultation and Communications /  
Directeur régional - Affaires publiques, consultation et communications  
British Columbia Region / Région de la Colombie-Britannique  
Health Canada / Santé Canada  
Tel. / tél.: (604) 666-2310  
Fax / télécopieur: (604) 666-2258  
Internet email / courriel: blair\_parkhurst@hc-sc.gc.ca  
Caroline Quinn

----- Original Message -----

**From:** Caroline Quinn  
**Sent:** 2011-02-23 09:49 AM EST  
**To:** Blair Parkhurst; Tamara Magnan; Debbie Paine; Cynthia Booden Firth; Jean-Christophe Senosier; Elissa Tilley; Jennifer Tramble; Janice Edgar; Rob Furlong; Jennifer Peddle  
**Subject:** Fw: Snapshot - salvia

Caroline Quinn  
Manager/Gestionnaire  
Public Environment Intelligence and Analysis/Analyse des renseignements sur l'environnement public  
Consultations and Outreach Division/Division des consultations et de la sensibilisation  
Consultations and Management Services Directorate/Direction générale des affaires publiques, de la consultation et des communications

Health Canada/Santé Canada  
Tel/Tél: 613-960-6074  
Fax/Télécopieur: 613-954-8637  
caroline.quinn@hc-sc.gc.ca

----- Forwarded by Caroline Quinn/HC-SC/GC/CA on 2011-02-23 09:49 AM -----

From: Caroline Quinn/HC-SC/GC/CA  
To: Dave Stephens/HC-SC/GC/CA@HWC, Ken Polk/HC-SC/GC/CA@HWC, Tim Vail/HC-SC/GC/CA@HWC  
Cc: Carol Della Penta/HC-SC/GC/CA@HWC, Aruna Sadana/HC-SC/GC/CA@HWC, Lisa Holmes/HC-SC/GC/CA@HWC, Brigitte Smith/HC-SC/GC/CA@HWC  
Date: 2011-02-23 08:55 AM  
Subject: Snapshot - salvia

---

Dave,

Here's a snapshot of comments in relation to the salvia annct.

Please let me know if you have any questions or need additional information.

Thanks,  
Caroline

Caroline Quinn  
Manager/Gestionnaire  
Public Environment Intelligence and Analysis/Analyse des renseignements sur l'environnement public  
Consultations and Outreach Division/Division des consultations et de la sensibilisation  
Consultations and Management Services Directorate/Direction générale des affaires publiques, de la consultation et des communications  
Health Canada/Santé Canada  
Tel/Tél: 613-960-6074  
Fax/Télécopieur: 613-954-8637  
caroline.quinn@hc-sc.gc.ca

---

Public Environment Intelligence and Analysis, Salvia Snapshot, 23 February 2011

1

## *Salvia – Snapshot*

Presented by Public Environment Intelligence and Analysis, Health Canada  
Contact Caroline Quinn, Tel 613-960-6074, PEIA.AREP@hc-sc.gc.ca  
Coverage Date February 22, 2011

### *Media and Comments Review*

Five articles appeared online on February 22<sup>nd</sup>. The CBC article generated the most comments at a count of 150.

Government moves to criminalize hallucinogenic salvia, CBC , 55 tweets, 129 comments,  
<http://www.cbc.ca/news/health/story/2011/02/21/man-salvia-glover-crime.html?ref=rss>

---

A sample of the 50 highest rated comments was reviewed. None of the comments support the ban on Salvia. Comment with the highest "agreed" at 187 agree and 22 disagree:

*Health Canada knows very little about the long term effects. SO BAN IT, QUICK!! Don't bother studying it first. why is it that our masters always believe that if it feels good, then it must be bad. the exception being good old taxable liquor. good thing it never hurts anyone. those weeds and herbs though, ooh, ooh , better lock up anyone partaking is such evilness.*

Health Canada appeared 8 times in the comments. Only one was in support of the ban, one undecided and six were against the ban.

**Positive:** *And when it kills someone as a result of the adverse affects the same people advocating testing with no public warnings will be the first to cry how incompetant the Conservatives and Health Canada have been. Same old, damned if they do and damned if they don't.*

**Negative:** *If its not sold through a drug company so that government can make millions off it they want it against the law, sounds more like Health Canada protecting big drug companies once again.*

Alcohol or "booze" was mentioned in approximately 30 comments. Several commentators referenced how alcohol was harmful, yet it was legal. Some commentators were suggesting to treat Salvia like Alcohol and sell it in a controlled environment (like LCBO).

*I have never understood how such harmful things such as alcohol and tobacco are perfectly fine and legal for people to use and buy, while other much less harmful things that can be found growing naturally on this planet that can bring about 'out of body' experiences and altered states of reality are illegal?*

Government, Harper or Conservatives were mentioned in almost 50 of the comments. Comment examples:

*Police have long complained they're powerless to halt the sale of salvia, which has been known to produce some adverse reactions, including one case reported by Health Canada in 2006 in which an incoherent, suicidal teenage boy threatened to kill police officers." CBC This Article*

*I have to ask Health Canada how many times a week some drunk threatens to kill police officers but alcohol is still perfectly legal. One reported adverse salvia incident is hardly an epidemic. This is just one more Conservative measure to whittle away at the freedom of Canadians. However, I fully expect Harper's usual gang of sycophants to jump on this bandwagon because it is getting tough on crime. What nonsense; it is getting tough on individual rights.*



**Re: FYI: Salvia NOI correspondence from retailer**

Jocelyn Kula to: Stephanie Chandler

2011-02-24 10:35 AM

Cc: Denis Arsenault

History: This message has been forwarded.

Good news on the standard acknowledgment. I will discuss with Brenda how she wants to be kept in the loop.....I don't see any value in sending up single letters just cause they are addressed to Cathy. I also know that ADMO has received a few directly to them and have suggested to Jesse that they send to us and we use the same acknowledgement for all. Consistency is important!

JK

---

Jocelyn Kula

Acting Director/ Directrice par intérim

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs

Health Canada/ Santé Canada

Tel: (613) 952-2177 Fax: (613) 946-4224

---

Stephanie Chandler I was actually just going through the Salvia co...

2011-02-24 10:30:48 AM

From: Stephanie Chandler/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2011-02-24 10:30 AM  
Subject: FYI: Salvia NOI correspondence from retailer

I was actually just going through the Salvia comments we have received and attached below is the email from [REDACTED] (who was interviewed by CBC).

**s.19(1)** Given the volume of emails we have received so far, I have drafted a standard reply/acknowledgement that is currently with Denis for review. However, as she has written it is for Cathy's attention, may want to forward this to DGO.

Stephanie

Stephanie Chandler

Junior Regulatory Project Officer

Regulatory Policy Division/ Division de la politique réglementaire

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs

Health Canada/ Santé Canada

Tel: (613) 946-0124, Fax: (613) 946-4224

E-Mail: stephanie.chandler@hc-sc.gc.ca

----- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2011-02-24 10:24 AM -----

From: OCS Policy and Regulatory Affairs/HC-SC/GC/CA  
To: Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2011-02-24 10:23 AM  
Subject: Fw: Salvia divinorum and salvinorin A

002978



**Re: Standard Reply to Salvia NOI Comments** 

Jocelyn Kula to: Stephanie Chandler

2011-02-24 01:42 PM

Cc: Denis Arsenault

---

yes definitely re translation but let's wait to see if there are comments from above....

---

Jocelyn Kula

Acting Director/ Directrice par intérim

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs

Health Canada/ Santé Canada

Tel: (613) 952-2177 Fax: (613) 946-4224

---

Stephanie Chandler Hi Jocelyn, Revised as requested.

2011-02-24 01:40:01 PM

---

From: Stephanie Chandler/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2011-02-24 01:40 PM  
Subject: Standard Reply to Salvia NOI Comments

---

Hi Jocelyn,

Revised as requested.

[attachment "Standard Reply to Salvia NOI Comments.wpd" deleted by Jocelyn Kula/HC-SC/GC/CA]

Denis has also suggested that we have this translated (once approved) in case we receive any French comments.

Regards,

Stephanie

Stephanie Chandler

Junior Regulatory Project Officer

Regulatory Policy Division/ Division de la politique réglementaire

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs

Health Canada/ Santé Canada

Tel: (613) 946-0124, Fax: (613) 946-4224

E-Mail: stephanie.chandler@hc-sc.gc.ca

**Standard Reply to Comments Received Regarding the Salvia Notice to Interested Parties**

Dear Mr./Ms. [insert name],

I am writing to acknowledge receipt of your email with regards to the publication of the Notice to Interested Parties outlining Health Canada's proposal to add *Salvia divinorum* and salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA).

~~Health Canada appreciates that you have taken the time to provide your thoughts on this proposal. Your comments will be taken into consideration as the federal regulatory process progresses. There will also be additional opportunities for comment, in particular once a complete regulatory package is pre-published in *Canada Gazette*, Part I.~~

For your information, Health Canada has developed an *It's Your Health* article about *Salvia divinorum* to help inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at:  
<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/life-vie/salvia-eng.php>

Thank you for writing.

Sincerely,

Stephanie Chandler  
Regulatory Policy Division  
Office of Controlled Substances

I thank you for your comments and can assure you they will be...  
regarding this proposal



Stephanie C.

I am good with this, pls revise and send to me by email. Will

**Standard Reply to Comments Received Regarding the Salvia Notice to Interested Parties**

Just run by DGO before we implement

Dear Mr./Ms. [insert name],

I am writing to acknowledge receipt of your email with regards to the publication of the Notice to Interested Parties outlining Health Canada's proposal to add *Salvia divinorum* and salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA).

I thank you for your comments regarding this proposal and can assure you they will be taken into consideration as the federal regulatory process progresses. There will also be additional opportunities for comment, ~~in particular once a complete regulatory package is pre-published in *Canada Gazette*, Part I.~~ when proposal

For your information, Health Canada has developed an *It's Your Health* article about *Salvia divinorum* ~~to help~~ inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at: <http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/life-vie/salvia-eng.php>

Thank you for writing.

that aims to

Sincerely,

Stephanie Chandler  
Regulatory Policy Division  
Office of Controlled Substances



**Re: Fw: Standard Reply to Salvia NOI Comments**

Jocelyn Kula to: Brenda Paine

2011-02-24 02:54 PM

Cc: CSTD-DGO, Denis Arsenault, Michael Assad, stephanie.chandler

No I can take care of it; will cc you and DGO.  
JK

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

---

Brenda Paine Good note .. and good strategy. Will you handle... 2011-02-24 02:53:02 PM

---

From: Brenda Paine/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: CSTD-DGO, Denis Arsenault/HC-SC/GC/CA@HWC, Michael Assad/HC-SC/GC/CA@HWC,  
stephanie.chandler@hc-sc.gc.ca  
Date: 2011-02-24 02:53 PM  
Subject: Re: Fw: Standard Reply to Salvia NOI Comments

---

Good note .. and good strategy. Will you handle ADMO or do you want us to?

.. and yes, I hope that they understand the flexibility for the first line of the response .. may not always be  
by e-mail!!

B

---

Jocelyn Kula Brenda I am attaching what we propose to send... 2011-02-24 02:08:42 PM

---

From: Jocelyn Kula/HC-SC/GC/CA  
To: brenda.paine@hc-sc.gc.ca  
Cc: Michael Assad/HC-SC/GC/CA@HWC, CSTD-DGO, stephanie.chandler@hc-sc.gc.ca, Denis  
Arsenault/HC-SC/GC/CA@HWC  
Date: 2011-02-24 02:08 PM  
Subject: Fw: Standard Reply to Salvia NOI Comments

Brenda

I am attaching what we propose to send out in response to all the emails RPD has received in response to  
the NOI on salvia. It is consistent with emails we have used for the same purpose but in relation to other  
regulatory files, and is also akin to what we typically send in response to respondents who file comments  
during a prepublication comment period. As you will see, it is very generic and does not seek to respond  
to any particular issue(s) raised by the correspondent, and this is on purpose as it avoids us having to get  
into long defensive letters where we have to keep explaining our actions in acknowledging every set of  
comments received.

In conversation with Jesse yesterday, she mentioned that ADMO has already received a few letters re  
salvia directly, and she asked what our process was in terms of responding to them. If you are OK with

**Standard Reply to Comments Received Regarding the Salvia Notice to Interested Parties**

Dear Mr./Ms. [insert name],

I am writing to acknowledge receipt of your email with regards to the publication of the *Notice to Interested Parties* outlining Health Canada's proposal to add *Salvia divinorum* and salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA).

I thank you for your comments regarding this proposal and can assure you they will be taken into consideration as the federal regulatory process progresses. There will also be additional opportunities for comment when a complete regulatory proposal is pre-published in *Canada Gazette*, Part I.

For your information, Health Canada has developed an *It's Your Health* article about *Salvia divinorum* that aims to inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at:  
<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/life-vie/salvia-eng.php>

Thank you for writing.

Sincerely,

Stephanie Chandler  
Regulatory Policy Division  
Office of Controlled Substances



**Re: Fw: Standard Reply to Salvia NOI Comments**

Jocelyn Kula to: Stephanie Chandler

2011-02-24 02:58 PM

Cc: Denis Arsenault, Isabel Shanahan

History: This message has been forwarded.

I am aware entering into MECS is a burden, so as long as we have the means to track who sent in what and what action we took, I am OK with not doing it. I would suggest some kind of table that Isabel can fill in and perhaps a numbering system for the hard copies where the number is noted in the table as well.

I am sure you can come up with something spectacular!

Pls send draft standard response out for translation....

JK

---

Jocelyn Kula

Acting Director/ Directrice par intérim

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs

Health Canada/ Santé Canada

Tel: (613) 952-2177 Fax: (613) 946-4224

Stephanie Chandler Hi Jocelyn, With regards to the comments we...

2011-02-24 02:53:44 PM

---

From: Stephanie Chandler/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC, Isabel Shanahan/HC-SC/GC/CA@HWC  
Date: 2011-02-24 02:53 PM  
Subject: Fw: Standard Reply to Salvia NOI Comments

Hi Jocelyn,

With regards to the comments we are receiving on the Salvia NOI, given the volume of comments and the fact that we are issuing a standard response, do the emails need to be entered in MECS?

FYI Isabel and I haven't found the BZP NOI comments in MECS (though there were only 5 of them), so I don't believe we entered them in 2008.

Thanks,

Stephanie

Stephanie Chandler

Junior Regulatory Project Officer

Regulatory Policy Division/ Division de la politique réglementaire

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs

Health Canada/ Santé Canada

Tel: (613) 946-0124, Fax: (613) 946-4224



**Re: Fw: URGENT: Need questions answered asap (re: salvia)** 

Jocelyn Kula to: Dave Stephens

2011-02-24 02:52 PM

Cc: Alastair Sinclair, christine.roush, heidi.jackson, Jesse Arnup-Blondin,  
ken.polk, Stephanie Szick, Suzanne Desjardins

Dave,

Suzanne and I have discussed briefly and here is our proposed response.

**Where have we received complaints?**

CSTD has not heard any complaints. Rather it has received, as invited by the publication of the NOI, comments from some stakeholders suggesting that they are not supportive of the proposed regulatory action. It is completely normal for a department to receive both positive and negative comments further to an NOI.

**Why are alternatives (such as regulation like alcohol) the best course of action?**

It is entirely premature to suggest that any alternative to what the GoC has proposed, i.e., scheduling under the CDSA, is a better course of action. The notion that regulation like alcohol, e.g., the establishment of some kind of licensing scheme for retailers and perhaps an age limit in order to purchase, etc., are just ideas that have been put forward in comments received further to the publication of the NOI. It is common practice to wait until the end of the comment period before analyzing the incoming comments in full and determining whether examination of any alternatives to the proposed regulatory action is warranted.

Please let me know if you need anything else.

Jocelyn

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

---

Dave Stephens      Hi all, Please see below. MO is looking for resp...      2011-02-24 02:29:29 PM

---

From: Dave Stephens/HC-SC/GC/CA  
To: Suzanne Desjardins/HC-SC/GC/CA@HWC, jocelyn.kula@hc-sc.gc.ca  
Cc: Stephanie Szick/HC-SC/GC/CA@HWC, Jesse Arnup-Blondin/HC-SC/GC/CA@HWC,  
heidi.jackson@hc-sc.gc.ca, christine.roush@hc-sc.gc.ca, ken.polk@hc-sc.gc.ca, Alastair  
Sinclair/HC-SC/GC/CA@HWC  
Date: 2011-02-24 02:29 PM  
Subject: Fw: URGENT: Need questions answered asap (re: salvia)

---

Hi all,

Please see below. MO is looking for responses to those two questions on Salvia by 3pm

Dave

Dave Stephens  
Senior Communications Executive-Gestionnaire Principal des Communications  
HECSB/DGSCSE  
Health Canada/Sante Canada  
6th Floor, Room 6-033, 269 Laurier Ave. W., Ottawa, ON  
Tel: (613) 946-8107  
Cell: (613) 859-3581  
----- Forwarded by Dave Stephens/HC-SC/GC/CA on 2011-02-24 02:27 PM -----

From: Alastair Sinclair/HC-SC/GC/CA  
To: Jenny VanAlstyne/HC-SC/GC/CA@HWC, Dave Stephens/HC-SC/GC/CA@HWC  
Cc: Gary Holub/HC-SC/GC/CA@HWC  
Date: 2011-02-24 02:26 PM  
Subject: Re: URGENT: Need questions answered asap (re: salvia)

Hello, Dave.  
Can you please assist and reply directly to Jenny?  
Thank you,  
Alastair

Alastair Sinclair  
Chief, Media Relations | Chef, Relations avec les médias  
Public Affairs, Consultation and Communications Branch | Direction  
générale des affaires publiques, de la consultation et des communications  
Health Canada | Santé Canada  
(t) 613.957.2985  
(f) 613.960.0208  
(e) alastair.sinclair@hc-sc.gc.ca

From: Jenny VanAlstyne/HC-SC/GC/CA  
To: Alastair Sinclair/HC-SC/GC/CA@HWC, Gary Holub/HC-SC/GC/CA@HWC  
Date: 2011-02-24 02:24 PM  
Subject: URGENT: Need questions answered asap (re: salvia)

Can I get answers to these two questions on salvia by 3 p.m?

-where have you heard complaints

- there were alternatives put forward by those who disagreed (such as  
regulating it like alcohol), why is this the best course of action



**Fw: URGENT: Need questions answered asap (re: salvia)**  
Suzanne Desjardins to: Jocelyn Kula

2011-02-24 03:02 PM

History: This message has been replied to.

Hi Jocelyn,

I think for the second point there could also be something like

"*Salvia divinorum* was assessed against the criteria for the addition of a substance to one of the Schedules to the CDSA to determine whether it should be regulated as a controlled substance in Canada. These criteria are:

- International Requirements and Trends in the Control and/or Scheduling
- Chemical and/or Pharmacological Similarity to Substances Listed in the Schedules to the CDSA
- Legitimate Use of the Substance, including Therapeutic, Scientific, Industrial or Commercial Uses
- Potential for Abuse and/or Addiction Liability
- Evidence of Extent of Actual Abuse of the Substance in Canada and Internationally
- Risk to Personal and Public Health and Safety

Our preliminary assessment showed that Salvia met most, if not all, of these criteria, hence the NOI as a means to request comments and information before finalising the assessment.

What do you think?

→ NOT used; will keep until we have more questions

Suzanne

----- Forwarded by Suzanne Desjardins/HC-SC/GC/CA on 2011-02-24 02:44 PM -----

From: Dave Stephens/HC-SC/GC/CA  
 To: Suzanne Desjardins/HC-SC/GC/CA@HWC, jocelyn.kula@hc-sc.gc.ca  
 Cc: Stephanie Szick/HC-SC/GC/CA@HWC, Jesse Arnup-Blondin/HC-SC/GC/CA@HWC, heidi.jackson@hc-sc.gc.ca, christine.roush@hc-sc.gc.ca, ken.polk@hc-sc.gc.ca, Alastair Sinclair/HC-SC/GC/CA@HWC  
 Date: 2011-02-24 02:29 PM  
 Subject: Fw: URGENT: Need questions answered asap (re: salvia)

Hi all,

Please see below. MO is looking for responses to those two questions on Salvia by 3pm

Dave

Dave Stephens  
 Senior Communications Executive-Gestionnaire Principal des Communications HECSB/DGSCSE  
 Health Canada/Sante Canada  
 6th Floor, Room 6-033, 269 Laurier Ave. W., Ottawa, ON  
 Tel: (613) 946-8107  
 Cell: (613) 859-3581

----- Forwarded by Dave Stephens/HC-SC/GC/CA on 2011-02-24 02:27 PM -----

From: Alastair Sinclair/HC-SC/GC/CA  
 To: Jenny VanAlstyne/HC-SC/GC/CA@HWC, Dave Stephens/HC-SC/GC/CA@HWC  
 Cc: Gary Holub/HC-SC/GC/CA@HWC



**Fw: One thing I forgot! Salvia...**

Denis Arsenault      Jocelyn Kula  
Stephanie Chandler

2011-02-24 04:19 PM

This message has been forwarded.

Hi Jocelyn,

While I know Brenda asked for a Q&A, we've presented the information requested in list form as it seemed to make more sense given the number of penalties involved.

Let me know if you think this will meet Brenda's needs.

Denis

P.S. Stephanie - I've made some slight edits, so please keep this one for our records.



Max Penalties Under Schedule III.doc

Denis Arsenault      For action Denis

2011-02-24 03:30:44 PM

From:            Denis Arsenault/HC-SC/GC/CA  
To:                Stephanie Chandler/HC-SC/GC/CA@HWC  
Date:             2011-02-24 03:30 PM  
Subject:         Fw: One thing I forgot! Salvia...

For action

Denis

Denis Arsenault, A/Manager / Gestionnaire p.i.  
Regulatory Policy Division /  
Division des politiques réglementaires,  
Office of Controlled Substances /  
Bureau des substances contrôlées,  
Health Canada / Santé Canada  
Tel/Tél: (613) 957-6828  
Fax / Télécopieur : (613) 946-4224  
E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca

----- Forwarded by Denis Arsenault/HC-SC/GC/CA on 2011-02-24 03:30 PM -----

From:            Jocelyn Kula/HC-SC/GC/CA  
To:                Brenda Paine/HC-SC/GC/CA@HWC  
Cc:                Denis Arsenault/HC-SC/GC/CA@HWC  
Date:             2011-02-24 02:59 PM  
Subject:         Re: One thing I forgot! Salvia...

sure.

Denis/ Stephanie for action pls



JK

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

Brenda Paine ..could your group prepare a Q and A .. on the fi... 2011-02-24 02:56:00 PM

From: Brenda Paine/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Date: 2011-02-24 02:56 PM  
Subject: One thing I forgot! Salvia...

---

..could your group prepare a Q and A .. on the fines/penalties for salvia .. ie when salvia is placed under  
the CDSA .. what would the fine be for possession?

... ADM asked & I didn't know the response ... not urgent, but we can flip up to them tomorrow end of day?  
Or Monday a.m.

Thanks  
Brenda Paine  
Director | Directrice  
Office of Policy and Strategic Planning | Bureau des politiques et de la planification stratégique  
Controlled Substances and Tobacco Directorate | Direction des substances contrôlées et de la lutte au  
tabagisme  
Health Canada | Santé Canada  
Tele/télé: (613) 941-9826

**Page(s) 002990 to\à 002993**

**Is(Are) exempted pursuant to section(s)  
est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**21(1)(a), 21(1)(b)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**

Draft

## Salvia divinorum NOI Stakeholders

### Groups

- CSTD - RCMP
- CSTD - Police
- CSTD - Class A Precursor Licensed Dealers
- CSTD - Class B Precursor Licensed Dealers - SPIC
- CSTD - Controlled Substances Licensed Dealers - QPIC
- CSTD - RPD - Deans of Canadian Universities
- CSTD - RPD - P/T Licensing Authorities - Registrars of Pharmacy
- CSTD - RPD - P/T Licensing Authorities - Registrars of Physicians and Surgeons
- CSTD - RPD - P/T Licensing Authorities - Registrars of Dental Surgeons
- CSTD - RPD - P/T Licensing Authorities - Registrars of Veterinary Medicine
- CSTD - RPD - P/T Licensing Authorities - Registrars of Naturopathy
- CSTD - RPD - Professional Associations - Pharmacy Associations
- CSTD - RPD - Professional Associations - Medical Associations
- CSTD - RPD - Professional Associations - Dental Associations
- CSTD - RPD - Professional Associations - Veterinary Associations
- CSTD - RPD - P/T Deputy Ministers of Health

### Individual Associations/ Agencies

- ✓Canadian Psychiatric Association
- ✓Canadian Association of Naturopathic Doctors
- ✓Canadian Public Health Association (6)
  
- ✓Natural Health Products Manufacturers of Canada
  
- ✓CSTD - RPD - Other Government Departments - Canada Border Services Agency (3 Contacts)
- ✓CSTD - RPD - Other Government Departments - Public Safety (5 Contacts)
  
- ✓Canadian Mental Health Association
- ✓Canadian Centre on Substance Abuse
- ✓Canadian Homeopathic Pharmaceutical Association
- ✓Centre for Addiction and Mental Health (6 Contacts) ||
- ✓Public Health Agency of Canada (Johnson, Mary - Manager)
- ✓Public Health Agency of Canada (Vieira, Gaby - Policy Analyst)
- ✓Public Health Agency of Canada (Director General's Office, Palak, Monica)
- ✓Public Health Agency of Canada (Mental Health Promotions Unit)
- ✓Public Health Agency of Canada (Strategic Policy and Research)

### CBSA Contacts

~~Roger Lavigne?~~  
Brian McGruther ✓  
Raymond Bedard ✓

Bcc:

*dr*

Salvia divinorum NOI Stakeholders

Groups

- ~~CSTD - RCMP~~
- ~~CSTD - Police~~
- ~~CSTD - RPD - Deans of Canadian Universities~~
- ~~CSTD - RPD - P/T Licensing Authorities - Registrars of Pharmacy~~ ✓
- ~~CSTD - RPD - P/T Licensing Authorities - Registrars of Physicians and Surgeons~~ ✓
- ~~CSTD - RPD - P/T Licensing Authorities - Registrars of Dental Surgeons~~ ✓
- ~~CSTD - RPD - P/T Licensing Authorities - Registrars of Veterinary Medicine~~ ✓
- ~~CSTD - RPD - P/T Licensing Authorities - Registrars of Naturopathy~~ ✓
- ~~CSTD - RPD - Professional Associations - Pharmacy Associations~~ ✓
- ~~CSTD - RPD - Professional Associations - Medical Associations~~ ✓
- ~~CSTD - RPD - Professional Associations - Dental Associations~~ ✓
- \* ~~CSTD - RPD - Professional Associations - Veterinary Associations~~ ✓
- ~~CSTD - RPD - P/T Deputy Ministers of Health~~

Individual Associations/ Agencies

- ~~Canadian Psychiatric Association~~ ✓
- ~~Canadian Association of Naturopathic Doctors~~ ✓
- ~~Canadian Public Health Association (4 Contacts)~~ ✓

~~Natural Health Products Manufacturers of Canada~~

- ~~CSTD - RPD - Other Government Departments - Canada Border Services Agency (3 Contacts)~~ ✓
- ~~CSTD - RPD - Other Government Departments - Public Safety (5 Contacts)~~

~~Canada Border Services Agency - OGD Programs Unit (3 Contacts)~~ ✓

- ~~Canadian Mental Health Association~~ ✓
- ~~Canadian Centre on Substance Abuse~~ ✓
- ~~Canadian Homeopathic Pharmaceutical Association~~ ✓
- ~~Centre for Addiction and Mental Health (13 Contacts)~~ ✓
- ~~Public Health Agency of Canada (Johnson, Mary - Manager)~~ ✓
- ~~Public Health Agency of Canada (Vieira, Gaby - Policy Analyst)~~
- ~~Public Health Agency of Canada (Director General's Office, Palak, Monica)~~
- ~~Public Health Agency of Canada (Mental Health Promotions Unit)~~
- ~~Public Health Agency of Canada (Strategic Policy and Research)~~ ✓

Martin.Burt@cbsa-asfc.gc.ca

George.Mezher@cbsa-asfc.gc.ca

Nicole.Rougier@cbsa-asfc.gc.ca

To:  
Cc:  
From:

Subject: Fw: Salvia divinorum - Notice to Interested Parties / Avis d'intention aux parties intéressées

[le français suit]

Dear Sir/Madam:

The purpose of this email is to advise you that a *Notice of Intent to Interested Parties* (NOI) regarding the following substances was published in the *Canada Gazette*, Part I on February 19, 2011:

- *Salvia divinorum*
- Salvinorin A

The electronic version of the NOI is available at the following website:

<http://www.gazette.gc.ca/rp-pr/p1/2011/2011-02-19/pdf/g1-14508.pdf>, pages 8-9 in PDF format (pages 438-439 in *Canada Gazette*, Part I).

This NOI outlines Health Canada's proposal to include *Salvia divinorum* and salvinorin A in Schedule III to the *Controlled Drugs and Substances Act* (CDSA). In particular, Health Canada is seeking further information from stakeholders as to whether these substances have any legitimate industrial, scientific or medical uses in Canada. Information received in response to this notice will be instrumental in determining appropriate regulatory controls.

If you are interested in this process or wish to provide us with information for our consideration, please do so by March 21, 2011. You may send your comments to Stephanie Chandler, Regulatory Policy Division, Office of Controlled Substances, Address Locator: 3503D, 123 Slater St., Ottawa, Ontario, Canada K1A 1B9, by fax at (613) 946-4224 or by email to [OCS.Policy.and.Regulatory.Affairs@hc-sc.gc.ca](mailto:OCS.Policy.and.Regulatory.Affairs@hc-sc.gc.ca)

PLEASE FORWARD THIS EMAIL TO OTHERS WHO MAY BE INTERESTED.

Should this notification have reached you in error, it would be appreciated if you could please forward it to the appropriate person in your organization and ask that person to inform us of this by sending an e-mail to: [OCS.Policy.and.Regulatory.Affairs@hc-sc.gc.ca](mailto:OCS.Policy.and.Regulatory.Affairs@hc-sc.gc.ca)

Thank you,

Regulatory Policy Division  
Office of Controlled Substances  
Controlled Substances and Tobacco Directorate  
Healthy Environments and Consumer Safety Branch

\*\*\*\*\*  
\*\*\*\*\*

Madame, Monsieur,

Le présent courriel a pour but de vous informer qu'un *Avis d'intention aux parties intéressées* concernant les substances ci-dessous a été publié dans la Partie I de la *Gazette du Canada* , le 19 février 2011:

- *Salvia divinorum* (sauge des devins)
- Salvinorine A

La version électronique de l'Avis d'intention est disponible à l'adresse Internet <http://www.gazette.gc.ca/rp-pr/p1/2011/2011-02-19/pdf/g1-14508.pdf> , pages 8-9 ,en format PDF (pages 438-439 dans la Partie I de la *Gazette du Canada* ).

Cet avis d'intention décrit la proposition de Santé Canada qui consiste à inclure la *Salvia divinorum* (sauge des devins) et la salvinorine A dans l'annexe III de la *Loi réglementant certaines drogues et autres substances* . Santé Canada cherche précisément à obtenir plus d'information de la part des intervenants afin de déterminer si ces substances ont une utilité légitime sur les plans industriel, scientifique ou médical au Canada. Les renseignements qui seront obtenus permettront de prendre des mesures réglementaires appropriées.

Si vous désirez participer à ce processus ou tout simplement nous fournir de l'information, veuillez communiquer avec nous d'ici le 21 mars 2011. Vous pouvez envoyer vos commentaires par la poste à Stephanie Chandler, Division de la politique réglementaire, Bureau des substances contrôlées, indice de l'adresse : 3503D, 123 rue Slater, Ottawa, Ontario, Canada K1A 1B9, par télécopieur, au 613-946-4224, ou par courriel à [OCS.Policy.and.Regulatory.Affairs@hc-sc.gc.ca](mailto:OCS.Policy.and.Regulatory.Affairs@hc-sc.gc.ca)

VEUILLEZ TRANSFÉRER LE PRÉSENT COURRIEL AUX PERSONNES QUI  
POURRAIENT ÊTRE INTÉRESSÉES.

Si vous avez reçu cet avis par erreur, nous vous saurions gré de le transférer à la personne concernée de votre organisation et de lui demander de nous en informer par courriel à : [OCS.Policy.and.Regulatory.Affairs@hc-sc.gc.ca](mailto:OCS.Policy.and.Regulatory.Affairs@hc-sc.gc.ca)

Merci.

Division de la politique réglementaire  
Bureau des substances contrôlées  
Direction des substances contrôlées et de la lutte au tabagisme  
Direction générale de la santé environnementale et de la sécurité des consommateurs

## RPD Telephone Enquiry

**Date of Call:** February 25, 2011

**s.19(1)**

**Subject:** Publication of Salvia NOI

**Language of Correspondence:** English

**Caller Name:** [REDACTED]

**Caller Organization:** N/A

**Caller Telephone Number:** [REDACTED]

### CALL SUMMARY:

The caller wanted to confirm how long the comment period for the *Salvia divinorum* Notice to Interested Parties (NOI) was. I informed him that we are requesting all comments on the NOI be submitted by March 21, 2011. The caller also asked if after the 30-day comment period ended would *Salvia divinorum* be illegal. I told the caller that the publication of the NOI was meant to obtain comments on the initial proposal and that the scheduling of *Salvia divinorum* would have to go through the entire federal regulatory process which could take between 18 and 24 months. I also informed him that there would be additional opportunities for comment once a regulatory proposal is pre-published in *Canada Gazette*, Part I. The caller thanked me and indicated that he would be emailing us his comments.

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division  
Office of Controlled Substances





**Re: Fw: Standard Reply to Salvia NOI Comments - translation**

Isabel Shanahan     Stephanie Chandler

2011-02-25 02:45 PM

History

This message has been forwarded.



8069752\_FR\_1\_Standard\_Reply\_to\_Salvia\_NOI\_Comments[1].wpd

Isabel Shanahan  
Assistant to the Manager  
Regulatory Policy Division  
Office of Controlled Substances  
Healthy Environments and Consumer Safety Branch  
Tel: (613) 946-0123 Fax: (613) 946-4224

Stephanie Chandler     Hi Isabel, This is the standard reply approved...

2011-02-24 03:03:58 PM

From:            Stephanie Chandler/HC-SC/GC/CA  
To:                Isabel Shanahan/HC-SC/GC/CA@HWC  
Cc:                Denis Arsenault/HC-SC/GC/CA@HWC  
Date:             2011-02-24 03:03 PM  
Subject:          Fw: Standard Reply to Salvia NOI Comments

Hi Isabel,

This is the standard reply approved by DGO for translation into French. Not a rush as we haven't received any French comments yet.

[attachment "Standard Reply to Salvia NOI Comments.wpd" deleted by Isabel Shanahan/HC-SC/GC/CA]

I've already started working on a table to track the comments. I know you have gotten a few phone calls already so I will probably add a table to track those as well.

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca  
----- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2011-02-24 02:58 PM -----

From:            Jocelyn Kula/HC-SC/GC/CA  
To:                Stephanie Chandler/HC-SC/GC/CA@HWC  
Cc:                Denis Arsenault/HC-SC/GC/CA@HWC, Isabel Shanahan/HC-SC/GC/CA@HWC  
Date:             2011-02-24 02:58 PM  
Subject:          Re: Fw: Standard Reply to Salvia NOI Comments

I am aware entering into MECS is a burden, so as long as we have the means to track who sent in what

003000

**Réponse type aux commentaires reçus dans le cadre de l'avis aux parties intéressées  
concernant la Salvia**

Madame/Monsieur,

J'ai bien reçu votre courriel en réponse à l'*avis aux parties intéressées* qui a été publié au sujet de la proposition de Santé Canada d'inscrire la *Salvia divinorum* (sauge des devins) et la salvinorine A à l'annexe III de la *Loi réglementant certaines drogues et autres substances* (LRCIDAS).

Vos commentaires relativement à la proposition ont été fort appréciés et je peux vous assurer que nous en tiendrons compte dans le cadre du processus de réglementation fédéral. Vous aurez de nouveau l'occasion de transmettre vos commentaires lors de la publication préalable du projet de réglementation intégral dans la Partie I de la *Gazette du Canada*.

Vous trouverez dans le portail *Votre santé et vous* de Santé Canada un article concernant la *Salvia divinorum* visant à informer la population des risques associés à l'utilisation de cette plante. L'article peut être consulté à l'adresse suivante :  
<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/life-vie/salvia-fra.php>

Je vous remercie de nous avoir écrit et vous prie d'agréer, Madame/Monsieur, l'expression de mes sentiments les meilleurs.

Stephanie Chandler  
Division de la politique réglementaire  
Bureau des substances contrôlées



**Fw: Salvia calls**

Arafo Talane    Stephanie Chandler

2011-02-25 04:33 PM

OK.

Thanks!

----- Forwarded by Arafo Talane/HC-SC/GC/CA on 2011-02-25 04:30 PM -----

From: Stephanie Chandler/HC-SC/GC/CA  
To: Arafo Talane/HC-SC/GC/CA@HWC  
Cc: Lisa Marie NG/HC-SC/GC/CA@HWC  
Date: 2011-02-25 04:29 PM  
Subject: Salvia calls

---

Hi Arafo,

As I suspect we will be getting more calls about Salvia... I spoke to Denis and he has advised that you can forward any calls straight to me, instead of to Denis.

Thanks and have a great weekend!!

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

**Re: Fw: For input/approval: Interview request - CBC Calgary - Salvia** 

Stephanie Chandler Denis Arsenault

2011-02-28 11:57 AM

Hi Denis,

Q1 looks okay to me, and Q2 is for input from Suzanne's group.

For Q3), as the reporter is asking " what kind of ban?" I would suggest including the following line from the media lines:

The proposed inclusion of *Salvia divinorum* and salvinorin A in Schedule III to the *Controlled Drugs and Substances Act* would make possession, trafficking, importation, exportation, production (or cultivation), possession for the purpose of trafficking or possession for the purposes of exporting illegal unless authorized by regulation.

Q4) Is about Spice. I assume it is from the media lines, but may want to forward to Nathan to have a look at?

For Q5, I'm not sure what we want to say as far as other substances that we are looking to schedule. Your thoughts?

Regards,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

Denis Arsenault Thoughts? ----- Original Message -----

2011-02-28 11:45:46 AM

From: Denis Arsenault/HC-SC/GC/CA  
To: stephanie.chandler@hc-sc.gc.ca  
Date: 2011-02-28 11:45 AM  
Subject: Fw: For input/approval: Interview request - CBC Calgary - Salvia

Thoughts?

Nicole Prentice

----- Original Message -----

**From:** Nicole Prentice

**Sent:** 2011-02-28 11:37 AM EST

**To:** Jocelyn Kula; Suzanne Desjardins

**Cc:** Denis Arsenault; CSTD-OCS-DO; Chantal Routhier-Garner; Christine Roush

**Subject:** For input/approval: Interview request - CBC Calgary - Salvia

Hi Jocelyn and Suzanne,

Below is a new CBC enquiry for your input and approval. Reporter is looking for an interview, however, we are going to provide written responses only. This is due COB so a response by 1:30 today would be greatly appreciated.

Suzanne - I believe Q2 is the only one you need to look at/approve.

Thanks!  
Nicole

\*\*\*\*\*

Salvia & Synthetic marijuana & other semi-legal highs (salvia his main interest)

**Q1) Are there 2 separate initiatives going on here? (Private members bill here and HC also looking at it - 30 day period for comments)?**

A1) After reviewing available information and reports that suggest *Salvia divinorum* and its main active ingredient salvinorin A have the potential for abuse, especially among young people, Health Canada is proposing to schedule both *Salvia divinorum* and its main active ingredient salvinorin A as controlled substances. The Government of Canada is taking these steps in order to protect the health and safety of Canadians, particularly youth, from the potentially harmful effects of *Salvia divinorum* and/or salvinorin A. The first step in the process of scheduling a substance under the CDSA is the publication of a *Notice to Interested Parties* (NOI) in *Canada Gazette*, Part I, which was published on February 19, 2011 for a 30-day comment period. This notice provides interested stakeholders with the opportunity to provide comments on Health Canada's proposal to add *Salvia divinorum* and its main active ingredient salvinorin A to Schedule III to the CDSA. Any comments received are considered during the preparation of a regulatory proposal. There will be additional opportunities for comment as the federal regulatory process progresses, which usually takes about 18 to 24 months to complete. Health

Health Canada is not aware of a private members bill regarding *Salvia divinorum*.

**Q2) Broad history over last 5 years - HC monitoring this? studying it? ban it? restrict it?**

A2) Health Canada has reviewed information and reports from a variety of sources regarding the use and dangers of salvia and has assessed its findings against several key factors involved in the determination of the scheduling of a substance, including

- its pharmacological similarity to other substances already regulated under the CDSA;
- its potential for abuse related to its hallucinogenic properties, and the fact that about 7% of youth 15-24 years of age have used it - this represents about 300,000 youth;
- the health risks associated with this substance as shown from some reports of adverse incidents, for example, an article in the *Journal of Emergency Medicine* in 2009 indicates that 39 adverse neurological, cardiovascular and gastrointestinal events associated with the use of salvia were reported to a statewide (California) poison control system over the span of a decade. Health Canada is also aware of a case reported in the U.S. in which a 17 year old boy committed suicide after smoking *S. divinorum* for an unknown period of time, and although a direct causal link between salvia use and the death cannot be firmly established, the state of Delaware passed a law which classified *S. divinorum* as a Schedule I controlled substance along with other hallucinogenic substances.

In addition, in one case report, published in the *Journal of Clinical Psychiatry* in 2008, a woman who had concomitantly consumed cannabis and salvia *divinorum* experienced severe psychotic symptoms (symptomatic toxic psychosis) along with emerging and life-threatening medical consequences. In 2006, there was also an incident in Canada in which an incoherent suicidal teenager threatened to kill police officers after apparently consuming salvia.

Health Canada is continuing to survey the prevalence of salvia use and in 2009, Health Canada started including questions on salvia use in both the Youth Smoking Survey and the Canadian Alcohol and Drug Use Monitoring Survey. The Centre for Addiction and Mental Health in Toronto similarly included questions on salvia use in the Ontario Student Drug Use and Health Survey. As results from these

surveys became available in 2009-2010, the Department was able to include Canadian surveillance data in its ongoing assessment of salvia.

**Q3) Current initiative - what is behind this? Why is HC looking to ban it? What kind of ban? Reasons behind it?**

A3) See A2.

Scheduling these products will reduce the potential risks to the health and safety of Canadians associated with their ready availability, with their increased use and their unknown effects. The scheduling of *Salvia divinorum* and salvinorin A will also eliminate the current misconception that these substances are a safe alternative to other illegal drugs. Furthermore, the scheduling will also enable law enforcement agencies to take action against suspected illegal activities involving these substances.

**Q4) Also - issue of synthetic marijuana - "legal" highs K2 / spice / Yucatan fire / Skunk - what is HC's position on these?**

A4) There is no such thing as synthetic marijuana as marijuana (cannabis) is a plant that is also a controlled substance. Health Canada is aware that there are products being sold in Canada that contain synthetic cannabinoids, the family of molecules that give marijuana its psychoactive properties. It is, however, illegal to sell, import, produce, export or possess any product that contains synthetic cannabinoids as these compounds are captured under Item I of Schedule II to the Controlled Drugs and Substances Act (CDSA). Any offences of this nature are subject to criminal prosecution in Canada. Law enforcement can take action if they suspect illegal activity. In Canada, these synthetic cannabinoids are considered to be similar synthetic preparations of cannabis, and thus are subject to the *Controlled Drugs and Substances Act*

While products sold under the brand names "Spice" and "K2" are marketed as herbal incense for use in the home, it is believed that these products are generally smoked by consumers because they are known to produce effects similar to those induced by marijuana. It is believed, that the cannabis-like effects of these products come from the infusion of one or more synthetic cannabinoids and analysis of some "Spice" products being sold in Canada has shown that these products contain the synthetic cannabinoids JWH-018 and CP-47497. These substances are considered to be similar synthetic preparations of cannabis, which are listed in Item 1 of Schedule II of the *Controlled Drugs and Substances Act* (CDSA).

It is illegal to sell, import, produce, export or possess products that contain these controlled substances in Canada, and offences of this nature are subject to criminal prosecution in Canada. When identified as such, illegal herbal incense products will be seized at points of entry into Canada and removed from retail outlets. Law enforcement can take action if they suspect illegal activity.

**Q5) Any other similar drugs Canada is looking at banning as well?**

A5) For OCS input.

**Nicole Prentice**

Junior Communications Officer | Agente junior des Communications  
Regulatory Communications and Media Relations Division | Division des communications  
réglementaires et des relations avec les médias  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires  
publiques, de la consultation et des communications  
Health Canada | Santé Canada  
Tel: 613.941.3107  
Fax: 613.948.8085

----- Forwarded by Nicole Prentice/HC-SC/GC/CA on 2011-02-28 11:33 AM -----

From: Christine Roush/HC-SC/GC/CA  
To: Nicole Prentice/HC-SC/GC/CA@HWC  
Date: 2011-02-28 11:20 AM  
Subject: Re: Fw: Interview request - CBC Calgary - Salvia

---

OK - made a number of changes below.

Christine Roush  
Senior Communications Advisor/

Nicole Prentice      For your review: Salvia & Synthetic marijuana...      2011-02-28 11:02:59 AM

s.19(1)



**Fw: Proposed addition of Salvia divinorum and salvinorin A to Schedule III to the Controlled Drugs and Substances Act...**

OCS Policy and Regulatory Affairs to: Denis Arseneault

2011-02-28 04:03 PM

Sent by: Stephanie Chandler

OCS Policy and Regulatory Affairs: Fw: Proposed addition of Salvia divinorum and salvinorin A to Schedule III to

Hi Denis,

FYI Please see the email below addressed to Cathy, which was cc'ed to various politicians and newspapers.

Stephanie

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada  
----- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2011-02-28 04:02 PM -----

**Proposed addition of Salvia divinorum and salvinorin A to Schedule III to the Controlled Drugs and Substances Act...**

[Redacted] to: OCS.Policy.and.Regulatory.Affairs

2011-02-28 02:17 PM

Cc: [Redacted] layton.J, ignatieff.M, Editor-Westender, [Redacted]

Carol Sabiston  
Director General  
Controlled Substances and Tobacco Directorate  
Health Canada

Re: Proposed addition of Salvia divinorum and salvinorin A to Schedule III to the Controlled Drugs and Substances Act

Monday, February 28th 2011

Dear Ms. Sabiston,

I am writing to express my concern with the proposed addition of *Salvia divinorum* and salvinorin A to Schedule III to the Controlled Drugs and Substances Act (1). The Government



has not demonstrated that any significant harm comes from smoking or ingesting *Salvia divinorum* and salvinorin A. Reading through the proposal, the only detriment that can be determined is that the effects may be "unpleasant". Health Canada should ask itself if protecting Canadians from unpleasant experiences is part of its mandate, or if the personal decisions that arise from one's conscience are not enshrined in the Canadian Charter of Rights and Freedoms. There is no published evidence that demonstrates addiction or harm from ingesting *S. divinorum* or salvinorin A. The proposal claims that *Salvia* is a hallucinogen similar to LSD, and offers this as a reason why it should be regulated, but research suggests that the effects of *S. divinorum* or salvinorin A are not the same as LSD and cannot be placed in the same category (2, 3). The proposal cites statistics published in the Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) claiming that up to 7.3% of young Canadians between the ages of 15-24 have used *S. divinorum* or salvinorin A at least once in their lifetime, but over all, demonstrates a very low use among Canadians in general (0.5%) (4). Despite the fact that *S. divinorum* or salvinorin A are currently unscheduled, the rates of use (and hence abuse) among young people are lower than for either *Cannabis* (10.6%) and alcohol (75.5%), two substances that are otherwise illegal or restricted to youth (5). Very clearly, creating legal impediments to recreational use has not effectively diminished the consumption of either marijuana or alcohol, and my concern is that once *S. divinorum* and salvinorin A are placed in Schedule III and hence become restricted substances they will acquire greater notoriety among youth, and more importantly, will be distributed by criminal elements, putting our youth at greater risk not just from criminal activity but from adulteration. If it were Health Canada's intent to remove all substances that youth consume recreationally, then perhaps Health Canada might consider banning petroleum distillates and solvents, since this represents a greater danger, with upwards of 5% of Canadian youth at risk from inhalant abuse (6). Compared to the "unpleasant" effects of *Salvia divinorum* or salvinorin A, inhalation of petroleum distillates and solvents leads to very real medical and health issues, and yet these substances remain widely available with restriction. Based on the balance of evidence I strongly urge Health Canada to withdraw this proposal and focus its energies on more meaningful enterprises including education and harm-reduction. If we expect youth to be responsible and mindful about their recreational choices then let's avoid these sorts of paternalistic, heavy-handed measures to criminalize personal choices. Let us create an informed and intelligent society.

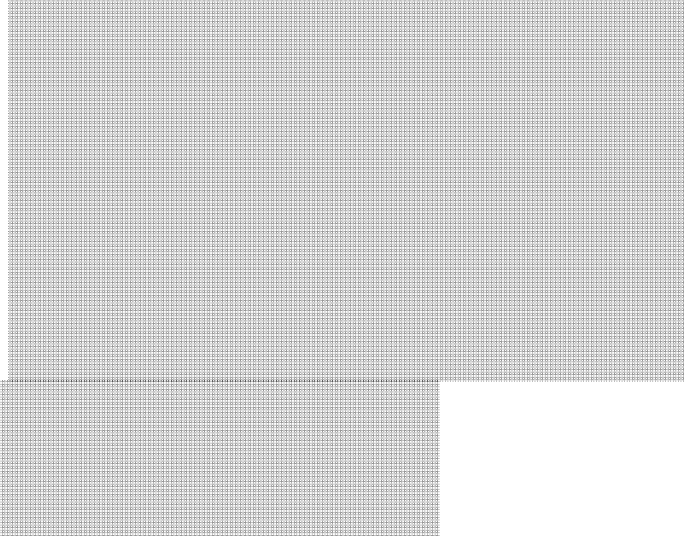
Competing Interests: None declared.

Yours sincerely, [REDACTED]

#### References

1. Canada Gazette, Part I. Feb 19 2011. Available from: <http://www.gazette.gc.ca/rp-pr/p1/2011/2011-02-19/pdf/g1-14508.pdf>
2. Albertson DN, Grubbs LE. 2009. Subjective effects of *Salvia divinorum*: LSD- or marijuana-like? *J Psychoactive Drugs*. 2009 Sep;41(3):213-7.
3. Killinger BA, Peet MM, Baker LE. 2010. Salvinorin A fails to substitute for the discriminative stimulus effects of LSD or ketamine in Sprague-Dawley rats. *Pharmacol Biochem Behav*. 96(3):260-5.
4. Health Canada, Drug and Alcohol Use Statistics, Major findings from the Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) 2009. Available from: <http://www.hc-sc.gc.ca/hc-ps/drugs-drogues/stat/index-eng.php>
5. Ibid.

6. Weir E. 2001. Inhalant use and addiction in Canada. *CMAJ* . 164(3):397.





**Fw: Salvia NOI Comments**  
Denis Arsenault to Jocelyn Kula  
Stephanie Chandler

2011-02-28 04:28 PM

Hi,

A couple of follow-up questions to my previous email:

- 1) While it appears we now have to include these comments/responses in MECS, do you think a physical docket is necessary for each of these?
- 2) One of the comments we received cc'd Jack Layton, Michael Ignatieff and other political figures. Do you think we should simply cc them in our response?

Denis

---

Denis Arsenault, A/Manager / Gestionnaire p.i.  
Regulatory Policy Division /  
Division des politiques réglementaires,  
Office of Controlled Substances /  
Bureau des substances contrôlées,  
Health Canada / Santé Canada  
Tel/Tél: (613) 957-6828  
Fax / Télécopieur : (613) 946-4224  
E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca  
----- Forwarded by Denis Arsenault/HC-SC/GC/CA on 2011-02-28 04:24 PM -----

From: Denis Arsenault/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2011-02-28 04:23 PM  
Subject: Salvia NOI Comments

Hi Jocelyn,

Just confirmed with Stephanie that we have received thus far 36 comments in response to the NOI. No responses to these have been sent thus far.

For now, Isabel will create MECS dockets as needed and Stephanie will coordinate with her to send responses and ensure these are also included in MECS.

Some of these comments are pressing as they ask for specific info (i.e. when does the comment period close?)

Denis

---

Denis Arsenault, A/Manager / Gestionnaire p.i.  
Regulatory Policy Division /  
Division des politiques réglementaires,  
Office of Controlled Substances /  
Bureau des substances contrôlées,  
Health Canada / Santé Canada  
Tel/Tél: (613) 957-6828

Fax / Télécopieur : (613) 946-4224  
E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca

Fw: LTE - Winnipeg Free Press

Jocelyn Kula Denis Arsenault, stephanie.chandler

2011-02-28 04:32 PM

Normal Priority.

for the file pls

Jocelyn Kula

Acting Director/ Directrice par intérim

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs

Health Canada/ Santé Canada

Tel: (613) 952-2177 Fax: (613) 946-4224

----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2011-02-28 04:32 PM -----

From: Dave Stephens/HC-SC/GC/CA  
To: jocelyn.kula@hc-sc.gc.ca, Suzanne Desjardins/HC-SC/GC/CA@HWC,  
brenda.paine@hc-sc.gc.ca, Jesse Arnup-Blondin/HC-SC/GC/CA@HWC,  
christine.roush@hc-sc.gc.ca, ken.polk@hc-sc.gc.ca  
Date: 2011-02-28 04:09 PM  
Subject: LTE - Winnipeg Free Press

not sure if it was picked up in the press clippings on Friday, but I found  
it on the paper's web site. It appears they took MP Glover's name off.  
I've included another letter on the same subject, that apparently didn't  
require the same # of approvals ;)

Letters to the Editor

Winnipeg Free Press - PRINT EDITION

Have your say

By: Staff Writer

Posted: 02/25/2011 1:00 AM | Comments: 6

· Powerful hallucinogen  
· We would like to respond to the Feb. 23 editorial No need to ban  
salvia on the Government of Canada's recent proposal to control salvia  
divinorum and salvinorin A.

· We want to eliminate the misconception that salvia is a safer  
alternative to street drugs.  
It is not.

Salvia divinorum, and its active ingredient salvinorin A, can produce  
powerful hallucinations similar to those associated with the use of the  
well-known hallucinogen LSD, which is a controlled substance. Other  
effects include confusion, disorientation and anxiety.  
In Canada, about seven per cent of youth aged 15 to 24 have tried salvia.  
This represents about 300,000 young people -- a rate that is similar to  
that for cocaine and ecstasy, and a rate much higher than that for LSD.  
The move to control these substances is also consistent with actions taken  
by several other countries, such as Australia, Belgium, Denmark, Finland,  
Germany, Italy, Japan, Norway, South Korea, Spain and Sweden. All have  
placed similar controls on the import and/or sale of salvia divinorum  
and/or salvinorin A. Some U.S. states have taken action to restrict their  
use, sale and/or distribution.

003012

Leona Aglukkaq  
Minister of Health  
Ottawa  
\*\*\*\*\*

Your Feb. 22 article Feds eye ban on obscure herb indicates a dangerous disconnect with reality and perception. Bart Stras, owner of the head shop The Joint, clearly has been smoking too much of his own product when he says "salvia has never had any issues as a herbal incense product." Of course it hasn't, because he knows that people who buy salvia want a hallucinogenic high and aren't looking to have their boudoir smell minty fresh. If it weren't so pathetic, it would be almost comical that salvia is sold as a so-called natural health product. I believe that poisonous mushrooms are also a 100 per cent natural product.  
Paul Doyle

Dave Stephens  
Senior Communications Executive-Gestionnaire Principal des Communications  
HECSB/DGSCSE  
Health Canada/Sante Canada  
6th Floor, Room 6-033, 269 Laurier Ave. W., Ottawa, ON  
Tel: (613) 946-8107  
Cell: (613) 859-3581



**Re: Salvia NOI Comments**  
Jocelyn Kula cc: Denis Arsenault  
Stephanie Chandler

2011-02-28 04:33 PM

should hear back from Jesse tomorrow- if not I will follow up  
for now, you can get responses ready to go in draft, but just don't hit send

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

Denis Arsenault Hi Jocelyn, Just confirmed with Stephanie that...

2011-02-28 04:23:32 PM

---

From: Denis Arsenault/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2011-02-28 04:23 PM  
Subject: Salvia NOI Comments

---

Hi Jocelyn,

Just confirmed with Stephanie that we have received thus far 36 comments in response to the NOI. No responses to these have been sent thus far.

For now, Isabel will create MECS dockets as needed and Stephanie will coordinate with her to send responses and ensure these are also included in MECS.

Some of these comments are pressing as they ask for specific info (i.e. when does the comment period close?)

Denis

---

Denis Arsenault, A/Manager / Gestionnaire p.i.  
Regulatory Policy Division /  
Division des politiques réglementaires,  
Office of Controlled Substances /  
Bureau des substances contrôlées,  
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Tel/Tél: (613) 957-6828  
Fax / Télécopieur : (613) 946-4224  
E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca

**Re: Question about Salvia IAS**   
Stephanie Chandler to: Hanan Abramovici

2011-03-02 12:11 PM

Hi Hanan,

Here is the most recent draft of the IAS, however, keep in mind that it has not been approved by the Director, OCS as it will have to be updated again once I have collected all the comments on the NOI.



Draft Salvia Divinorum IAS\_Jan 6 2011.doc

May I ask what you mean by scheduling decision...? Is Salvia going back to the CSS-WG?

Thanks,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

Hanan Abramovici Hi Stephanie, Do you have a copy of the latest S...

2011-03-02 12:06:14 PM

From: Hanan Abramovici/HC-SC/GC/CA  
To: Stephanie Chandler/HC-SC/GC/CA@HWC  
Date: 2011-03-02 12:06 PM  
Subject: Question about Salvia IAS

Hi Stephanie,

Do you have a copy of the latest Salvia IAS that you could send me? I think I'm going to have to review it in anticipation of the scheduling decision that's coming up.

Thanks very much,  
Hanan



# Issue Analysis Summary

DRAFT

## Scheduling *Salvia Divinorum* under the CDSA

Regulatory Policy Division  
Office of Controlled Substances

Controlled Substances and Tobacco and Directorate

January 6, 2011

Deleted: December

Deleted: 0

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### 1. APPROVALS

This Issue Analysis Summary is approved.

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Office of Controlled Substances  
Controlled Substances and Tobacco Directorate

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[DD/MM/2010]

### 2. ISSUE

Health Canada has received a number of enquiries from various municipalities and members of the public asking why Health Canada has not taken steps to control the availability of *Salvia divinorum* (*S. divinorum*) under the *Controlled Drugs and Substances Act* (CDSA). These requests are further to reports from scientific and media sources suggesting that *S. divinorum* is being used by youth specifically for its hallucinogenic properties. Health Canada has also noted an ongoing media interest regarding the availability of *S. divinorum* in Canada.

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### 3. PURPOSE

To assess *S. divinorum* against the criteria for the addition of a substance to one of the Schedules to the CDSA, and determine whether this substance should be regulated as a controlled substance in Canada.

### 4. CONTEXT

*S. divinorum* is a species of sage which belongs to the mint family, and which is found in the form of dried leaves, extracts and plant cuttings. Also called "diviner's sage", the plant is known to induce illusions and hallucinations when chewed or smoked. Salvinorin A, the psychoactive ingredient in *S. divinorum* is a neoclerodane diterpene which is found primarily in the leaves, and to a lesser extent in the stem of the plant.<sup>1</sup>

*S. divinorum* is widely touted as a "legal" hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs among adolescents and young adults.<sup>2</sup> While very little is known about how and where *S. divinorum* is sold in Canada, it is suspected that it is mainly purchased over the Internet and/or bought at head shops or alternative life style stores, etc. *S. divinorum* cuttings are also available from a number of garden supply companies.

*S. divinorum* is a substance not currently scheduled under the CDSA. It can be imported and sold legally in Canada to anyone of any age, anywhere in Canada provided it is not sold as a health product or marketed as a hallucinogen. In addition, the *S. divinorum* sold in Canada is currently not subject to any specific quality or safety standards.

The use of *S. divinorum* as a psychotropic agent first came to Health Canada's attention in 2002. In 2004, Health Canada received four adverse drug reaction (ADR) reports associated with the use of *S. divinorum* as a hallucinogen, with three being considered non-serious (requiring no medical attention) and the fourth being considered serious (medical intervention was required). The serious ADR report involved the concomitant use of alcohol in a person diagnosed with Attention Deficit Disorder.

Further to the receipt of the aforementioned ADRs, the Marketed Health Products Directorate (MHPD) and the Natural Health Products Directorate (NHPD) of the Health Products and Food Branch (HPFB) prepared an issue analysis summary (IAS) in November 2005, which recommended that *S. divinorum* and its active ingredient salvinorin A be regulated as controlled substances. This recommendation was maintained when the IAS was updated in November

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<sup>1</sup> U.S. Department of Justice Drug Enforcement Administration. 2002. Drugs and Chemicals of Concern: Salvia Divinorum (salvinorin A, divinorin A) URL:

[http://www.deadiversion.usdoj.gov/drugs\\_concern/salvia\\_d/salvia\\_d.htm](http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm) Nov 2008

<sup>2</sup> Dennehy CE, Tsourounis C, Miller AE. Evaluation of Herbal Dietary Supplements Marketed on the Internet for Recreational Use. *Annals of Pharmacotherapy*. 2005 Oct;39(10):1634-9.

2006.

Later, in December 2005, MHPD and NHPD prepared a Signal Assessment (SA) (updated in June 2007) that eventually led to the preparation of a Health Risk Assessment (HRA), which concluded that *S. divinorum* or salvinorin A-containing health products would constitute a Type II Health Risk according to the Health Hazard Classification set out in the Health Products and Food Branch Inspectorate (HBFBI) Recall Policy. Such a risk is defined as “a situation in which the use of, or exposure to, a product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote”.

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Further to a discussion with the Assistant Deputy Minister (ADM) of the Healthy Environments and Consumer Safety Branch (HECSB) in April 2007, the (then) Drug Strategy and Controlled Substances Directorate (DSCSD) (now the Controlled Substances and Tobacco Directorate, CSTD) organized a meeting with MHPD, NHPD and HPFBI to discuss *S. divinorum*. HPFBI was to determine appropriate compliance activities regarding *S. divinorum* and consult with the Canada Border Services Agency (CBSA) regarding the movement of products containing *S. divinorum* into and out of Canada.

On September 13, 2007, a further meeting between DSCSD, MHPD, NHPD and HPFBI led to the conclusion that DSCSD would conduct a scheduling assessment of *S. divinorum* in order to explore the possibility of scheduling this substance under the CDSA.

In September 2008, the Director Generals of DSCSD, MHPD, TPD and the HPFBI agreed that media lines and an “It’s Your Health” article on *S. divinorum* should be prepared.

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#### 4.1 Relevant Legislative Frameworks in Canada

##### 4.1.1 Food and Drug Regulations (under the Food and Drugs Act)

The *Food and Drug Regulations* (F&DR) serve to ensure the safety, efficacy, and quality of health products offered for sale in Canada, including drugs and medical devices. Prior to being given market authorization, a manufacturer must present substantive scientific evidence that their product is safe, efficacious and of high quality. For drugs, Health Canada reviews this information carefully and, if the review is satisfactory, a Notice of Compliance (NOC) is issued and appropriate Drug Identification Numbers (DINs) are assigned.

A “drug” is defined under the F&DR as any substance or mixture of substances manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
- (b) restoration, correction or modification of organic functions in human beings or animals, or

- (c) disinfection in premises in which food is manufactured, prepared or kept;

As no products containing *S. divinorum* or its extracts have been reviewed and approved by Health Canada as of October 2010, it is illegal to market *S. divinorum* when it is represented as a drug.

#### 4.1.2 Natural Health Products Regulations (under the Food and Drugs Act)

The *Natural Health Products Regulations* (NHPR) aim to provide Canadians with ready access to natural health products (NHPs) that are safe, effective, and of high quality, while respecting freedom of choice and philosophical and cultural diversity. The NHPR require that all licensed products display a Natural Product Number (NPN), or, in the case of a homeopathic medicine, a Drug Identification Number - Homeopathic Medicine (DIN-HM), on their labels. These numbers are issued once a product is authorized for sale in Canada. A product licence may be obtained pursuant to an application in which the applicant attests to all of the conditions set out in a natural health product monograph prepared and published by the Natural Health Products Directorate. Alternatively, an applicant may submit a product license application that provides evidence of quality, safety and efficacy that is assessed as being sufficient and approved by NHPD by the full submission route. The NHPR also require that all manufacturers, packagers, labelers, and importers have a site license issued on the basis of sufficient evidence of procedures respecting distribution records, product recalls, product handling, storage and delivery, and all other aspects of Good Manufacturing Practices as set out in the NHPR.

The definition of an NHP under the NHPR has both a function and substance component. The function component refers to those substances that are manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
- (b) restoring or correcting organic functions in humans; or
- (c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

The substance component refers to the requirement that all of the medicinal ingredients of an NHP must be substances set out in Schedule 1 (a list of included substances) to the NHPR, a traditional medicine or a homeopathic medicine, and none of the ingredients can be substances set out in Schedule 2, a list of excluded substances which includes any substance listed on Schedules I to V of the CDSA. Section 2(2) of the NHPR excludes those substances (except homeopathic medicines) whose sale is required to be pursuant to a prescription as per Section C.01.043 of the F&DR.

As per section 93(1)(b)(vi) of the NHPR, every natural health product must be labeled with its

authorized recommended use or purpose. Products that contain *S. divinorum* and that are manufactured, sold or represented for use as a hallucinogen meet the definition of an NHP.

Health Canada has not authorized for sale any natural health products containing *S. divinorum* or salvinorin A as an ingredient. Therefore, sales of *S. divinorum* are illegal under the NHPR if the product is represented for use as a hallucinogen or if other health claims are made.

#### 4.1.3 Controlled Drugs and Substances Act and its Regulations

The CDSA provides a legislative framework for the control of substances that can alter mental processes and that may produce harm to the health of an individual or to society when diverted or misused. Except as authorized under its regulations, activities such as possession, possession for the purposes of trafficking, trafficking, importation, exportation, possession for the purposes of exportation and production of controlled substances are prohibited under the CDSA.

The substances regulated under the CDSA are grouped into six Schedules, and each Schedule is associated with particular offences and penalties as described in Part I of the CDSA.

In determining whether a substance should be regulated as a controlled substance, and into which Schedule to the CDSA it should be placed, Health Canada considers the following factors:

- International requirements and trends in control and/or scheduling;
- Chemical and/or pharmacological similarity to substances listed in the Schedules to the CDSA;
- Legitimate use of the substance, including therapeutic, scientific, or industrial uses;
- Potential for abuse and/or addiction liability;
- Evidence of extent of actual abuse of the substance in Canada and internationally; and
- Risk to personal and public health and safety.

#### 4.2 Assessment of *S. Divinorum* for Scheduling Purposes

##### 4.2.1 International Requirements and Trends in Control and/or Scheduling

At the present time, neither *S. divinorum* nor salvinorin A are listed under the United Nations Drug Control Conventions and therefore do not have to be regulated as controlled substances in any of the countries (including Canada) that are signatories to these Conventions.

##### *Australia*

In June 2002, Australia became the first country to prohibit the sale, supply, possession and use of *S. divinorum* and salvinorin A. Both *S. divinorum* and salvinorin A are listed in Schedule 9 of Australia's *Standard for the Uniform Scheduling of Drugs and Poisons* on the basis of "high

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potential for abuse and risk to public health and safety.”<sup>3</sup> Schedule 9 is Australia’s most restrictive drug schedule, and includes “substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities.”<sup>4</sup>

### **Belgium**

A decree was passed in Belgium on October 22, 2006 which added *S. divinorum* to the list of controlled substances. This list includes substances such as psilocybin mushrooms, khat and peyote cactus.<sup>5</sup>

Comment [S1]: Spelling OK

### **Denmark**

In 2003, Denmark added *S. divinorum* and salvinorin A to their list of “category B” controlled substances, a category which also includes psilocybin mushrooms, cocaine, amphetamine, and several other substances that are only legal for medicinal and scientific purposes. Illegal possession carries a penalty of up to two years in prison.

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### **Germany**

*S. divinorum* (plant and plant parts) was added to Appendix I of the *Narcotics Act* in Germany on March 1, 2008, making it illegal to produce, traffic, or possess. The law does not specifically mention salvinorin A.

### **Italy**

On June 25, 2004, the Italian Ministry of Health issued an ordinance prohibiting the sale of *S. divinorum* and its active constituent salvinorin A. On January 11, 2005, the Ministry of Health made possession of *S. divinorum* and salvinorin A illegal by placing them in “*Tabella I*” of the *Tabella Sostanze Stupefacenti o Psicotrope*.

### **Japan**

On November 9, 2006, the Japanese government added a group of thirty-three drugs to its list of controlled substances, including salvinorin A. The drugs are banned under a revised pharmaceutical law, under which persons involved in their illegal import, production, and sale, i.e. beyond medical treatment or research purposes, will be subject to up to five years imprisonment or a fine of up to five million yen.

<sup>3</sup> <http://www.tga.gov.au/ndpsc/record/rr200111.pdf>

<sup>4</sup> [http://www.cognitiveliberty.org/news/salvia\\_australia.htm](http://www.cognitiveliberty.org/news/salvia_australia.htm)

<sup>5</sup> <http://eldd.emcdda.europa.eu/html.cfm/index5176EN.html?pluginMethod=eldd.shownewsdetails&id=20/12/2006BELGIUM:%20New%20substances%20controlled%20include%20mCPP%20and%20khat>

### **Spain**

On January 28, 2004, the Spanish Ministry of Health and Consumption issued an order prohibiting the sale of *S. divinorum*. The regulation went into effect on May 6, 2004 and only prohibits activities related to commerce. Possession and/or use are not considered to be criminal offences.

### **Other Countries**

It is illegal to possess or sell *S. divinorum* in Croatia, Latvia, Lithuania, Poland, Romania, South Korea and Sweden. In Russia it is illegal to grow or sell *S. divinorum*, but it is legal to possess it. In Estonia, Finland, Iceland and Norway, *S. divinorum* is treated as a medicinal herb and it is illegal to import it without a relevant prescription from a doctor.

### **United States of America**

*S. divinorum* and salvinorin A are not included in the Schedules to the United States *Controlled Substances Act*. Although both *S. divinorum* and salvinorin A have been added to a list of chemicals "of concern", this has no legal implications. According to the National Institute for Drug Abuse, the Drug Enforcement Administration is considering classifying *S. divinorum* and/or salvinorin A as Schedule I drugs. This Schedule includes substances such as LSD and marihuana.

At the state level, a number of state legislatures have implemented laws restricting the use, sale and/or distribution of *S. divinorum* and/or salvinorin A, including Delaware, Georgia, Florida, Hawaii, Illinois, Kansas, Kentucky, Maryland, Mississippi, Missouri, Nebraska, North Dakota, Ohio, Oklahoma, South Dakota, Wisconsin, Virginia, California, Louisiana, Maine, North Carolina, and Tennessee. By way of example, additional details regarding the regulation of *S. divinorum* in these last five states are provided below.

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#### **California**

As of January 1, 2009, the sale or distribution of *S. divinorum* or salvinorin A, or any substance or material containing *S. divinorum* or salvinorin A, to any person under 18 years of age is a misdemeanor punishable by imprisonment in a county jail for not more than six months, a fine of no more than \$1,000, or both.

#### **Louisiana**

In 2005, Louisiana passed a bill which prohibits the possession, production, manufacture and distribution of a material, compound, mixture, or preparation intended for human consumption and that contains a hallucinogenic plant. A "hallucinogenic plant" is defined as "any part or portion" of a plant on a list of forty plants, which includes *S.*

*divinorum*.

### **Maine**

In Maine, *S. divinorum* and salvinorin A are regulated in the same way as tobacco products; adults eighteen years of age or over can legally purchase and use the material, but selling or providing *S. divinorum* or salvinorin A to anyone under the age of eighteen is a criminal offence. Possession by a minor is a civil violation, punishable by a fine, community service, or both.

### **North Carolina**

On December 1, 2009, the North Carolina State Legislature brought a new law into force which made *S. divinorum* and salvinorin A illegal. The only legal *S. divinorum* activities are the growing for aesthetic, landscaping, or decorative purposes or university-affiliated medical or pharmacological research.

### **Tennessee**

On July 1, 2006, Tennessee classified the deliberate production, manufacture, distribution, or possession of the active chemical ingredient in the hallucinogenic plant *S. divinorum* as a Class A misdemeanor. It is not, however, a criminal offence to possess, plant, cultivate, grow, or harvest *S. divinorum* for aesthetic, landscaping, or decorative purposes. The law also does not apply to any dosage that is legally obtainable from a retail establishment without a prescription when (and if) it is recognized by the Food and Drug Administration as a homeopathic drug.

#### **4.2.2 Chemical and/or Pharmacological Similarity to Substances Listed in the Schedules to the CDSA**

The psychoactive ingredient in *S. divinorum* is the neoclerodane diterpene salvinorin A.<sup>6</sup> As a diterpene, salvinorin A is part of a family of substances that contain terpenoids. Another plant which contains psychotropic terpenoids is *Artemisia absinthium* (wormwood).<sup>7</sup> Salvinorin A is a hallucinogen with a distinct structure and it does not interact with the serotonin type-2A receptor or any other molecular target of classical hallucinogens.<sup>8</sup> Instead, the available research suggests that the psychotropic effects of salvinorin A are mediated by its agonistic actions at the  $\kappa$ -opioid (KOR) receptor.<sup>9</sup> Its mechanism of action is therefore unique.<sup>10</sup>

<sup>6</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage *Salvia divinorum*. *Life Sci.* 2005 Dec 22;78(5):527-31.

<sup>7</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.

<sup>9</sup> Roth BL, Baner K, Westkaemper R, Siebert D, Rice KC, Steinberg S, Ernsberger P, Rothman RB. Salvinorin A: a potent naturally occurring nonnitrogenous kappa opioid selective agonist. *Proc Natl Acad Sci U S A.* 2002 Sep 3;99(18):11934-9.



The psychoactive effects of *S. divinorum* vary in onset and duration and include perceptual distortions such as the sensation of becoming an object, having visions of various two-dimensional surfaces, films and membranes, revisiting places of the past (particularly childhood), perceived loss of the body and/or identity, various sensations of motion (being pulled or twisted by a force of some kind), uncontrollable hysterical laughter, and overlapping realities (perceptions of being in more than one place).<sup>11</sup> Laughter, happiness, a sense of well-being and dissociative effects were deemed the most positive aspects of *S. divinorum* by users, second only to the "trip" that the drug elicits.<sup>12</sup> Depersonalization, speaking gibberish, widening of consciousness and subjective illusions of rapid movement, flying or hovering have also been reported.<sup>13</sup>

The psychotomimetic effects of *S. divinorum* closely resemble the schizoid symptoms induced by lysergic acid diethylamide (LSD) or phencyclidine (PCP).<sup>14</sup> Yet, it is said to have only a weak influence on the prevailing mood of the user which differentiates it from other hallucinogens such as LSD and psilocybin.<sup>15</sup> Its strong dissociative effects are often compared to those of ketamine.<sup>16</sup> Users have reported that the psychedelic effects of *S. divinorum* were most similar to those caused by psilocybin mushrooms.<sup>17</sup> However, users familiar with the effects of other hallucinogens agree that despite certain similarities to classical hallucinogens, the visions and overall experience are quite unique.<sup>18</sup>

*S. divinorum* causes an unusually high degree of sedation, weakness and fatigue, and the increased de-realization is not commonly reported for classical psychedelics.<sup>19</sup> The combination

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<sup>10</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>11</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>12</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>13</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5 and Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>14</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of Salvia divinorum (Diviner's Sage). Pharmacopsychiatry. 2005 Jan;38(1):1-5.

<sup>15</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>16</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five Salvia divinorum herbal products. Pharmacotherapy. 2006 Sep;26(9):1268-72.

<sup>17</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>18</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6 and González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

<sup>19</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of Salvia divinorum among recreational users. Drug Alcohol Depend. 2006 Nov 8;85(2):157-62.

of these effects seems to correlate with that of other KOR agonists such as pentazocine.<sup>20</sup>

The onset and intensity of the effects of *S. divinorum* appear to be related to the route of administration. Traditional uses generally produce mild effects because the leaves are rolled and chewed or crushed and prepared as a foamy infusion whereby the salvinorin A is degraded in the gastrointestinal system before being absorbed into the bloodstream. Hence, the level of effect relates quite closely to the length of time the material spends in the mouth, with the onset of effect generally taking 5-10 minutes. The effects build over the next hour and last for another hour before they begin to subside.<sup>21</sup>

Routes of administration that avoid the hepatic first-pass effect (i.e. inhalation, intravenous, intramuscular and sublingual use) provide the quickest and most intense effect.<sup>22</sup> Salvinorin A can be isolated from the plant to make a powder which can be vaporized and inhaled. The effects felt from vaporizing salvinorin A are experienced in about 30 seconds, last for about 5-10 minutes, and then subside over the next 30 minutes.<sup>23</sup>

Smoking the dried leaves or a concentrated extract using a pipe or bong is by far the most popular method of administration.<sup>24</sup> Dried leaves may also be fortified with a concentrated extract of salvinorin A. A concentrated extract can also be used sublingually. Neither *S. divinorum* nor salvinorin A can be injected because they are insoluble in water.<sup>25</sup>

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#### 4.2.3 Legitimate Use of the Substance (Therapeutic, Scientific, Industrial)

*S. divinorum* has traditionally been used for spiritual and medicinal purposes by the Mazatec Indians in Oaxaca, Mexico.<sup>26</sup> For medicinal purposes (gastrointestinal problems, headaches, rheumatism, anemia and swelling of the stomach) an infusion of the leaves or the leaves themselves are ingested.<sup>27</sup> However, its main use in Mexico today is believed to be for its

<sup>20</sup> Arasteh K, Poudevida S, Farre M, Roset PN, Cami J. Response patterns of the Spanish version of the 49-item short form of the Addiction Research Center Inventory after the use of sedatives, stimulants, and opioids. *Drug Alcohol Depend.* 1999 Jun 1;55(1-2):117-25.

<sup>21</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>22</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy.* 2006 Sep;26(9):1268-72.

<sup>23</sup> Siebert DJ. *Salvia divinorum* and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>24</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62 and Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico. 2004.

<sup>25</sup> Valdés LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs.* 1994 Jul-Sep;26(3):277-83.

<sup>26</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.* 2006 Nov 8;85(2):157-62.

<sup>27</sup> Munro, T. *The Chemistry of Salvia divinorum*. PhD dissertation, 2006. Accessed from: <http://eprints.infodiv.unimelb.edu.au/archive/00002327/01/Munro2006thesis.pdf> February 2007.

psychedelic properties in the aid of producing "mystical" or hallucinogenic experiences as part of spiritual rituals.<sup>28</sup>

Although selective KOR agonists have been shown to produce analgesic effects, adverse effects such as psychotomimesis, dysphoria and diuresis have been observed in studies investigating their therapeutic use.<sup>29</sup> In addition, while it has been speculated that KOR agonists may be useful in the treatment of certain psychiatric disorders including Alzheimer's disease, schizophrenia, dementia and bipolar disorder, there has been no clinical research to support these hypotheses.<sup>30</sup> There are presently no recognized medical uses for *S. divinorum* in Canada.

Similarly, there are no known industrial or commercial uses for *S. divinorum* in Canada. Most websites offering *S. divinorum* cuttings and seeds for sale appear to do so in the context of growing the plant for "recreational" purposes, rather than out of horticultural interest or for its esthetic appeal. However, it should be acknowledged that this does not preclude the possibility of a person growing this plant for purely decorative purposes. *S. divinorum* is also marketed as incense. However, there is no evidence that *S. divinorum* has any fragrant properties that would legitimize such a use. Therefore it is believed that the marketing of this plant as an incense is a means to avoid compliance and enforcement actions by Health Canada.

#### 4.2.4 Potential for Abuse and/or Addiction Liability

Salvinorin A is a potent, KOR-selective agonist and in contrast to the euphoria produced by  $\mu$ -opioid receptor (MOR) agonists such as morphine, KOR agonists are negatively reinforcing and aversive.<sup>31</sup> In addition, KOR agonists have analgesic properties, but are not associated with respiratory depression like MOR agonists.<sup>32</sup> Finally, while MOR agonists increase the release of dopamine, the activation of KOR decreases dopamine release in the nucleus accumbens.<sup>33</sup> In the case of MOR agonists, the increase of dopamine acts as a positive reinforcer. This action motivates the user to use the drug again, which could lead to drug abuse and/or addiction. For KOR agonists, this is not the case.

<sup>28</sup> Prisinzano TE. Psychopharmacology of the hallucinogenic sage *Salvia divinorum*. *Life Sci.* 2005 Dec 22;78(5):527-31.

<sup>29</sup> Barker RL, Fawcett J, Barkin SJ. 2002. Chronic pain management with a focus on the role of newer antidepressants and centrally acting agents. In: *Pain Management: A Practical Guide for Clinicians*, 6th edition, Weiner RS ed. CRC Press, Boca Raton, FL. pp. 415-34 and Tidgewell et al., 2004. A facile method for the preparation of deuterium labelled salvinorin A: *Biorganic & Medicinal Chemistry Letters*, 14: 5099-5102.

<sup>30</sup> Sheffler DJ & Roth BL. Salvinorin A: the 'magic mint' hallucinogen finds a molecular target in the kappa opioid receptor. *Trends Pharmacol Sci.* 2003 Mar;24(3):107-109.

<sup>31</sup> Killinger BA, Peet MM, Baker LE. Salvinorin A fails to substitute for the discriminative stimulus effects of LSD or ketamine in Sprague-Dawley rats. *Pharmacology, Biochemistry & Behaviour.* 2010 May 96; 260-265.

<sup>32</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.

<sup>33</sup> Gustein HB & Akil H. Opioid Analgesics. In: *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 11th Ed. Brunton LL, Lazo JS and Parker KL (editors). McGraw-Hill, New York, USA, 2006, pp. 547-590.

The aversive effects of KOR agonists suggest that the risk of addiction to *S. divinorum* is negligible. Users have reported the negative effects of *S. divinorum* as: the short duration of action, lack of control over the experience, persisting negative effects (most often anxiety),<sup>34</sup> sweating, chills, increased diuresis, impaired vigilance,<sup>35</sup> and negative after-effects including tiredness, feeling head heavy, dizziness, physical exhaustion, and some degree of malaise or 'hangover' as they 'comedown' from the drug.<sup>36</sup> Despite these reports, very few controlled scientific studies of the physical and psychotropic effects of *S. divinorum* on humans have been carried out and the results have been conflicting. For example, one author states: "Many who have used salvinorin A find the experience extremely unnerving, frightening and overly intense and most have no desire to repeat the experience."<sup>37</sup> However, another study suggested that this is not the experience of all recreational users of *S. divinorum*.<sup>38</sup> Over eighty percent of users surveyed on a web-based questionnaire about their *S. divinorum* use said that they would probably or definitely use *S. divinorum* again.<sup>39</sup>

In addition, some users have noted that they require increasing doses of salvinorin A in order to achieve the desired effect and the stimulated cerebral KOR may act as a mechanism of tolerance.<sup>40</sup> Therefore, it is difficult to predict with certainty its potential for addiction and abuse. In studies that have been conducted, there is conflicting information around the addiction liability of *S. divinorum* in both animals and humans. Further studies in this area and on the KOR mediated decrease of dopamine are also required in order to fully understand the addiction potential of this substance.

While concerns for the potential of abuse were initially considered minimal given that 1 kg of dried leaves only yields 3 to 6 human doses of salvinorin A for oral consumption, it was then discovered that vaporizing and inhaling 200-500 micrograms has profound hallucinogenic

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<sup>34</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>35</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

<sup>36</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62.

<sup>37</sup> Turner DM. *Salvinorin - The Psychedelic Essence of Salvia Divinorum*. Panther Press, San Francisco, CA 1996.

<sup>38</sup> González D, Riba J, Bouso JC, Gomez-Jarabo G, Barbanoj MJ. Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend*. 2006 Nov 8;85(2):157-62, Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5, and Valdés LJ 3rd. *Salvia divinorum* and the unique diterpene hallucinogen, Salvinorin (divinorin) A. *J Psychoactive Drugs*. 1994 Jul-Sep;26(3):277-83.

<sup>39</sup> Baggot MJ, Erowid E, Erowid F and Mendelson JE. Poster presented at the meeting of The College on Problems of Drug Dependence (CPDD), in San Juan, Puerto Rico, 2004.

<sup>40</sup> Bücheler R, Gleiter CH, Schwoerer P, Gaertner I. Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsychiatry*. 2005 Jan;38(1):1-5.

effects.<sup>41</sup> Given that only small doses of this substance are necessary to achieve the desired effects through inhalation, the potential for abuse is much higher. Also, the extraction of salvinorin A from the plant is simple, and with care, approximately 1.5 grams of pure salvinorin A per kilogram of dried leaves (8kg of fresh leaves) can be isolated. This is enough for 2000 oral doses.<sup>42</sup>

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#### 4.2.5 Evidence of Extent of Actual Abuse of the Substance in Canada and Internationally

In Canada, the prevalence of use of *S. divinorum* has recently been documented. Questions about the use of salvia were included in the 2009 Ontario Student Drug Use and Health Survey, the 2008-2009 Youth Smoking Survey and the 2009 Canadian Alcohol and Drug Use Monitoring Survey.\*

The results from the 2009 Ontario Student Drug Use and Health Survey were published on November 18, 2009 and indicate that:

- Among all responding students in Ontario, 4.4% reported using *S. divinorum* at least once in the past year. In comparison, 58.2% indicated they had used alcohol, 25.6% indicated they had used cannabis and 5.0% indicated they had used hallucinogens other than LSD and PCP in the past year;
- Males (6.2%) were significantly more likely than females (2.3%) to report using *S. divinorum*;
- There is significant grade variation, with *S. divinorum* use most likely among 11<sup>th</sup> graders (8.6%) and 12<sup>th</sup> graders (8.4%); and

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The results of the 2008-2009 Youth Smoking Survey were published on May 31, 2010 and indicate that:

- 4.9% of students stated that they had used salvia in the last twelve months. In comparison, 53.0% indicated they had used alcohol, 27.3% indicated they had used cannabis and 6.9% indicated they had used other hallucinogens in the last twelve months;
- 2.6% of students in Grades 7-9 and 7.0% of students in Grades 10-12 had used salvia in the last twelve months; and
- Males (6.6%) were more likely to have used salvia in the past twelve months compared to females (3.2%).

<sup>41</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. J Ethnopharmacol. 1994 Jun;43(1):53-6.

<sup>42</sup> Valdés LJ 3rd. Salvia divinorum and the unique diterpene hallucinogen, Salvinorin (divinorin) A. J Psychoactive Drugs. 1994 Jul-Sep;26(3):277-83.

\* It should be noted that in some cases it is not clear if responses indicate the use of *S. divinorum* or salvinorin A given the use of the term "salvia" within the survey question.

The Canadian Alcohol and Drug Use Monitoring Survey specifically examined salvia for the first time in 2009. An estimated 1.6% of Canadians, aged 15 years and older, reported that they had used salvia in their lifetime, and 0.2% reported using it in the past-year. In comparison, the prevalence of past-year cannabis use among Canadians 15 years of age and older was 10.6%, while 1.2% of respondents reported using cocaine or crack in the past 12 months, 0.9% ecstasy and 0.7% illicit hallucinogens. In conclusion, 'salvia' appears to be a substance that is tried largely by youth with a 7.3% prevalence of lifetime use.

According to the 2009 Monitoring the Future survey, the annual prevalence of use of *S. divinorum* among 12th graders in the United States is 5.7%. The American Substance Abuse and Mental Health Services Administration's 2006 National Survey on Drug Use and Health found that, of respondents aged 12 or older, 1.8 million had used *S. divinorum* at least once in their lifetime and 756,000 had used the substance in the past year. Among youth aged 12 to 17, males were more likely than females to have used *S. divinorum* in the past year (0.9% vs. 0.3%).

Health Canada's Drug Analysis Services (DAS) has identified salvinorin A in a number of samples seized by law enforcement, ranging from 9 samples in 2006 to 20 samples in 2009. It is, however, difficult to determine how this data reflects the extent of actual abuse of salvinorin A in Canada, given that it is not an illegal substance and would likely only have been seized accidentally or during the seizure of other controlled substances.

Between 2003 and 2009, the Border Integrity Unit of the Health Products and Food Branch Inspectorate (HPFBI) reported a total of 26 (23 refused, 3 released) records of imports and attempted imports of *S. divinorum* products. These records represent British Columbia and Ontario only however, and data for other provinces is not available. However, the practice of recording imports has since been replaced by a national database in which only refused shipments are tracked. As of November 2010, there is no record of a refused shipment of *S. divinorum* in the national database. This may reflect decreased volume of incoming shipments, decreased referral of such shipments by Canada Border Services Agency (CBSA), or adaptation by importers/sellers to import requirements (e.g. labelling as incense).

Deleted: that  
Deleted: alvia  
Deleted: in their databases  
Deleted: . D  
Deleted: alvia

The National Forensic Laboratory Information System (NFLIS) and the System to Retrieve Information from Drug Evidence (STRIDE) in the United States are Drug Enforcement Administration (DEA) databases that collect scientifically verified data on analyzed samples in state and local forensic labs as well as samples from DEA labs. While in 2000 no seized samples were found to contain *S. divinorum* or salvinorin A, 70 samples tested positive in 2008. Once again, it is difficult to determine how this data can be used to reflect the actual extent of abuse of *S. divinorum* and salvinorin A in the United States as neither substance is listed in the *Controlled Substances Act*.

The increase in both the number of enquiries to Health Canada from various municipalities and members of the public and the amount of media interest regarding the availability of *S. divinorum* in Canada may be an indication that the recreational use of *S. divinorum* as a hallucinogen is on the rise. However, it may also reflect an increased awareness of the phenomenon, rather than an increased incidence of use.

#### 4.2.6 Risk to Personal and Public Health and Safety

The potential for harm to the user and/or other individuals is primarily related to the hallucinogenic properties of the substance. As this substance is typically smoked, there is no risk of infectious disease transmission as is the case when a drug is injected. Users may get up and walk around without apparent awareness of their movements, behaviour or surroundings, and distinction between self and surroundings is often lost. At doses greater than 1mg of salvinorin A, out of body experiences are frequent and loss of consciousness has been reported.<sup>43</sup> There is little information regarding the social behaviours of persons under the influence of *S. divinorum* products, and what risks their activities such as operating a motorized vehicle may pose to the general public. There is also very little data regarding the toxicity, teratogenicity or other long-term effects of *S. divinorum* use.<sup>44</sup>

As far as law enforcement is concerned, the Department has only received a limited number of communications indicating concern with respect to *S. divinorum*. The Royal Canadian Mounted Police (RCMP) has stated that while *S. divinorum* is readily available, it has not become a popular drug in Canada, probably due to its aversive effects such as anxiety and introversion.

A handful of case reports regarding physiological and psychotropic effects of *S. divinorum* use have been published in the scientific/medical literature. For example, an international case report described the perceptions of a 19 year-old man after inhaling *S. divinorum* smoke. The peak psychotropic effects, including prickling of the skin, fever-like hot flashes, muscular tremor, and depersonalization, were reached in less than five minutes after inhalation of an unknown amount of smoke from burning dried leaves.<sup>45</sup> Another report involved a 15-year-old male who presented to psychiatric emergency services with acute onset of paranoia, déjà vu, blunted affect, difficulties in thought processing and slowed speech after smoking *S. divinorum* over an unknown period of time. During his hospitalization all symptoms improved significantly except the feeling of déjà vu. Based on this case presentation, the author suggested that the feelings of déjà vu may be a long-term effect of *S. divinorum* use.<sup>46</sup> However, given that this is the only case report in which déjà vu was associated with the use of *S. divinorum*, more reports are needed to substantiate this finding.

In addition to the above-mentioned reports, in 2006, a case was reported in the U.S. in which a 17-year-old boy committed suicide after smoking *S. divinorum* for an unknown period of time.<sup>47</sup> It should be noted that alcohol and general depression were the main confounders in this case. After this case was reported, the state of Delaware passed a law which classified *S. divinorum* as a Schedule I controlled substance along with other hallucinogenic substances.

Like many drugs of abuse, users are often unaware of the potency and adulterants in the product they purchase. A study by Wolowich *et al.* (2006), showed that the salvinorin A content in five

<sup>43</sup> Siebert DJ. Salvia divinorum and salvinorin A: new pharmacologic findings. *J Ethnopharmacol.* 1994 Jun;43(1):53-6.

<sup>44</sup> Grundmann O, Phipps SM, Zadezensky I, Butterweck V. *Salvia divinorum* and Salvinorin A: An Update on Pharmacology and Analytical Methodology. *Planta Med* 2007 Jun;73:1039-1046.

<sup>46</sup> Singh S. (2007) Adolescent salvia substance abuse. *Addiction.* 102, 823-824.

<sup>47</sup> <http://www.kvbc.com/Global/story.asp?S=4893692>

out of five *S. divinorum* products was falsely indicated on the label and 4 out of 5 products contained unidentified adulterants (i.e. vitamin E, caffeine).<sup>48</sup>

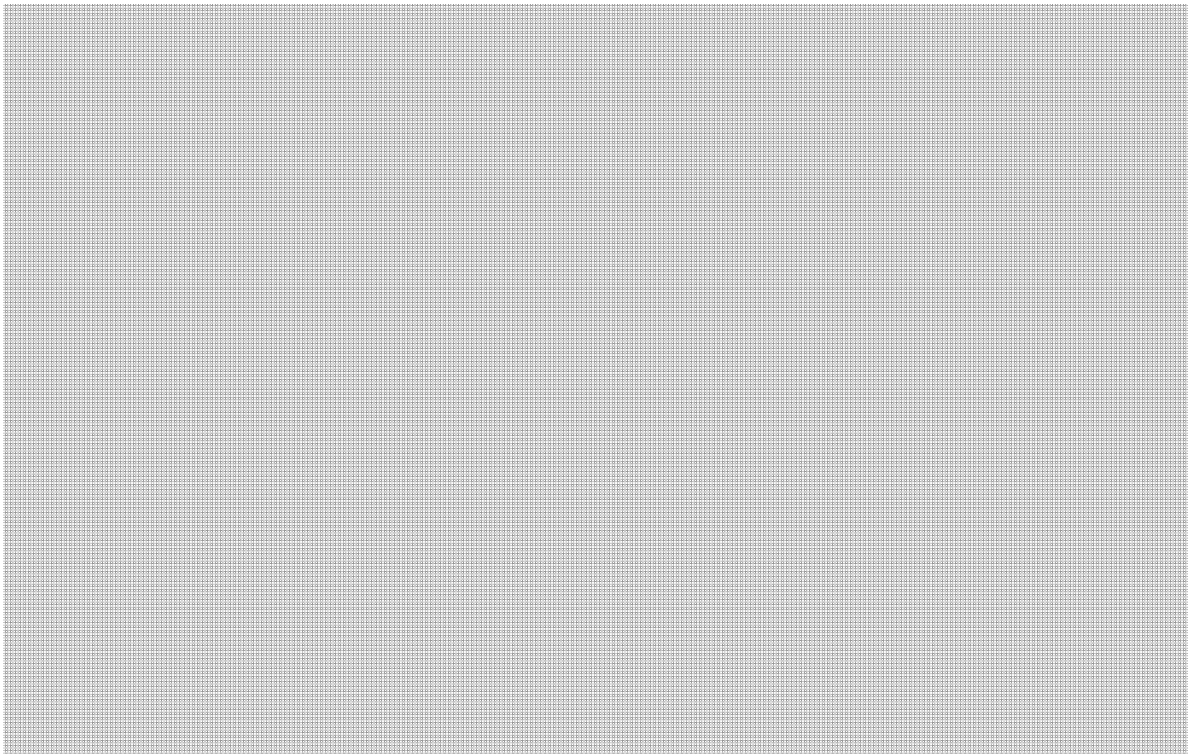
There are also several reports of domestic adverse reactions related to the use of *S. divinorum* that have been received through the Canada Vigilance database. However, this does not reflect true incidence due to under-reporting.

s.21(1)(a)  
s.21(1)(b)

**5. ASSESSMENT OF RISKS AND BENEFITS**



**6. IDENTIFICATION AND ANALYSIS OF OPTIONS**



<sup>48</sup> Wolowich WR, Perkins AM, Cienki JJ. Analysis of the psychoactive terpenoid salvinatorin A content in five *Salvia divinorum* herbal products. *Pharmacotherapy*. 2006 Sep;26(9):1268-72.



s.21(1)(a)

s.21(1)(b)

## 7. CONSIDERATIONS

The NHPR are limited in their capacity to control the availability of *S. divinorum* in that *S. divinorum* products are often declared as incense and therefore cannot be considered unapproved natural health products. In addition, compliance and enforcement actions such as voluntary stop-sales, forfeiture, destruction, and administrative seizure, cannot be implemented unless the marketing of the product indicates that it is to be sold for human consumption in order to modify an organic function. Moreover, while the sale of unauthorized natural health products containing *S. divinorum* or its active ingredient salvinorin A may be subject to such actions by Health Canada under the *Food and Drugs Act* (FDA), the penalties applicable to incidences of unauthorized sale under the FDA are very low and would likely not deter a retailer from continuing to market unauthorized products. Unlicensed natural health products are also permitted to be imported provided they are for personal use only.

Field Code Changed

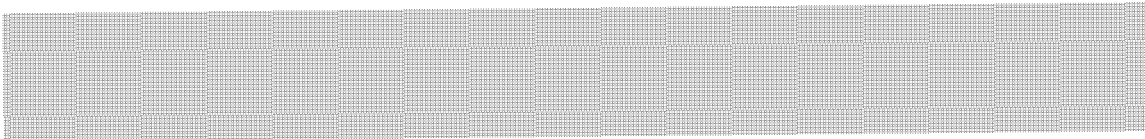
Non-regulatory options for the control of *S. divinorum*, such as the development of an educational campaign to highlight the risks associated with using this plant, were also considered. However, the risks associated with this substance, as well as the confusion concerning its enforcement as a natural health product only when it is sold for use with a health claim, do not make this option viable.

*S. divinorum* meets the criteria for scheduling a substance under the CDSA. While neither the plant nor its main active component salvinorin A are scheduled under any of the UN Drug Control Conventions, a number of countries and American states have taken steps to control the distribution and use of these substances. *S. divinorum* and salvinorin A are pharmacologically similar to other substances included in Schedule III to the CDSA, such as LSD and psilocybin. There are also currently no legitimate therapeutic, commercial or industrial uses for *S. divinorum*.

While the addiction potential of *S. divinorum* appears to be low, there is a significant potential for its abuse as a 'legal' hallucinogen. There is very little information with regards to the long-term effects of *S. divinorum* use. There is also evidence of use, particularly by Canadian youth and potential for individual health risks as well as risks to public health and safety.

In light of a recommendation to include *S. divinorum* under Schedule III to the CDSA, it is also recommended that the main psychoactive ingredient of this plant, salvinorin A, be scheduled. Salvinorin A can easily be extracted from *S. divinorum* and this substance gives the plant its hallucinogenic properties. Therefore the use of salvinorin A poses the same risks as *S. divinorum* and should also be controlled under the CDSA in the same manner as *S. divinorum*.

## 8. RECOMMENDATIONS



s.21(1)(a)  
s.21(1)(b)

## 9. CONSULTATIONS

The Drug Analysis Services (DAS) was contacted in order to provide any data available regarding the identification of salvinorin A in samples submitted by law enforcement.

The Royal Canadian Mounted Police (RCMP) was contacted in order to establish their views with respect to *S. divinorum* use in Canada. The RCMP advised that *S. divinorum* is readily available and law enforcement agencies have no legal means to prevent its sale.

OCS has received a number of correspondences from Canada Border Services Agency (CBSA) officers concerning a lack of information regarding the status of *S. divinorum* and how the plant should be treated at the border. At present, only shipments of *S. divinorum* that are represented for sale as health products that modify organic functions can be refused for import under the NHPR.

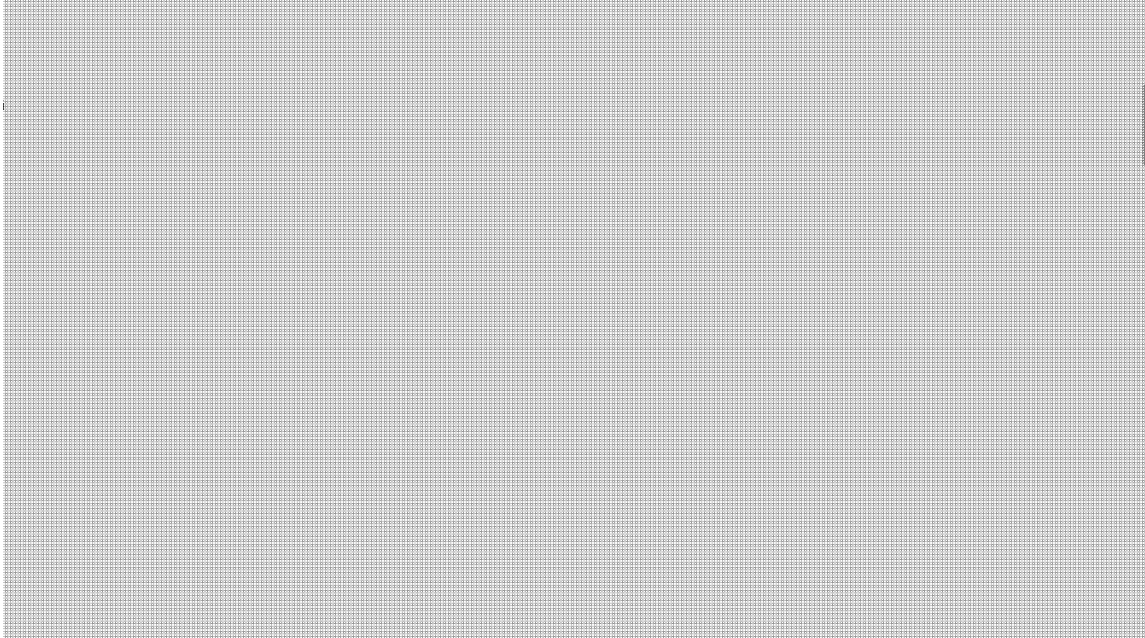
**Deleted:** CBSA officers have also expressed concern regarding the plant's hallucinogenic properties.

OCS brought *S. divinorum* to the Controlled Substances Scheduling Working Group (CSS-WG) in August 2010 to discuss the possibility of regulatory control of this substance. After assessing the available information against the six criteria listed in the Context section of this Issue

Analysis Summary, the CSS-WG recommended that *S. divinorum* be added to Schedule III to the CDSA.

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**10. IMPLEMENTATION AND EVALUATION**



**s.21(1)(a)**  
**s.21(1)(b)**

s.23



**Fw:** [REDACTED]  
Denis Arsenault to Stephanie Chandler

2011-03-02 02:19 PM

Follow Up: Normal Priority.

Hi Stephanie,

[REDACTED]

Denis

Denis Arsenault, A/Manager / Gestionnaire p.i.  
Regulatory Policy Division /  
Division des politiques réglementaires,  
Office of Controlled Substances /  
Bureau des substances contrôlées,  
Health Canada / Santé Canada  
Tel/Tél: (613) 957-6828  
Fax / Télécopieur : (613) 946-4224  
E-Mail/Courriel: denis\_arsenault@hc-sc.gc.ca

----- Forwarded by Denis Arsenault/HC-SC/GC/CA on 2011-03-02 02:18 PM -----

From: Chantal Trepanier/HC-SC/GC/CA  
To: Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2011-03-02 11:50 AM  
Subject: [REDACTED]

Bonjour Denis,

[REDACTED]

Chantal  
Tél/Tel: 613 946-5682  
Télec/Fax: 613 954-9485

Solicitor-Client Privilege/Protected

This message is intended for the use of the individual or entity to which it is addressed and may contain information that is privileged or confidential and exempt from disclosure under applicable law. Unauthorized disclosure, copying or re-transmission is prohibited. Modification of the transmission is prohibited. If you have received this transmission in error, please notify me immediately by sending me a

return e-mail copy. Then, delete the original message. Thank you.

**Secret professionnel de l'avocat/Protégé**

Cette communication est exclusivement destinée à l'individu ou l'entité à qui elle est adressée. Elle peut contenir de l'information privilégiée, confidentielle et ne pouvant être divulguée selon la loi applicable à l'espèce. Toute divulgation non-autorisée est défendue. Toute copie non-autorisée ou re-transmission non-autorisée de ce message sont défendues. Si vous avez reçu cette communication par erreur, veuillez m'en aviser immédiatement par retour de courriel. Puis, supprimez le courriel reçu. Merci.

s.19(1)

**RPD Telephone Enquiry**

**Date of Call:** March 3, 2011

**Subject:** Publication of Salvia NOI

**Language of Correspondence:** English

**Caller Name:** [REDACTED]

**Caller Organization:** [REDACTED]

**Caller Telephone Number:** [REDACTED]

**CALL SUMMARY:**

[REDACTED] had a number of questions with regards to the publication of the *Salvia divinorum* Notice to Interested Parties (NOI). He first wished to confirm the final date to submit comments, which I informed him was March 21, 2011. He also wanted to know how he could go about submitting comments, and I informed him that he could submit comments by mail, email or fax. [REDACTED] also asked if Health Canada was currently looking at scheduling any other plants similar to *S. divinorum*. I told him that while I was not in a position to answer that question, if we were to look at the scheduling of a plant it would undergo a separate scheduling assessment separate from *S. divinorum*. [REDACTED] also indicated that he had sent an email to the OCS PRAD email account, and I informed him that he would receive an acknowledgement shortly. The caller then asked me whether making all activities with *S. divinorum* illegal or not scheduling *S. divinorum* were the only two options Health Canada could possibly move forward with. I told him that after a review of the comments received from the NOI, Health Canada could potentially consider other regulatory options or schedules for the plant. He also wanted to know when *S. divinorum* would be considered illegal. I informed him that a regulatory process typically takes 18 to 24 months to complete. [REDACTED] thanked me for returning his call and indicated that he would be submitting comments on the NOI.

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division  
Office of Controlled Substances

**Re: Salvia responses and dockets**

Jesse Arnup-Blondin to: Jocelyn Kula  
CSTD-DGO, jeannine.ritchot, Michael Assad, Paula Robert,  
stephanie.chandler, Denis Arsenault, Arafo Talane

2011-03-03 12:03 PM

Priority: Normal Priority.

Summary: This message has been forwarded.

Just heard back from ECD. On a go forward basis, they will keep all letters with comments on salvia NOI, and will reply with the standard. We'll still need the letter below to be approved by MO up the line before it starts being used for Ministerial letters, but hopefully it will be approved.

For the ones you already have, just use this response for all.

Jocelyn Kula      Excellent, and thank you. Stephanie/Denis- ple...      2011-03-03 11:31:15 AM

From: Jocelyn Kula/HC-SC/GC/CA  
To: Jesse Arnup-Blondin/HC-SC/GC/CA@HWC  
Cc: CSTD-DGO, jeannine.ritchot@hc-sc.gc.ca, Michael Assad/HC-SC/GC/CA@HWC, Paula Robert/HC-SC/GC/CA@HWC, stephanie.chandler@hc-sc.gc.ca, Denis Arsenault/HC-SC/GC/CA@HWC, Arafo Talane/HC-SC/GC/CA@HWC  
Date: 2011-03-03 11:31 AM  
Subject: Re: Salvia responses and dockets

Excellent, and thank you.  
Stephanie/Denis- please note, and you can start rolling out, Please also revise translation. DO will now forward ministerial dockets.

Jocelyn

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

Jesse Arnup-Blondin      Hi Jocelyn - Sorry about the delay in getting...      2011-03-03 11:17:51 AM  
Jocelyn Kula      Hi Jesse Just wondering if there was any decisi...      2011-03-03 10:56:26 AM

**Re: Fw: CBC.ca/health - Move to ban hallucinogenic herb questioned** 

Dave Stephens (cc) Jocelyn Kula

2011-03-03 12:12 PM

Christine Roush, Denis Arsenault, Stephanie Chandler

Follow Up

Normal Priority.

Thanks Jocelyn.

Given the unlikelihood that we'd get approval to send a correction, I think we should let it go.

Dave Stephens

Senior Communications Executive-Gestionnaire Principal des Communications HECSB/DGSCSE

Health Canada/Sante Canada

6th Floor, Room 6-033, 269 Laurier Ave. W., Ottawa, ON

Tel: (613) 946-8107

Cell: (613) 859-3581

Jocelyn Kula

Am unclear what you mean by "removing the Fe...

2011-03-03 12:07:48 PM

From: Jocelyn Kula/HC-SC/GC/CA

To: Dave Stephens/HC-SC/GC/CA@HWC

Cc: Christine Roush/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC

Date: 2011-03-03 12:07 PM

Subject: Re: Fw: CBC.ca/health - Move to ban hallucinogenic herb questioned

Am unclear what you mean by "removing the Feb 4 date" as that is unfortunately how all NOIs are published, and we would have to go through departmental approvals to republish an NOI without that date, ie. the content of the doc is not in our hands, it is with the Gazette Office.

In this regard, I think asking the outlets to issue a correction would be better. Or we just suck it up and move on. I personally, don't think the date is what is influencing people whether to write or not!

JK

Jocelyn Kula

Acting Director/ Directrice par intérim

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs

Health Canada/ Santé Canada

Tel: (613) 952-2177 Fax: (613) 946-4224

Dave Stephens

an alternative would be to contact the media outl...

2011-03-03 12:02:47 PM

Christine Roush

Dave - once again, this CBC story reports the wr...

2011-03-03 12:01:18 PM



s.19(1)



**Re: Fw: Salvia responses and dockets** 

Jocelyn Kula to: Stephanie Chandler

Cc: Denis Arsenault

2011-03-03 01:30 PM

Normal Priority.

Yes we use the same response for ministerial dockets (until told otherwise or it comes back on approvals) and for PRAD account emails.....

Yes you can call the person back, but if he gives you a rant about scheduling and why, just listen and acknowledge his concerns.....do not attempt to defend the Dept's actions.....

JK

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

Stephanie Chandler Hi Jocelyn, As the email trail below seems to s...

2011-03-03 12:59:58 PM

---

From: Stephanie Chandler/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2011-03-03 12:59 PM  
Subject: Fw: Salvia responses and dockets

Hi Jocelyn,

As the email trail below seems to specifically address the ministerial dockets, I would just like to confirm that RPD is cleared to go ahead sending the standard response (with Jesse's revision) to the emails that have been received to the OCS PRAD account.

I have also received a phone call from [REDACTED]  
According to his voicemail he just had general questions regarding the NOI process. I will return his call this afternoon unless you have any concerns?

Thanks,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224

003040

E-Mail: stephanie.chandler@hc-sc.gc.ca

----- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2011-03-03 12:55 PM -----

From: Jesse Arnup-Blondin/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: CSTD-DGO, jeannine.ritchet@hc-sc.gc.ca, Michael Assad/HC-SC/GC/CA@HWC, Paula Robert/HC-SC/GC/CA@HWC, stephanie.chandler@hc-sc.gc.ca, Denis Arsenault/HC-SC/GC/CA@HWC, Arafo Talane/HC-SC/GC/CA@HWC  
Date: 2011-03-03 12:03 PM  
Subject: Re: Salvia responses and dockets

Just heard back from ECD. On a go forward basis, they will keep all letters with comments on salvia NOI, and will reply with the standard. We'll still need the letter below to be approved by MO up the line before it starts being used for Ministerial letters, but hopefully it will be approved.

For the ones you already have, just use this response for all.

Jocelyn Kula                      Excellent, and thank you. Stephanie/Denis- ple...                      2011-03-03 11:31:15 AM

From: Jocelyn Kula/HC-SC/GC/CA  
To: Jesse Arnup-Blondin/HC-SC/GC/CA@HWC  
Cc: CSTD-DGO, jeannine.ritchet@hc-sc.gc.ca, Michael Assad/HC-SC/GC/CA@HWC, Paula Robert/HC-SC/GC/CA@HWC, stephanie.chandler@hc-sc.gc.ca, Denis Arsenault/HC-SC/GC/CA@HWC, Arafo Talane/HC-SC/GC/CA@HWC  
Date: 2011-03-03 11:31 AM  
Subject: Re: Salvia responses and dockets

Excellent, and thank you.

Stephanie/Denis- please note, and you can start rolling out, Please also revise translation. DO will now forward ministerial dockets.

Jocelyn

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

Jesse Arnup-Blondin                      Hi Jocelyn - Sorry about the delay in getting...                      2011-03-03 11:17:51 AM

From: Jesse Arnup-Blondin/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: CSTD-DGO, jeannine.ritchet@hc-sc.gc.ca, Michael Assad/HC-SC/GC/CA@HWC, Paula Robert/HC-SC/GC/CA@HWC  
Date: 2011-03-03 11:17 AM  
Subject: Re: Salvia responses and dockets

Hi Jocelyn -

Sorry about the delay in getting back to you. I haven't been able to get a response from ECD on this yet, so in the interest of getting these dockets done on time, send them up with the response you have drafted, and I will keep working to see if we can get future dockets replied to with a standard so we don't need to send them to the directorate.

The one change I would suggest is to change the "when" to a "should" for publication in CGI, since we don't want to draw the conclusion prematurely that the Minister will approve proposed regs.

There will also be additional opportunities for comment should a complete regulatory proposal be pre-published in *Canada Gazette* , Part I.

Will keep you posted on path forward for future dockets.

Jesse

Jocelyn Kula

Hi Jesse Just wondering if there was any decisi...

2011-03-03 10:56:26 AM

From: Jocelyn Kula/HC-SC/GC/CA  
To: Jesse Arnup-Blondin/HC-SC/GC/CA@HWC  
Cc: Michael Assad/HC-SC/GC/CA@HWC, Paula Robert/HC-SC/GC/CA@HWC, CSTD-DGO,  
jeannine.ritchot@hc-sc.gc.ca  
Date: 2011-03-03 10:56 AM  
Subject: Salvia responses and dockets

---

Hi Jesse

Just wondering if there was any decision as to whether our proposed standard response to comments received in response to the NOI and/or any ministerial or departmental correspondence. Just that we have three ministerial dockets now in hand, and obviously, we would like to respond in time.

If memory serves, you were going to check with ECD re. whether we could "get out of" including more substantive text regarding why the Dept has taken the action it has, which as I pointed out, is only going to irritate the drug decriminalization advocates that have been writing to us.....

Happy to discuss further as needed.

Jocelyn

---

Jocelyn Kula

Acting Director/ Directrice par intérim

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs

Health Canada/ Santé Canada

Tel: (613) 952-2177 Fax: (613) 946-4224



**Re: Salvia Divinorum**  
OCS Policy and Regulatory Affairs to: [REDACTED]  
Sent by: **Stephanie Chandler**  
Bcc: **Stephanie Chandler, Isabel Shanahan**

2011-03-03 01:57 PM

**Salvia Divinorum**  
OCS Policy and Regulatory Affe Dear [REDACTED] *I am writing to acknowledge receipt of your email with*

Dear [REDACTED]

I am writing to acknowledge receipt of your email with regards to the publication of the *Notice to Interested Parties* outlining Health Canada's proposal to add *Salvia divinorum* and salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA).

I thank you for your comments regarding this proposal and can assure you they will be taken into consideration as the federal regulatory process progresses. There will also be additional opportunities for comment should a complete regulatory proposal be pre-published in *Canada Gazette* , Part I.

For your information, Health Canada has developed an *It's Your Health* article about *Salvia divinorum* that aims to inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at:  
<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/life-vie/salvia-eng.php>

Thank you for writing.

Sincerely,

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada

Shaun Hello, I'd like to comment on the proposal to ban... 2011-02-19 07:30:39 AM

**Salvia Divinorum**

[REDACTED] to: OCS.Policy.and.Regulatory.Affairs 2011-02-19 07:30 AM

Hello,

I'd like to comment on the proposal to ban salvia divinorum.

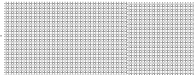
There is no evidence whatsoever that salvia divinorum causes dependence or other negative long-term health effects. Compared to alcohol and tobacco, salvia is practically harmless. While some people may describe the effects as "unpleasant", others have found it to be useful for meditation and relaxation. The herb is used by indigenous tribes in Central America for the latter purposes.

I strongly believe that it should not be the place of the government to tell people what they can and can't ingest, without strong evidence that a substance is dangerous. It seems to me that salvia is being banned primarily due to prejudice, as the media often associates it with drugs like LSD, even though it is a vastly different drug. I think that for the government to restrict the freedom of its citizens in such an arbitrary manner is disgusting.

The proposal cites protecting teenagers as one of the primary reasons for this ban. However, there is no reason given as to why teenagers need to be protected from it. "Protecting children" these days seems to be more of a euphemism for infringing on freedom, rather than an actual reason. Furthermore, teenagers are already using alcohol, tobacco, marijuana, and many other much more harmful drugs, regardless of the legality. The drug war has done nothing to protect children from drugs (and some even argue it has made it worse). This ban would simply be a step further in the wrong direction.

Please respect the freedom of responsible adults and do not ban this substance.

Thank you



s.19(1)



**Re: Proposed Regulation of Salvia Divinorum**  
OCS Policy and Regulatory Affairs to: [REDACTED]  
Sent by: Stephanie Chandler

2011-03-03 02:00 PM

**Proposed Regulation of Salvia Divinorum**  
OCS Policy and Regulatory Affairs Dear [REDACTED] I am writing to acknowledge receipt of your email with

Dear [REDACTED]

I am writing to acknowledge receipt of your email with regards to the publication of the *Notice to Interested Parties* outlining Health Canada's proposal to add *Salvia divinorum* and salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA).

I thank you for your comments regarding this proposal and can assure you they will be taken into consideration as the federal regulatory process progresses. There will also be additional opportunities for comment should a complete regulatory proposal be pre-published in *Canada Gazette*, Part I.

For your information, Health Canada has developed an *It's Your Health* article about *Salvia divinorum* that aims to inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at: <http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/life-vie/salvia-eng.php>

Thank you for writing.

Sincerely,

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada

Martin Lynch

Firstly, thank you for the opportunity to comment...

2011-02-19 11:53:14 AM



**Proposed Regulation of Salvia Divinorum**

[REDACTED] to: OCS.Policy.and.Regulatory.Affairs

2011-02-19 11:53 AM

Firstly, thank you for the opportunity to comment on the proposed addition of salvia divinorum to Schedule III of the CDSA. It is certainly important, and appropriate, to invite consultation before making such profound decisions.

Secondly, I would like to request information about any and all scientific studies regarding the health impacts (detrimental or positive) of consumption of salvia divinorum. I see your notice in *Canada Gazette* mentions the number of people who report using it, however what I don't see is

**s.19(1)**

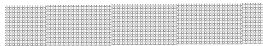
any scientifically based studies guiding Health Canada's decision-making on this issue. To my knowledge, salvia divinorum is not physically addictive, is short acting (in the neighbourhood of five minutes), poses no danger of death via overdose (as far as I'm aware, no known alkaloid hallucinogenic can cause death directly, except perhaps ibogaine (although reports regarding ibogaine's toxicity are somewhat dubious also)) and has not been clinically shown to cause any adverse health effects.

Altering one's perception of reality is rather fundamental to the human experience - this is, after all, why amusement parks are in business, and why children enjoy swings and merry-go-rounds and seesaws while adults enjoy alcohol and 3D movies. Other than a general bias against particular **methods** of altering one's reality, is there any **science** backing up this proposal?

I look forward to hearing from you.

--

Kind regards,

A rectangular area of the document is redacted with a grey grid pattern, obscuring the signature of the sender.

s.19(1)



**Re: Proposal regarding the addition of Salvia divinorum and salvinorin A to Schedule III to the Controlled Drugs and Substances Act**

OCS Policy and Regulatory Affairs to: [REDACTED]

2011-03-03 02:03 PM

Sent by: Stephanie Chandler

Bcc: Stephanie Chandler, Isabel Shanahan

[REDACTED] Proposal regarding the addition of Salvia divinorum and salvinorin A to Sch  
OCS Policy and Regulatory Aff: Dear [REDACTED] I am writing to acknowledge receipt of your email

Dear [REDACTED]

I am writing to acknowledge receipt of your email with regards to the publication of the *Notice to Interested Parties* outlining Health Canada's proposal to add *Salvia divinorum* and salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA).

I thank you for your comments regarding this proposal and can assure you they will be taken into consideration as the federal regulatory process progresses. There will also be additional opportunities for comment should a complete regulatory proposal be pre-published in *Canada Gazette*, Part I.

For your information, Health Canada has developed an *It's Your Health* article about *Salvia divinorum* that aims to inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at: <http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/life-vie/salvia-eng.php>

Thank you for writing.

Sincerely,

Stephanie Chandler  
Regulatory Policy Division

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada

[REDACTED] Dear Stephanie, I was perturbed this morning to...

2011-02-19 01:00:43 PM

**Proposal regarding the addition of Salvia divinorum and salvinorin A to Schedule III to the Controlled Drugs and Substances Act**

[REDACTED] to: OCS.Policy.and.Regulatory.Affairs

2011-02-19 01:00 PM

Cc: inspire



**s.19(1)**

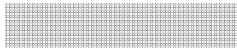
Dear Stephanie,

I was perturbed this morning to read that Health Canada is proposing the addition of Salvia divinorum and salvinorin A to the Controlled Drugs and Substances Act. To add context, I have never used nor do I intend to use this substance. My concerns with this change include the following:

- This change would likely affect individuals who choose to use this substance for self exploration, expansion of spiritual growth. I, and many other Canadians, believe that this is a legitimate use of psychotropic substances. It is a right to inhibit peoples' choice to expand their awareness.
- Prohibition of salvia would shift profits from legitimate, tax-paying enterprises to organized criminals. Profits would certainly increase with prohibition, expanding a criminal underworld that is strongly resented and feared. Increased enforcement and punishment, as has been demonstrated clearly by the US model of drug prohibition while doing nothing to limit access to salvia. The health impact (mental health, HIV, etc.) of increased prison is a negative impact of salvia's continued status as a legal substance.
- There is no evidence that salvia is addictive.
- There is no evidence supporting a conclusion that salvia use, in and of itself, is harmful to human health.

Health Canada's role in this matter should involve educating Canadians on the known effects and responsible use of salvia. Sales of salvia to irresponsible minors should also be considered. Further expansion of a policy of prohibition without a fact-based understanding of substance abuse, damage prevention, and economics. I urge you to consider these issues in your policy on the regulation of salvia divinorum and salvinorin A.

Sincere regards,



s.19(1)



**Re: Comments on the proposed addition of Salvia divinorum and salvinorin A to Schedule III to the Controlled Drugs and Substances Act**

OCS Policy and Regulatory Affairs to: [redacted]

2011-03-03 02:04 PM

Sent by: Stephanie Chandler

Bcc: Stephanie Chandler, Isabel Shanahan

Comments on the proposed addition of Salvia divinorum and salvinorin A to  
OCS Policy and Regulatory Affairs Dear [redacted] I am writing to acknowledge receipt of your email

Dear [redacted]

I am writing to acknowledge receipt of your email with regards to the publication of the *Notice to Interested Parties* outlining Health Canada's proposal to add *Salvia divinorum* and salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA).

I thank you for your comments regarding this proposal and can assure you they will be taken into consideration as the federal regulatory process progresses. There will also be additional opportunities for comment should a complete regulatory proposal be pre-published in *Canada Gazette*, Part I.

For your information, Health Canada has developed an *It's Your Health* article about *Salvia divinorum* that aims to inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at: <http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/life-vie/salvia-eng.php>

Thank you for writing.

Sincerely,

Stephanie Chandler  
Regulatory Policy Division

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada

In regards to the proposed Salvia divinorum ban...

2011-02-19 03:39:49 PM

Comments on the proposed addition of Salvia divinorum and salvinorin A to Schedule III to the Controlled Drugs and Substances Act

to: OCS.Policy.and.Regulatory.Affairs

2011-02-19 03:39 PM

In regards to the proposed Salvia divinorum ban,

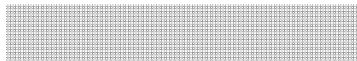
s.19(1)

It always make me laugh, the hypocrisy of drug laws. Salvia is indeed a very powerful drug. However, it is not habit-forming, it is non-toxic, and most people only try it once or twice as a novelty. It is not pleasurable, but rather intensely hallucinogenic and disorienting. On a scale of relative harm, salvia would be lower than coffee, and alcohol and cigarettes would be at the top.

When the government goes out of its way to ban a harmless plant, when alcohol and cigarettes, or even energy drinks, are legal, it destroys their credibility. Regulation is fine, but banning salvia will only make the government look like a foolish old nanny. Prohibition has never worked, and it won't work for salvia either. I would further argue that it is none of the governments business to tell me, an educated consenting adult, what plants I may consume, when there is no evidence of toxicity or harm.

Furthermore, your department should be focusing it's efforts, and my tax dollars, on actual dangerous drugs that are unregulated, such as MDPV, mephedrone, synthetic cannabinoids, etc. These substances are both addictive and potentially harmful, unlike salvia.

Sincerely,



s.19(1)



**Re: Salvia Divinorum Ban is very concerning**

OCS Policy and Regulatory Affairs to: [redacted]  
Sent by: Stephanie Chandler  
Bcc: Stephanie Chandler, Isabel Shanahan

2011-03-03 02:05 PM

<b>Salvia Divinorum Ban is very concerning</b>	
OCS Policy and Regulatory Affs	Dear [redacted] I am writing to acknowledge receipt of your email w
OCS Policy and Regulatory Aff	Dear [redacted] I am writing to acknowledge receipt of your ema

Dear [redacted]

I am writing to acknowledge receipt of your email with regards to the publication of the *Notice to Interested Parties* outlining Health Canada's proposal to add *Salvia divinorum* and salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA).

I thank you for your comments regarding this proposal and can assure you they will be taken into consideration as the federal regulatory process progresses. There will also be additional opportunities for comment should a complete regulatory proposal be pre-published in *Canada Gazette*, Part I.

For your information, Health Canada has developed an *It's Your Health* article about *Salvia divinorum* that aims to inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at: <http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/life-vie/salvia-eng.php>

Thank you for writing.

Sincerely,

Stephanie Chandler  
Regulatory Policy Division

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada

[redacted] Hello, I am very concerned the proposed ban on... 2011-02-19 04:45:03 PM

**Salvia Divinorum Ban is very concerning**

[redacted] to: OCS.Policy.and.Regulatory.Affairs 2011-02-19 04:45 PM

Please respond to [redacted]

Hello,

I am very concerned the proposed ban on Salvia Divinorum will do more harm than good, as well

**s.19(1)**

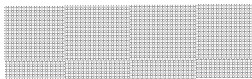
as take away the choice of adults.

I can certainly understand the concerns about it getting to young people, which is why it makes sense for a ban, such as with cigarettes, to sell to people under the age of majority. However, having taken the substance myself one time, I can assure you that it is not an addictive substance nor one that does anything but commands respect from the user. With responsible use, it can have profound spiritual meaning and depth and allow for insight.

This isn't a party drug. By making it a schedule III substance, it will provide the perfect opportunity for the criminal underworld to take over the trade in salvia divinorum and make sure it gets to young people and is used irresponsibly.

Instead, I would suggest talking with adults versed in both responsible and effective drug policy, as well as those who have a holistic understanding of entheogens. The best way to minimize harm from salvia is to treat it with respect and take appropriate steps that responsible adults are the ones who can make the choice to use it.

Sincerely,

A rectangular area with a grey grid pattern, used to redact the signature of the sender.



**Re: Regulating salvia divinorum**

OCS Policy and Regulatory Affairs to: [redacted]

2011-03-03 02:07 PM

Sent by: Stephanie Chandler

Bcc: Stephanie Chandler, Isabel Shanahan

[redacted] **Regulating salvia divinorum**

OCS Policy and Regulatory Affairs Dear [redacted] *I am writing to acknowledge receipt of your email*

Dear [redacted]

I am writing to acknowledge receipt of your email with regards to the publication of the *Notice to Interested Parties* outlining Health Canada's proposal to add *Salvia divinorum* and salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA).

I thank you for your comments regarding this proposal and can assure you they will be taken into consideration as the federal regulatory process progresses. There will also be additional opportunities for comment should a complete regulatory proposal be pre-published in *Canada Gazette*, Part I.

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Thank you for writing.

Sincerely,

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada

Neil Magnuson The prohibition of plants and /or their derivatives... 2011-02-19 06:51:04 PM

**Regulating salvia divinorum**

[redacted] to: ocs.policy.and.regulatory.affairs

2011-02-19 06:51 PM

The prohibition of plants and /or their derivatives is an abomination and an assault against nature and the rights of adults to

choose as they desire UNLESS they are harming OTHERS.

Attempting to prohibit Salvia will only INCREASE the allure and demand, GUARANTEEING a black market supply completely void of regulations

that would otherwise serve to address any potential harms that can arise from the substances abuse.

While reasonable regulations imposed on the commercial sale of Salvia are warranted, IT is not in the purview of public SERVANTS to prohibit adults

from possessing ANY plants and or their derivatives UNTIL and UNLESS they are harming OTHERS in significant and demonstrative ways.

Natural law endows adults with unalienable human rights which override any man made laws. Using criminal sanctions against people possessing natural plants CAUSES far more harm than the substance in question and as such is itself a criminal act against sovereign individuals as well as the very foundation of our FREE society.

These prohibitions (opium, cocoa including and especially cannabis) and proposed prohibitions, are gross violations and are in violation of the publics trust.

To fail to properly regulate the COMMERCIAL sale of plants and or their derivatives that are PROVEN to have potential negative consequences, is a dereliction of duty,

To leave the commercial sale to the black market forces is inviting "Al Capone" and his cronies to prey upon our children in yet another way, directly CAUSED by the prohibition.

Salvia is not the problem, lack of education and regulations is the problem. and prohibition MAKES THE PROBLEM WORSE.

These are not my opinions, these are the findings of study after study and experts from all related fields. Prohibition CREATES and FUELS a black market that gets increasingly more violent the more enforcement of the laws is increased.

Sincerely,



s.19(1)



Re: Regarding Salvia

OCS Policy and Regulatory Affairs to: [redacted]

2011-03-03 02:08 PM

Sent by: Stephanie Chandler

Bcc: Stephanie Chandler, Isabel Shanahan

Regarding Salvia

OCS Policy and Regulatory Aff: Dear [redacted] I am writing to acknowledge receipt of your email w

Dear [redacted]

I am writing to acknowledge receipt of your email with regards to the publication of the *Notice to Interested Parties* outlining Health Canada's proposal to add *Salvia divinorum* and salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA).

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Thank you for writing.

Sincerely,

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada

To whoever may read this,

2011-02-20 12:25:41 PM

Regarding Salvia

to: ocs.policy.and.regulatory.affairs

2011-02-20 12:25 PM

To whoever may read this,

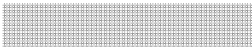
I was recently made aware of Health Canada's move to add Salvia to the Controlled Drugs and Substances Act, and am, in all honesty, confused as to why. There are no medically supported negative effects to Salvia, and as such to claim that it is a 'risk' is fundamentally a falsehood. One of the justifications oft heard was that it is, in some way, comparable to LSD which is on the Controlled Drugs and Substances Act, but to compare the two simply on the basis that they are both psychedelic is not a logical way to approach legislation. LSD's effects are far more significant, often lasting for hours, while



Salvia lasts only a few minutes (I would still argue that for LSD to be on the Controlled Drugs and Substances Act is also illogical, seeing as it too has been shown time and time again to be harmless, but that is an issue for another day). Although there have been a few highly publicized instances of people with mental issues, namely depression, having adverse effects to Salvia, to ban its use for the whole public is not a reasonable response. Surely if a substance has no medically documented negative effects then it must remain legal? Shouldn't the men and women of Canada be allowed to decide if they want to consume mind altering substances?

If you wanted to disallow minors from consuming Salvia, you would have my full support, but this is a fundamental insult to the dignity of the adult citizens of Canada. What justification can Health Canada possibly procure to justify further controlling the day to day lives of Canadians?

Sincerely,

A rectangular area of the document is redacted with a grey grid pattern, obscuring the signature.

s.19(1)



**Re: Salvia ban**

OCS Policy and Regulatory Affairs to: [REDACTED]

2011-03-03 02:10 PM

Sent by: Stephanie Chandler

Bcc: Stephanie Chandler, Isabel Shanahan

[REDACTED] **Salvia ban**  
OCS Policy and Regulatory Affairs Dear [REDACTED] I am writing to acknowledge receipt of your email w

Dear [REDACTED]

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Thank you for writing.

Sincerely,

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada

[REDACTED] Health Canada proposes ban on popular...

2011-02-20 01:59:50 PM

**Salvia ban**

[REDACTED] to: OCS.Policy.and.Regulatory.Affairs

2011-02-20 01:59 PM

Health Canada proposes ban on popular hallucinogenic herb salvia  
<http://ca.news.yahoo.com/health-canada-proposes-ban-popular-hallucinogenic-herb-salvia-20110219-010509-653.html>

Hi,

I would like to know, on which double blind peer reviewed published study are you basing this

decision on ?

because based on your track record on the recreational drugs subject, I would say that you are based on hearsay, act of mentally unstable person on drugs, fear expressed by parents, corporate interests and whatever police officers think will make their jobs easier but little else

this is unacceptable for a supposedly science-based governmental organization

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**Re: Future criminalization of salvia**

OCS Policy and Regulatory Affairs to: [REDACTED]

2011-03-03 02:11 PM

Sent by: Stephanie Chandler

Bcc: Stephanie Chandler, Isabel Shanahan

[REDACTED] Future criminalization of salvia  
OCS Policy and Regulatory Affe Dear [REDACTED] I am writing to acknowledge receipt of your email with

Dear [REDACTED]

I am writing to acknowledge receipt of your email with regards to the publication of the *Notice to Interested Parties* outlining Health Canada's proposal to add *Salvia divinorum* and salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA).

I thank you for your comments regarding this proposal and can assure you they will be taken into consideration as the federal regulatory process progresses. There will also be additional opportunities for comment should a complete regulatory proposal be pre-published in *Canada Gazette*, Part I.

For your information, Health Canada has developed an *It's Your Health* article about *Salvia divinorum* that aims to inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at: <http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/life-vie/salvia-eng.php>

Thank you for writing.

Sincerely,

Stephanie Chandler  
Regulatory Policy Division

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada

[REDACTED] Dear Ms. Chandler, I am a master's candidate at...

2011-02-20 02:07:37 PM

Future criminalization of salvia

[REDACTED] to: OCS.Policy.and.Regulatory.Affairs

2011-02-20 02:07 PM

Dear Ms. Chandler,

I am a [REDACTED]  
and a concerned citizen. I recently became aware of the fact that Health Canada is planning to

s.19(1)

fully criminalize the hallucinatory herb salvia. While I understand the Government of Canada's position regarding illicit drugs, may I present an alternate viewpoint?

I attach a copy of [redacted] High Time for Change, which was published last year in the Queen's Policy Review. [redacted] paper solely regards cannabis use, production, and sale, many of the points regarding criminalization of drugs in general bear strongly on salvia and its future use.

I would suggest the Government of Canada, advised by Health Canada, control salvia (and other drugs) in a similar manner to that in which alcohol and tobacco are controlled. Require buyers to be of age (say 18 or 19), present ID to prove their age, and only allow licensed sellers to grow and sell the substance, thus allowing the government to regulate growing methods and potency. For example, in Ontario, only a select few sellers (the LCBO, the Beer Store, the Wine Rack, and licensed bars, pubs, and restaurants) can sell alcohol. Similar requirements for drugs such as salvia and cannabis would greatly restrict the number of possible sellers.

These measures require legalization of the drug, but it's a much better solution than driving an entire industry underground where dealers will not care how old the buyers are, where the drug could be laced with anything because one does not know who grew it or how it was grown, and where the government has no records whatever on the amount of use.

Criminalization also seriously diminishes the likelihood of someone who has used the drug to seek help if they are experiencing side effects or are becoming addicted.

Criminalization further takes all the power away from government, puts it in the hands of the police, and burdens our justice department with unnecessary criminal cases. It also makes criminals out of youth who then go to jail, are put in contact with actually dangerous offenders, and return to the real world far more violent than when they left.

It bears repeating how much more dangerous to one's lifetime health alcohol and tobacco are, as compared to salvia or cannabis. Full numbers to prove this point can be found in the attached document, but there is not a single death that has been recorded as being caused by cannabis ingestion, while the numbers - I'm sure I needn't tell you - are very different for alcohol and tobacco.

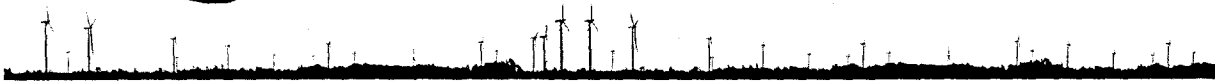
Please consider these points when making decisions on drug regulation. Being "touch on crime" never mean harsher penalties on users.

Regards,

[redacted]

# QPR

# Queen's Policy Review



*Volume 1, No. 1 (Spring 2010)*

## High Time for Change

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### A Sound, Humane, and Fiscally Responsible Marijuana Policy for Canada

Natassia Ciuriak

*Carleton University*

#### **Introduction**

If a country's legal framework is broadly in line with its society's values, it follows logically that crime will be minimized. No public policy more obstinately ignores this principle than that regarding marijuana. Despite statistics suggesting a large portion of the Canadian population uses cannabis regularly and an increasing portion of the public no longer supports its criminalized status, the current Conservative government under Prime Minister Stephen Harper is pushing for reforms that intensify its proscription including "reverse onus bail hearings, the elimination of conditional sentences and statutory release and especially, mandatory sentences."<sup>1</sup> These proposed legislative changes are symbolic of most governments' persistent and dominant mindset when it comes to drug laws: the sentiment is expressed as being 'tough on crime,' and the solution is to strengthen

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<sup>1</sup> McKnight, Peter. "Canada should learn from U.S. mistakes; Putting more non-violent criminals in jail is not the solution to our justice problems." *The Vancouver Sun*. April 4, 2009: D5.

enforcement and to put more people (generally non-violent offenders when related to marijuana) behind bars. However, there is an increasing civil society movement towards more progressive and informed marijuana laws that incorporate such policies as harm reduction, decriminalization or legalization, education and prevention, and health care.

Based on an international comparative analysis, this paper will argue that Canada's marijuana laws, rather than toughened, should be changed in the opposite direction, to align them with strong scientific, social, empirical, economic, and historical arguments and evidence against criminalization. The paper will further argue that legalization is preferable to decriminalization.

This paper will first provide a short social and legal history of marijuana in Canada, for we cannot understand the steps that must be taken without first understanding how and why we have arrived at our present position. It will then develop three arguments. First, it will show why marijuana prohibition has failed to prevent or even decrease usage by examining the lessons learned from alcohol prohibition and the American criminalization of marijuana, and by exploring the current Canadian marijuana position. Second, it will assess whether decriminalization might provide a better legal framework based on an examination of the legal approaches the Netherlands and Portugal have taken. Third, it will discuss the differences between decriminalization and legalization by comparing marijuana's health and social effects to those of alcohol and tobacco, weighing each possibility's benefits and drawbacks as discussed in a 2002 Senate Special Committee report that strongly recommended legalization, as well as briefly reviewing the international barriers to implementing either option.

### **History of Marijuana Regulation in Canada**

Marijuana was first criminalized in Canada in 1923 when Parliament added it to the Schedule of the Opium and Narcotic Drug Act,<sup>2</sup> with "no debate, no justification, [and despite the fact that] many members did not even know what cannabis was."<sup>3</sup> Canada did not have a significant marijuana-using population at the time, and "there were no seizures of marijuana in Canada until

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<sup>2</sup> Carstairs, Catherine. *Jailed for possession: Illegal Drug Use, Regulation and Power in Canada, 1920-1961*. Toronto: University of Toronto Press, 2006, p. 31.

<sup>3</sup> Senate Special Committee on Illegal Drugs. *Cannabis: our position for a Canadian public policy: Summary Report*. Ottawa: Senate of Canada, 2002, p. 22.

1937.”<sup>4</sup> In her book on historic Canadian drug regulations, Catherine Carstairs argues this action was probably taken due to discussions at the Hague Opium Conference in 1911-12, which Mackenzie King attended, and because of the Geneva Convention of 1925, which limited Indian hemp to “medical and scientific” consumption.<sup>5</sup> The Senate Special Committee on Illegal Drug suggests “early drug legislation was largely based on a moral panic, racist sentiment and a notorious absence of debate.”<sup>6</sup> The moral panic regarding drugs coincided with, and was very strongly linked to, the panic that led to the prohibition of alcohol. Regarding marijuana specifically, the Committee describes “the criminalization of the drug [marijuana] as a solution without a problem”<sup>7</sup>; essentially preemptive legislation.

In 1969, following the 1960s’ rapid increase in marijuana use and public outcry for reform, the government appointed Gerald Le Dain, dean of Osgoode Hall Law School, as chairman of the Commission of Inquiry into the Non-Medical Use of Drugs. It “concluded that the criminalization of cannabis had no scientific basis.”<sup>8</sup> Despite a number of concerns, including that of the ‘gateway theory,’ which posits that marijuana leads to hard drug use, and the drug’s possible effects on youths’ brain development<sup>9</sup> (thirty years’ experience and research have shown these to be factually wrong and greatly exaggerated, respectively), “all members supported movement toward decriminalisation.”<sup>10</sup> Prime Minister Pierre Trudeau subsequently promised to advance legislation that would comply with the Commission’s recommendations. However, he was unable to do so before Joe Clark took over government, forcing the issue off the political radar screen.<sup>11</sup>

Three years after the Controlled Drug and Substances Act replaced the Opium and Narcotic Drug Act in 1997, the Ontario Court of Appeal struck down a federal law prohibiting possession of less than 30 grams of marijuana, ruling that “banning marijuana for medicinal purposes violates the

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<sup>4</sup> Carstairs, Catherine. *Jailed for possession: Illegal Drug Use, Regulation and Power in Canada, 1920-1961*, p. 31.

<sup>5</sup> Carstairs *ibid.*, p. 31.

<sup>6</sup> Senate Special Committee on Illegal Drugs. *Cannabis: our position for a Canadian public policy: Summary Report*, p. 22.

<sup>7</sup> Senate Special Committee on Illegal Drugs. *Cannabis: our position for a Canadian public policy*. Ottawa: Senate of Canada, 2002, p. 256.

<sup>8</sup> Senate Special Committee on Illegal Drugs. *Cannabis: our position for a Canadian public policy: Summary Report*, p. 35.

<sup>9</sup> *Ibid.*, p. 36.

<sup>10</sup> “The LeDain Commission.” *MarijuanaParty.ca*. Marijuana Party/Parti Marijuana. January 7, 2004. Accessed November 25, 2009 <[http://www.marijuanaparty.ca/article.php?id\\_article=47](http://www.marijuanaparty.ca/article.php?id_article=47)>

<sup>11</sup> *Ibid.*



Canadian Charter of Rights and Freedoms.”<sup>12</sup> This led to the Marijuana Medical Access Regulations of 2001, which made Canada the first country to permit medicinal marijuana use, but failed to address recreational marijuana use.<sup>13</sup> In 2003, the Ontario Court of Appeal ruled that the new regulations provided acceptable access to medical marijuana, re-criminalizing possession of marijuana for recreational purposes.<sup>14</sup> Later that year, the Supreme Court ruled that our marijuana laws “do not violate the Charter of Rights and Freedom and its protection of life, liberty and security of person.”<sup>15</sup>

Then, under the Liberal minority government of Paul Martin, Bill C-17 was introduced. Had it passed, “adults caught with less than 15 grams of pot could be fined up to \$400, but wouldn't have a criminal record.”<sup>16</sup> It also called for a doubling in the length of jail terms for marijuana growers.

The road to decriminalization ended with the election of the Harper Conservatives in 2006, the debate within government over changing marijuana's legal status concluded; criminalization and harsher penalties would be sought.

### **Has Criminalization Succeeded?**

The prohibition of alcohol in both the United States (1920-33) and Canada (duration specific to municipalities and provinces) has given us many insights into the effects of marijuana prohibition. Prohibition was enacted namely “to reduce crime and corruption, solve social problems, reduce the tax burden created by prisons and poorhouses, and improve health and hygiene.”<sup>17</sup> It is, however, largely considered a failure today for several reasons, including the following: “Alcohol became more dangerous to consume; crime increased and became ‘organized’; the court and prison systems were stretched to the breaking point; and corruption of public officials was rampant.”<sup>18</sup> Many of these symptoms currently characterize marijuana prohibition, particularly the increase in

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<sup>12</sup> Khoo, Lisa. “Up in smoke? Canada's marijuana law and the debate over decriminalization.” *CBC.ca*. CBC News. November 25, 2004. Accessed November 25, 2009 <[http://www.cbc.ca/news/background/marijuana/marijuana\\_legalize.html](http://www.cbc.ca/news/background/marijuana/marijuana_legalize.html)>.

<sup>13</sup> Ibid.

<sup>14</sup> Ibid.

<sup>15</sup> Ibid.

<sup>16</sup> Ibid.

<sup>17</sup> Thornton, Mark. “Policy Analysis: Alcohol Prohibition Was a Failure.” *CATO.org*. The CATO Institute. July 17, 1991. Accessed November 26, 2009 <[http://www.cato.org/pub\\_display.php?pub\\_id=1017&full=1](http://www.cato.org/pub_display.php?pub_id=1017&full=1)>.

<sup>18</sup> Ibid.

organized crime and the incarceration rate, which are also expensive and have thus greatly increased government spending.

Furthermore, according to Richard Cowan, prohibition of any substance is subject to the "Iron Law of Prohibition," which states that "when drugs or alcoholic beverages are prohibited, they will become more potent, will have greater variability in potency, will be adulterated with unknown or dangerous substances, and will not be produced and consumed under normal market constraints."<sup>19</sup> During alcohol prohibition, there was an important increase in potency: it was uneconomical to produce bulky, weak alcohols like beer, "because the largest cost of selling an illegal product is avoiding detection"<sup>20</sup> and stronger liquors like whiskey consume less space for similar alcohol content. Although potency has increased in marijuana<sup>21</sup>, this does not negatively affect the health of users, "because THC [marijuana's active component] does not cause physiological damage to organs or tissues."<sup>22</sup> The main danger is that it might be adulterated, or 'laced,' with chemicals, namely pesticides, which can have significant detrimental health effects.<sup>23</sup> The legalization of marijuana would allow government to set production standards to eliminate this threat.

Prohibition also heightened the "attractiveness of alcohol to the young by making it a glamour product associated with excitement and intrigue."<sup>24</sup> Although statistics of this kind are difficult to obtain for marijuana, anecdotal evidence suggests this plays a significant part in first time use of marijuana by youth.

So why does most of the developed world, particularly the United States, insist on criminalization? If the era of American Prohibition taught us anything, it was that repeal of that legislation "dramatically reduced crime, including organized crime, and corruption. Jobs were created, and new voluntary efforts, such as Alcoholics Anonymous, which was begun in 1934, succeeded in helping alcoholics."<sup>25</sup> These are the results every country wants, but governments are too frightened of the unknowns of decriminalization.

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<sup>19</sup> Thornton, Mark. "Policy Analysis: Alcohol Prohibition Was a Failure."

<sup>20</sup> Ibid.

<sup>21</sup> Senate Special Committee on Illegal Drugs. *Cannabis: our position for a Canadian public policy: Summary Report*, p. 13.

<sup>22</sup> Zimmer, Lynn and John P. Morgan. *Marijuana Myths, Marijuana Facts*. New York: Lindesmith Center, 1997, p. 139.

<sup>23</sup> "Health Effects." *Toronto.ca*. The City of Toronto. April 2009. Accessed November 28, 2009 <[http://www.toronto.ca/health/pesticides/health\\_effects.htm](http://www.toronto.ca/health/pesticides/health_effects.htm)>.

<sup>24</sup> Thornton, Mark. "Policy Analysis: Alcohol Prohibition Was a Failure."

<sup>25</sup> Ibid.

The main consequence of criminalization of marijuana in the United States has been the high incarceration rate, which until the 1980s, was roughly in line with the rest of the developed world, but is now five times the rate of the rest of the developed world, or 756 people per 100,000 residents<sup>26</sup> – the United States has “five per cent of the world's population, but 25 per cent of the known prison population.”<sup>27</sup> Much of this results from the imposition of mandatory jail terms for drug offences (a policy the Harper government is currently seeking to emulate). This eliminates the judiciary's ability to keep non-violent offenders out of jail, where they are likely to become violent: “most drug offenders serving time have been convicted of non-violent offences involving possession or low-level trafficking.”<sup>28</sup>

Additionally, the way in which drug laws are enforced in the United States perpetuates racism: “while illicit drug use rates among black and white Americans are similar, black people total (...) 74 per cent of those sent to prison. Consequently, one in nine black men in America is serving time.”<sup>29</sup> This racial disparity is also present in Canada, where Aboriginals are overrepresented in our prisons, with many of them serving time for drug offences.<sup>30</sup> In the United States the growing incarceration rate has also created 1.7 million “prison orphans” – children with parents serving time – who are “six times more likely than their peers to end up in prison themselves.”<sup>31</sup>

The criminalization of drugs has also led to the high mortality rate of police officers fighting the War on Drugs: “Across the U.S., a police officer dies on duty nearly every other day. Even more officers are wounded, too many fighting the war on drugs.”<sup>32</sup> This is because the sale of illegal drugs, often undertaken by organized criminals or dealers who are also users, leads to an atmosphere of violence, where “disputes about money or respect are settled with guns.”<sup>33</sup> However, it is important to note that much of this violence is absent from the marijuana market, as marijuana does not incite

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<sup>26</sup> Ibid.

<sup>27</sup> McKnight, Peter. “Canada should learn from U.S. mistakes; Putting more non-violent criminals in jail is not the solution to our justice problems.”

<sup>28</sup> Ibid.

<sup>29</sup> Ibid.

<sup>30</sup> Ibid.

<sup>31</sup> “America's prison blues; The U.S. jail population is five times the world average - one in every 31 adult Americans is either in prison or on parole.” *The Gazette*. Montreal: April 5, 2009: p. A13.

<sup>32</sup> Moskos, Peter and Stanford Franklin. “Legalizing drugs will lead to cuts in crime.” *Times - Colonist*. Victoria: August 23, 2009: C2.

<sup>33</sup> Ibid.

violence, is less expensive than other illegal drugs, and is often sold “in residential settings by dealers who do not themselves have expensive habits.”<sup>34</sup>

Consistent with the failures of the War on Drugs in general, marijuana prohibition has failed to prevent its continued use: “If prohibition decreased drug use and drug arrests acted as a deterrent, America would not lead the world in illegal drug use and incarceration for drug crimes.”<sup>35</sup> In fact, the United States has some of the highest usage rates in the developed world, and this considering its high penalties: “32.9% of Americans aged 12 and above have experience with cannabis and 5.1% have used in the past month. These figures are twice as high as those in the Netherlands [a country with very liberal marijuana laws].”<sup>36</sup> In fact, “proportionally, more Americans have used cocaine than Portuguese [where drugs were decriminalized in 2001] have used marijuana.”<sup>37</sup> However, the United States refuses to officially acknowledge or understand the logic behind decriminalization and has instead “single-mindedly agitated for greater criminalization approaches and appears, at least to [European Union] officials, interested solely in enforcement actions, rather than empirically vindicated policy changes (...) designed to manage usage rates and ameliorate drug-related harms.”<sup>38</sup>

Canadian officials are following the Americans despite statistics that suggest our drug, and specifically marijuana, policies are ineffective. In fact, depending on the study, somewhere between 23%<sup>39</sup> and “over 30%”<sup>40</sup> of Canadians have used marijuana at least once in their lives. Furthermore, in 2002, the Senate Special Committee on Illegal Drugs reported that “approximately 2 million Canadians over age 18 have used cannabis during the previous 12 months, approximately 600,000 have used it during the past month, and approximately 100,000 use it daily.”<sup>41</sup> However, only 0.85% of them were charged with possession.<sup>42</sup> Furthermore, “over 50% of all drug-related incidents

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<sup>34</sup> Boyum, David and Mark A. R. Kleiman. “Breaking the Drug-Crime Link.” *The Public Interest* 152 (2003): p.19-38.

<sup>35</sup> Ibid.

<sup>36</sup> “The Netherlands Compared With The United States.” *Drug War Facts*. Borden, Mary Jane and Douglas McVay, eds. Canada: 2007. Accessed November 26, 2009 <<http://drugwarfacts.org/cms/node/67>>.

<sup>37</sup> Szalavitz, Maia. “Drugs in Portugal: Did Decriminalization Work?” *TIME.com*. TIME Magazine. April 26, 2009. Accessed November 26, 2009 <<http://www.time.com/time/health/article/0,8599,1893946,00.html>>.

<sup>38</sup> Greenwald, Glenn. *Drug Decriminalization in Portugal: Lessons for Creating Fair and Successful Drug Policies*. United States: Cato Institute, 2009, p. 27.

<sup>39</sup> Easton, Stephen T. *Public Policy Sources: Marijuana Growth in British Columbia*. Vancouver: The Fraser Institute, 2004, p. 3.

<sup>40</sup> Senate Special Committee on Illegal Drugs. *Cannabis: our position for a Canadian public policy: Summary Report*, p. 15.

<sup>41</sup> Ibid., p. 15.

<sup>42</sup> Senate Special Committee on Illegal Drugs. *Cannabis: our position for a Canadian public policy*, p. 359.

[reported by police] involve possession of cannabis.”<sup>43</sup> Those who are charged and convicted face negative effects to their financial situation, career opportunities, and restricted travel.<sup>44</sup> It is also important to note that, according to the Senate Special Committee, Canadian drug enforcement is unevenly applied, which could lead to “discriminatory enforcement, alienation of certain groups within society, and (...) disrespect for the law.”<sup>45</sup>

Marijuana law enforcement is thus a waste of time and taxes “not warranted by the danger posed by the substance.”<sup>46</sup> If the government passes Bill C-15, this waste can increase, without greatly affecting usage rates, as the bill is designed to discourage marijuana growers. However, the Fraser Institute’s Stephen Easton points out that the rewards are simply too high for Canadian marijuana growers (“the 100-plant grow-op makes around 55 percent return for a year’s worth of activity,”<sup>47</sup> according to conservative estimates) and that as soon as one of the roughly 17,500<sup>48</sup> British Columbia grow-operations is closed by police, another opens. In fact, the Senate Special Committee estimated in 2002 that 50% of the marijuana available in Canada is grown in the country, mostly in British Columbia, Ontario, and Québec.<sup>49</sup> Although C-15 might deter some growers due to mandatory prison terms, the cost of law enforcement would almost surely increase, from the estimated current costs of between \$700 million and \$1 billion.<sup>50</sup>

### **Decriminalization in Europe**

One must wonder if there is a better public policy option than such an ineffective, costly, and socially harmful one as criminalization. Much of Europe is experimenting with unofficial decriminalization: marijuana is technically criminalized, but few, if any, users are arrested or charged, and none are imprisoned – it is for the most part a depenalized system. A well-known example is the Netherlands, where “coffee-shops” are licensed to sell small quantities of marijuana to adults (buyers must show identification, similarly to when buying alcohol or tobacco). Marijuana is taxed and production is standardized, allowing buyers to know the strength of the marijuana and to be assured

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<sup>43</sup> Ibid., p. 24.

<sup>44</sup> Senate Special Committee on Illegal Drugs. *Cannabis: our position for a Canadian public policy: Summary Report*, p. 25.

<sup>45</sup> Ibid., p. 24.

<sup>46</sup> Ibid., p. 38.

<sup>47</sup> Easton, Stephen T. *Public Policy Sources: Marijuana Growth in British Columbia*, p. 11.

<sup>48</sup> Ibid., p. 3.

<sup>49</sup> Senate Special Committee on Illegal Drugs. *Cannabis: our position for a Canadian public policy: Summary Report*, p. 13.

<sup>50</sup> Ibid., p. 24.

of consistent quality. Sellers are also informed and able to provide important advice to first-time buyers. The public atmosphere is acceptant and non-judgmental. However, only 17% of the Dutch population 12 years or older have reported a lifetime prevalence (having used the drug at least once in one's life), compared to 36.9% in the United States.<sup>51</sup> In fact, a study comparing marijuana use in Amsterdam and San Francisco found that "there were no differences between the 2 cities in age at onset of use, age at first regular use, or age at the start of maximum use."<sup>52</sup> The study also notes that "Dutch decriminalization does not appear to be associated with greater use of other illicit drugs relative to drug use in San Francisco, nor does criminalization in San Francisco appear to be associated with less use of other illicit drugs relative to their use in Amsterdam;"<sup>53</sup> in fact, they found that the reverse may be true. Furthermore, they argue that the data they collected suggest that marijuana users "organize their use according to their own subcultural etiquette—norms and rules about when, where, why, with whom, and how to use—and less to laws or policies."<sup>54</sup>

Portugal has gone one step further than the Netherlands. In 2001, this deeply conservative, Catholic country decriminalized all drugs, not just marijuana, thus "no distinction is made between the types of drug (so-called hard drugs or soft drugs)."<sup>55</sup> Decriminalization, it should be clear, means that drugs are still prohibited, but the possession of small amounts of drugs for personal use has been removed from criminal law and is instead treated administratively. If police catch someone using drugs, they refer them to a Commission for Dissuasions of Drug Addiction, which may issue a fine or simply a warning to non-addicted consumers.<sup>56</sup> Though the Commissions may not force addicted users to seek treatment, they can suspend sanctions on the provision that he or she agrees to undergo treatment.<sup>57</sup> Although rarely used, they may also impose "suspension of the right to practice a licensed profession (...); a ban on visiting high-risk locales (nightclubs); a ban on associating with specified individuals; requiring periodic reports to the commission to show there is no ongoing

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<sup>51</sup> "The Netherlands Compared With The United States." *Drug War Facts*. Borden, Mary Jane and Douglas McVay, eds.

<sup>52</sup> Reinerman, Craig, Peter D.A. Cohen, and Hendrien L. Kaal. "The Limited Relevance of Drug Policy: Cannabis in Amsterdam and in San Francisco." *American Journal of Public Health*. 94.5 (2004): p. 836-842, p. 840.

<sup>53</sup> *Ibid.*, p. 841.

<sup>54</sup> Reinerman, Craig, Peter D.A. Cohen, and Hendrien L. Kaal. "The Limited Relevance of Drug Policy: Cannabis in Amsterdam and in San Francisco." p. 841.

<sup>55</sup> Greenwald, Glenn. *Drug Decriminalization in Portugal: Lessons for Creating Fair and Successful Drug Policies*, p. 3.

<sup>56</sup> *Ibid.*, p. 3.

<sup>57</sup> *Ibid.*, p. 3.

addiction or abuse; prohibitions on travel abroad; termination of public benefits for subsidies or allowances.”<sup>58</sup>

It is important to understand that the intent of the changes was specifically to reduce usage. Drug use rates in Portugal, specifically those for heroin, were among the highest in the EU, causing pervasive and perverse social repercussions. Legalization was not considered, however, as “numerous international treaties impose the ‘obligation to establish in domestic law a prohibition’ on drug use.”<sup>59</sup> Despite the seeming leniency of the system, the Portuguese have found it to be remarkably successful. Police have found that “treatment options (...) are far more effective than turning users into criminals (who (...) were typically back on the street the next day, but without real treatment options).”<sup>60</sup> In fact, both Portuguese and European officials emphasize that “the overriding goal of that process is to avoid the stigma that arises from criminal proceedings,”<sup>61</sup> allowing addicts to seek treatment without fear of reprisals. The important point is that Portugal defined the public policy problem of drug use as a health issue, not as a criminal one, as the United States have.

Prior to decriminalization, many Portuguese politicians worried that the proposed changes would make Portugal a “safe haven” for foreign drug users. This has been disproven: “Roughly 95 percent of those cited for drug offenses (...) have been Portuguese. Close to zero have been citizens of other EU states.”<sup>62</sup> There was also the worry that decriminalization would suggest that drug use was considered to be acceptable and that it would increase dramatically as a result. The data are, in fact, extremely favourable on this point: “for those two critical groups of youth (13–15 years and 16–18 years), prevalence rates have declined for virtually every substance since decriminalization.”<sup>63</sup> In 2006, Portugal had the lowest lifetime prevalence rates for marijuana use in the EU (8.2% for Portugal compared to 25% for Europe generally).<sup>64</sup>

Although it is not perfect, Portugal’s decriminalization framework appears to be far more effective at actually reducing drug use than criminalization. Law enforcement and the justice system have also seen significant savings, which have been re-routed into addiction-treatment facilities,

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<sup>58</sup> Ibid., p. 4.

<sup>59</sup> Ibid., p. 7.

<sup>60</sup> Ibid., p. 4.

<sup>61</sup> Ibid., p. 6.

<sup>62</sup> Ibid., p. 6.

<sup>63</sup> Ibid., p. 12.

<sup>64</sup> Ibid., p. 22.

reinforcing the system and its goals. But would legalization, with its accompanying regulations and taxation measures, be a better system? Is it even possible in Canada, given our relationship with the United States and our international commitments?

### **Decriminalization versus Legalization**

Before embarking upon this line of argument, it is important to note the differences between marijuana and the two prominent legal drugs in our society, alcohol and tobacco. Marijuana, unlike alcohol and tobacco, is significantly less harmful to one's health and does not produce similar societal externalities. From 2000-2001, there were "27,084 hospital admissions involving alcohol-related conditions."<sup>65</sup> Furthermore, 61% of alcohol-related severe trauma hospitalizations were related to traffic accidents, 21% were due to falls, and assaults and homicides accounted for 18%.<sup>66</sup> Also, in 2006, traffic crashes accounted for 3,122 deaths in Canada.<sup>67</sup> In 1996, 133 people were involved in fatal collisions, killing innocent people, while driving under the influence.<sup>68</sup> Alcohol is also a cause of fetal alcohol syndrome, spousal abuse, and other forms of violence.

Tobacco is also a significant killer: 45,000 Canadians die from smoking-related causes each year – the primary preventable cause of death – and 100 of these deaths are among infants.<sup>69</sup> Although there are no comprehensive Canadian statistics regarding second-hand smoke, "international scientific reviews indicate that [it] is the third leading cause of preventable death (after smoking and drinking alcohol)."<sup>70</sup> One needs no statistics to know that tobacco is highly addictive and linked to many different cancers.

Marijuana is very different. When the Senate Special Committee began hearing witnesses for its report, it found that most were very critical of the fact that the Controlled Drugs and Substances

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<sup>65</sup> Collin, Chantal. "Substance Abuse and Public Policy in Canada: V. Alcohol and Related Harms." *Parl.gc.ca*. The Library of Parliament. June 28, 2006. Accessed November 28, 2009 <<http://www2.parl.gc.ca/Content/LOP/ResearchPublications/prb0620-e.htm#ahospitalizations>>.

<sup>66</sup> Ibid.

<sup>67</sup> Mercer, B. and M. Marshall. "The Magnitude of the Alcohol/Drug-Related Crash Problem in Canada Overview." *MADD.ca*. MADD Canada Research Library. February 2009. Accessed November 28, 2009 <<http://www.madd.ca/english/research/magnitudememo.html>>.

<sup>68</sup> Collin, Chantal. "Substance Abuse and Public Policy in Canada: V. Alcohol and Related Harms."

<sup>69</sup> "Tobacco and the Health of Canadians." *Smoke-Free.ca*. Physicians for a Smoke-Free Canada. n.d. Accessed November 28, 2009 <[http://www.smoke-free.ca/health/pscissues\\_health.htm](http://www.smoke-free.ca/health/pscissues_health.htm)>.

<sup>70</sup> Ibid.



Act “did not categorize drugs on the basis of the dangers they represented [to society].”<sup>71</sup> According to a 1996 study published by the Canadian Centre for Substance Abuse based on 1992 data (thus these costs have probably increased), “the costs associated with all illegal drugs were \$1.4 billion, compared with \$7.5 billion [for] alcohol and \$9.6 billion [for] tobacco.”<sup>72</sup> The primary costs of illegal drugs are measured based on externalities: loss of productivity, health care, and losses in the workplace. Loss of productivity is measured by mortality and morbidity costs, which, apart from traffic fatalities caused by driving while high, are nil for marijuana.<sup>73</sup> Furthermore, the vast majority of marijuana users, especially heavy users, are youth that are not yet part of the workforce, and thus represent very little or no losses in the workplace.<sup>74</sup> Therefore, according to the Senate Special Committee, “cannabis itself entails few externalities.”<sup>75</sup>

It is also “not a cause of violence,” nor is it “a cause of delinquency and crime.”<sup>76</sup> Furthermore dependence or addiction caused by marijuana is both less severe and less frequent than those caused by alcohol or tobacco.<sup>77</sup> Marijuana does not lead to the use of harder drugs, and long-term effects are reversible.<sup>78</sup> Excluding its relation to organized crime and driving while impaired, “cannabis involves few of the factors that generate criminal behaviour.”<sup>79</sup> For these reasons, the criminalization of marijuana is clearly not related to any health reasons, as it is far less harmful than alcohol and tobacco, both legal and regulated substances. This calls into question why criminalization continues to this day; it is certainly not based on rational analysis of costs and benefits to society nor in any way consistent with legal treatment of other recreational drugs. One may speculate that it is based on a general moral panic towards drugs.

When the Senate Special Committee began its work, it developed a mission statement recognizing that the rule of law is not the only source of normative rules and that government must use the “instruments of constraint” only sparingly in a free society. The Committee asserted that “public policy on psychoactive substances must be structured around guiding principles respecting

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<sup>71</sup> Senate Special Committee on Illegal Drugs. *Cannabis: our position for a Canadian public policy: Summary Report*, p. 9.

<sup>72</sup> *Ibid.*, p. 28.

<sup>73</sup> Senate Special Committee on Illegal Drugs. *Cannabis: our position for a Canadian public policy: Summary Report*, p. 29.

<sup>74</sup> *Ibid.*, p. 29.

<sup>75</sup> *Ibid.*, p. 29.

<sup>76</sup> *Ibid.*, p. 15.

<sup>77</sup> *Ibid.*, p. 17.

<sup>78</sup> *Ibid.*, p. 36.

<sup>79</sup> *Ibid.*, p. 29.

the life, health, security and rights and freedoms of individuals, who, naturally and legitimately, seek their own well-being and development and can recognize the presence, difference and equality of others.”<sup>80</sup> They underline the importance of only criminalizing “offences involving significant direct danger to others.”<sup>81</sup> Marijuana use, significantly, is a victimless crime.

These statements make reference to a few important notions. First, it is time that our free and democratic society recognizes that adults are competent to decide for themselves whether or not they wish to use marijuana. We have already acknowledged this competence regarding far more harmful substances, namely alcohol and tobacco. Even prescription drugs, which may have significant ill health effects, as prominently listed on the labels, are merely regulated, with the discretion to use ultimately resting with the user. It is clearly not a perfect system, as many people become addicted to legal drugs, but “at least a system of distribution involving doctors and pharmacists works without violence and high-volume incarceration.”<sup>82</sup> Science has shown marijuana to be less harmful, which should dispel the moral panic surrounding this substance.

Second, the Committee’s statements make reference to instruments of constraint. Regarding drugs, criminalization is the most constraining policy tool available and is clearly ineffective. Decriminalization is much less socially damaging, but, nonetheless, removes many effective tools from the government’s control: they may only make drug violations administrative offences, exacting small fines from users. Legalization, on the other hand, affords governments the use of a wide array of policy tools that would enable them to make marijuana safer and ensure it is sold only to adults. In fact, the Senate Special Committee favoured a legalization framework primarily because of the lack of control associated with decriminalization.<sup>83</sup> Legalization allows government to assert control over the production of marijuana, which is primarily related to controlling pesticide use. This lowers the risk of adverse health effects from asymmetrical information regarding the product’s quality.

This framework would also allow governments to assure consistent quality, affording buyers confidence in the drug’s type and strength. The government or licensed companies would produce the marijuana and licensed retailers would sell it, thus completely removing the criminal element from the marijuana trade, which is the major danger associated with it. The end of alcohol

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<sup>80</sup> Senate Special Committee on Illegal Drugs. *Cannabis: our position for a Canadian public policy: Summary Report*, p. 7.

<sup>81</sup> *Ibid.*, p. 12.

<sup>82</sup> Moskos, Peter and Stanford Franklin. “Legalizing drugs will lead to cuts in crime.”

<sup>83</sup> Senate Special Committee on Illegal Drugs. *Cannabis: our position for a Canadian public policy: Summary Report*, p. 34.

prohibition did just that – organized crime elements could no longer profit from the sale of alcohol, as safer, better, and often cheaper alcohol was available from licensed sellers. A key improvement accompanying licensing systems for sellers is that of controlling youth's access to the drug. It is unlikely to be perfect – the current system for alcohol sales still allows many under-age drinkers to gain access to alcohol, but the legalized and regulated system works far better than prohibition did.

Finally, legalization would allow the government to apply a “sin tax” to marijuana sales, similar to those applied to alcohol and tobacco sales. This is not a primary motivation behind legalization, but it is an important one. Stephen Easton with the Fraser Institute attempted to conservatively estimate the revenue from sales taxes on marijuana. Based on the assumptions that the marijuana is valued at retail street price and sold by the gram,<sup>84</sup> quantities in which most licensed retailers would deal, the amount of British Columbian marijuana produced is worth approximately \$7.156 billion.<sup>85</sup> He calculates that the production costs per gram are approximately \$4.70 and the street returns per half gram of \$8.60.<sup>86</sup> Easton argues that consumers have already shown themselves willing to pay this price for marijuana; therefore, if the government or licensed companies were to produce the legal marijuana at lower costs (making use of economies of scale) and sell it at the current price, they could tax the difference (an amount that is currently profiting illegal producers). Easton estimates this tax revenue to be approximately \$2 billion.<sup>87</sup> This amount would be substantially higher if we were to consider an export tax, which is a difficult proposition because of American and international drug prohibitions. All the same, combined with the savings from reduced law enforcement, fewer trial costs (Canadian Alliance MP Keith Martin estimated that decriminalization of marijuana possession would save Canada \$150 million each year in court costs<sup>88</sup>), and lower prison budgetary needs, these substantial tax revenues could be re-routed to fund educational drug-prevention programs, which must be “credible, verifiable and neutral,”<sup>89</sup> as well as substance abuse treatment centers to help lower the social costs of other, still-criminalized drugs. As Easton points out, “the broader social question has become not whether we approve or disapprove of

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<sup>84</sup> Easton's calculations are made in terms of the amount of marijuana required to roll a marijuana cigarette, or joint. This is approximately one gram.

<sup>85</sup> Easton, Stephen T. *Public Policy Sources: Marijuana Growth in British Columbia*, p. 21.

<sup>86</sup> *Ibid.*, p. 27.

<sup>87</sup> *Ibid.*, p. 27.

<sup>88</sup> “Statistics.” *CBC.ca*. CBC News. November 25, 2004. Accessed November 29, 2009 <<http://www.cbc.ca/news/background/marijuana/statistics.html>>.

<sup>89</sup> Senate Special Committee on Illegal Drugs. *Cannabis: our position for a Canadian public policy: Summary Report*, p. 26.

local production, but rather who shall enjoy the spoils. (...) Unless we wish to continue the transfer of these billions from this lucrative endeavor to organized crime, the current policy on prohibition should be changed."<sup>90</sup> Despite the United States declining to implement such a regulated system with taxation, if it were to end its War on Drugs it would save \$44 billion annually, with an additional \$33 billion from taxation, according to Harvard economist, Jeffrey Miron.<sup>91</sup>

Finally, it is important to note that a legalization scheme for marijuana would necessitate some form of amnesty program for people previously convicted of simple possession, removing the negative social, career, and travel effects of a criminal conviction carries, which is advocated by the Senate Special Committee.<sup>92</sup> The government is attempting to encourage low-income earners to enter the workforce to help address the long-term problem in Canada of a rising dependency ratio that threatens the solvency of Canada's pension system. Restoring to potentially full employability the 600,000 Canadians whose employment prospects have been diminished through marijuana convictions would have a much greater effect in expanding the effective Canadian labour force with no fiscal costs.

Before concluding, it is necessary to briefly discuss the international constraints on legalization. We have already discussed the American War on Drugs and the fact that the United States is highly unlikely to change its stance on drug criminalization. Despite this, first-term Virginia democratic senator Jim Webb has advanced a bill to create an independent commission, similar to the Portuguese one that recommended decriminalization, to review the War on Drugs, its costs, and its results.<sup>93</sup>

However, there are a number of international drug control conventions, to which Canada is a party, that call for continued prohibition of drugs. As we have seen, this does not preclude decriminalization, but it would constrain legalization. The Senate Special Committee considers these conventions to be "an utterly irrational restraint that has nothing to do with scientific or public health considerations."<sup>94</sup> In fact, the Committee found that the conventions instead reflect 20<sup>th</sup> century geopolitical North-South relations: "the strictest controls were placed on organic substances

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<sup>90</sup> Easton, Stephen T. "BC's Marijuana Crop Worth Over \$7 Billion Annually." *FraserInstitute.org*. The Fraser Institute. June 9, 2004. Accessed November 29, 2009 <<http://www.fraserinstitute.org/newsandevents/news/3995.aspx>>.

<sup>91</sup> Moskos, Peter and Stanford Franklin. "Legalizing drugs will lead to cuts in crime."

<sup>92</sup> Senate Special Committee on Illegal Drugs. *Cannabis: our position for a Canadian public policy: Summary Report*, p. 46.

<sup>93</sup> Szalavitz, Maia. "Drugs in Portugal: Did Decriminalization Work?"

<sup>94</sup> Senate Special Committee on Illegal Drugs. *Cannabis: our position for a Canadian public policy: Summary Report*, p. 30.

– the coca bush, the poppy and the cannabis plant – which are often part of the ancestral traditions of the countries where these plants originate, whereas the North's cultural products, tobacco and alcohol, were ignored and the synthetic substances produced by the North's pharmaceutical industry were subject to regulation rather than prohibition.<sup>95</sup> These conventions echo a contributing factor to the original criminalization of most drugs: racial prejudices.

The Senate Special Committee therefore argues that Canada should request the removal of cannabis and its derivatives from these international conventions, as their classifications do not reflect the danger the drugs pose to health and society.<sup>96</sup> They also called for the creation of a Drugs and Dependency Monitoring Agency for the Americas, to be developed within the Organization of American States.<sup>97</sup> This would allow for accurate, unbiased collection of data to support research into drugs and their health and social effects and to help prevention and education efforts.

### Conclusion

Canadian public opinion regarding marijuana has become more informed and there is now growing public support for decriminalization and, to a lesser extent, legalization.<sup>98</sup> This is not surprising considering an estimated 4.5 million people (about 14% of the population) used marijuana in 2004 and 600,000 Canadians have a criminal record for marijuana possession,<sup>99</sup> which would be purged if the law changes. The Senate Special Committee argued that it is not the State's role to "impose a particular way of life on people."<sup>100</sup> The State must respect adults' freedom to choose which substances they wish to consume and to use exhortative, as opposed to coercive, means to promote "an ethic of responsibility [that] teaches social expectations (...) and responsible behaviour."<sup>101</sup>

Through a comparative analysis of the historic case study provided by the criminalization and subsequent legalization of alcohol, American criminalization, and Dutch and Portuguese decriminalization, this paper has shown that criminalization is ineffective at reducing drug

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<sup>95</sup> Ibid., p. 31.

<sup>96</sup> Ibid., p. 32.

<sup>97</sup> Ibid., p. 49-50.

<sup>98</sup> Senate Special Committee on Illegal Drugs. *Cannabis: our position for a Canadian public policy: Summary Report*, p. 20.

<sup>99</sup> "Statistics." *CBC.ca*.

<sup>100</sup> Senate Special Committee on Illegal Drugs. *Cannabis: our position for a Canadian public policy: Summary Report*, p. 38.

<sup>101</sup> Ibid., p. 38-39.

consumption and the accompanying crime. It has also demonstrated that legalization affords governments more regulatory tools, allowing the creation of a controlled environment, similar to the alcohol and tobacco markets. Legalization allows drug distribution to become “the combined responsibility of doctors, the government and a legal and regulated free market.”<sup>102</sup> Finally, the fiscal revenues that could be generated by legalization (approximately \$2 billion), combined with the fiscal savings on enforcement (approximately \$1 billion), prosecution (approximately \$150 million), and incarceration would not only cover the costs of proper regulation, but generate a fiscal bonus to fund other priorities. Going in the opposite direction, as the Harper government proposes, simply digs the fiscal hole even deeper.

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<sup>102</sup> Moskos, Peter and Stanford Franklin. “Legalizing drugs will lead to cuts in crime.”

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**Re: my thoughts on Salvia divinorum**

OCS Policy and Regulatory Affairs to: [redacted]

2011-03-03 02:12 PM

Sent by: Stephanie Chandler

Bcc: Isabel Shanahan, Stephanie Chandler

[redacted] my thoughts on Salvia divinorum

OCS Policy and Regulatory Affe Dear [redacted] I am writing to acknowledge receipt of your email with

Dear [redacted]

I am writing to acknowledge receipt of your email with regards to the publication of the *Notice to Interested Parties* outlining Health Canada's proposal to add *Salvia divinorum* and salvinin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA).

I thank you for your comments regarding this proposal and can assure you they will be taken into consideration as the federal regulatory process progresses. There will also be additional opportunities for comment should a complete regulatory proposal be pre-published in *Canada Gazette*, Part I.

For your information, Health Canada has developed an *It's Your Health* article about *Salvia divinorum* that aims to inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at: <http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/life-vie/salvia-eng.php>

Thank you for writing.

Sincerely,

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada

[redacted] " Because its psychoactive effects resemble tho... 2011-02-20 02:20:50 PM

my thoughts on Salvia divinorum

[redacted] to: OCS.Policy.and.Regulatory.Affairs 2011-02-20 02:20 PM

" Because its psychoactive effects resemble those of other substances included in Schedule III to the CDSA such as lysergic acid diethylamide (LSD) and psilocybin, Health Canada is concerned that the ready availability and use of *S. divinorum* poses a risk to the health and safety of Canadians, particularly youth."

My first comment is that this is only true in a general sense and I suspect that most people who

have used *S. divinorum* would object to this characterization. For a direct comparison of how the subjective effects of these drugs are described by users of *S. divinorum* and drugs such as LSD, I suggest you visit Erowid's "trip reports" section (at [www.erowid.org](http://www.erowid.org); see also Johnson et al., 2010). *Salvia divinorum* has a unique pharmacology and appears to elicit its effects via its action as a kappa-opioid receptor agonist (Chavkin et al., 2011).

The differences in subjective effects are likely due to differences in the mechanisms of actions. Indolealkylamine hallucinogens such as LSD and psilocin are thought to work via 5-HT<sub>2A</sub> agonism (Ebersole et al., 2003; Fantegrossi et al. 2008).

Similarity in the subjective effects of drugs does not necessarily imply a similarity in the safety profile of such drugs. This, is actually an unfortunate fact as LSD and psilocin are essentially non-toxic (Nichols, 2004 and references therein). It is unfortunate that the prohibition of physiologically safe molecules such as LSD and psiloc(yb)in has led to an almost 40 year hiatus in research on these hallucinogens.

The prohibition of these substances had not prevented their use, nor does it appear to have limited the use of hallucinogenic drugs. Instead of being able to access pure LSD or psiloc(yb)in, users risk obtaining adulterated products from the underground market. Some of the drugs that have been sold as LSD include much longer acting hallucinogens such as DOB (Microgram Bulletin, 2006). Substituting DOB for LSD can potentially lead to more adverse reactions due to the lengthy duration of DOB. In my opinion, drug prohibition has not reduced the harm from illicit drugs to any degree and may even increase the danger of using illicit drugs.

I have two objections related to the placement of *Salvia divinorum* and/or its active components on the Controlled Drugs and Substances Act schedule III. The first is that prohibiting the drug will simply drive its use and distribution underground, which will make it more dangerous to use the drug due to possible adulteration.

The second is that prohibition of the drug will halt medical and scientific study on *Salvia divinorum* and its active substances, as prohibiting LSD and other hallucinogens did in the 1960s. Research on the active compounds of *S. divinorum* which have implication for mood disorders (Vortherms and Roth, 2006), could grind to a halt. Two psychopharmacologists at Johns Hopkins, Griffiths and Johnson, stated that research with salvinorin A "has potentially important implications for understanding a variety of disease states, including Alzheimer's disease, schizophrenia, bipolar disorder, dementia, and drug dependence."

I have not seen any compelling evidence to suggest that *Salvia divinorum* is dangerous. The limited trials in humans suggest that it is safe, though the small sample size limits one's confidence in such conclusions (Johnson et al., 2010). If Health Canada's position is that prohibition of *Salvia divinorum* and salvinorin A would be intended to protect the health of Canadians, then I think Health Canada should fund some research to study the physiological effects of these drugs and determine their safety profile and toxicity. In the absence of such information, it is not reasonable to assume that the substances are dangerous and place them on the CDSA, because that would effectively prevent the scientific and medical communities from

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learning anything from these compounds and wouldn't do anything to prevent harm caused by use of these drugs anyway.

When people take drugs, most of them understand that they are taking risks and putting drugs on the CDSA doesn't cause anyone to believe that the drug is too dangerous to be used under any circumstance. Putting *S. divinorum* and salvinorin A on the CDSA will just anger users of the drug, slow scientific and medical research on the drug and drive use of the drug underground, which could potentially cause more harm.

I genuinely believe that placing *S. divinorum* and salvinorin A on the CDSA will do more harm than good.

Sincerely,

[REDACTED]

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Re: **Salvia**

OCS Policy and Regulatory Affairs to: [redacted]

2011-03-03 02:13 PM

Sent by: **Stephanie Chandler**

Bcc: Isabel Shanahan, Stephanie Chandler

[redacted] **Salvia**  
OCS Policy and Regulatory Affairs Dear [redacted] I am writing to acknowledge receipt of your email with  
[redacted] **This is exactly what I was writing \*against: \*\*Canadians should**

Dear [redacted]

I am writing to acknowledge receipt of your email with regards to the publication of the *Notice to Interested Parties* outlining Health Canada's proposal to add *Salvia divinorum* and salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA).

I thank you for your comments regarding this proposal and can assure you they will be taken into consideration as the federal regulatory process progresses. There will also be additional opportunities for comment should a complete regulatory proposal be pre-published in *Canada Gazette*, Part I.

For your information, Health Canada has developed an *It's Your Health* article about *Salvia divinorum* that aims to inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at: <http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/life-vie/salvia-eng.php>

Thank you for writing.

Sincerely,

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada

[redacted] Hello As a citizen of Canada, I want an evidence...

2011-02-20 05:50:49 PM

**Salvia**

[redacted] to: OCS.Policy.and.Regulatory.Affairs

2011-02-20 05:50 PM

Hello

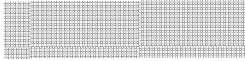
As a citizen of Canada, I want an evidence based drug control policy. In order for *Salvia divinorum* to become a controlled substance in Canada, it should first be shown by Health Canada to be more harmful and addictive than other legal substances like alcohol and tobacco. If a drug cannot be proven to be more harmful and addictive than *legal* substances in Canada, that substance should remain legal. Regardless of personal philosophies, this is merely just logical

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consistency.

I am not a drug user - I even avoid alcohol. But personal freedoms in Canada should not be under siege without strong scientific evidence. Please support an evidence based drug control policy.

Thanks



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**Re: Ban on Salvia divinorum is irresponsible**

OCS Policy and Regulatory Affairs to: [REDACTED]

2011-03-03 02:14 PM

Sent by: Stephanie Chandler

Bcc: Stephanie Chandler, Isabel Shanahan

**Ban on Salvia divinorum is irresponsible**  
OCS Policy and Regulatory Affairs Dear [REDACTED] I am writing to acknowledge receipt of your email with

Dear [REDACTED]

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Thank you for writing.

Sincerely,

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada

Hello, As a Canadian citizen I am absolutely ap...

2011-02-20 07:59:41 PM

**Ban on Salvia divinorum is irresponsible**

[REDACTED] to: OCS.Policy.and.Regulatory.Affairs

2011-02-20 07:59 PM

Hello,

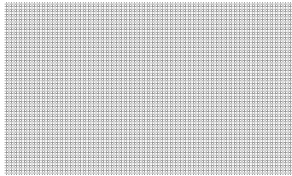
As a Canadian citizen I am absolutely appalled by Health Canada's recent decision to ban *Salvia divinorum*. Not only has Health Canada not backed up this proposed ban with scientific evidence, it is under the guise of protecting children. I don't know about you, but last time I checked drug dealers don't ask for ID when selling their products, and hold no qualms about selling our children drugs on the school playground.

**s.19(1)**

If you truly want to protect our nations youth, you would control the sale of Salvia divinorum similar to Alcohol and Tobacco, where it is only sold to adults and kept out of the hands of children. It is a complete hippocracy that Health Canada is proposing this ban while keeping drugs like Alcohol and Tobacco legal, which cause far more harm to the users health, and society as a whole. Even if Salvia divinorum is found to have noticeable health effects, the social and financial costs of enforcing this ban will far outweigh any health effects.

As a Canadian citizen I urge Health Canada to support an evidence based drug control policy, instead of a morals based one. I sincerely hope Health Canada will reconsider this decision, and not continue decades of failed drug policies.

Thank you for your time,



s.19(1)



**Fw: question about comment submission deadline**  
OCS Policy and Regulatory Affairs to: Denis Arsenault  
Sent by: Stephanie Chandler  
Cc: Stephanie Chandler

2011-03-03 02:22 PM

OCS Policy and Regulatory Affairs: Fw: question about comment submission deadline

Hi Denis,

Please see the proposed response for your review:

\*\*\*\*\*

Dear [redacted]

The 30-day comment period relating to the Notice to Interested Parties regarding the proposal to add *Salvia divinorum* and salvinin A to Schedule III of the *Controlled Drugs and Substances Act* (CDSA) began on the date of its publication in the *Canada Gazette*. Therefore, it would be appreciated if you could submit all comments regarding this proposal by March 21, 2011.

Sincerely,

Stephanie Chandler  
Regulatory Policy Division

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada  
---- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2011-03-03 02:15 PM ----



**question about comment submission deadline**

[redacted] to: OCS.Policy.and.Regulatory.Affairs

2011-02-24 07:11 PM

Please respond to [redacted]

Hello,

I am hoping you can clarify: Is the "30 day comment period" based on the gazette publication date of Feb 19, 2011 or the date in the notice about Salvia, Feb 4, 2011?

Thanks for clarifying,



**Page(s) 003088 to\à 003088**

**Is(Are) exempted pursuant to section(s)  
est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**19(1)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**

s.19(1)



**Fw: Proposal regarding the addition of Salvia divinorum and salvinorin A to Schedule III to the Controlled Drugs and Substances Act**

OCS Policy and Regulatory Affairs to: Denis Arseneault

2011-03-03 02:24 PM

Sent by: Stephanie Chandler

Cc: Stephanie Chandler

OCS Policy and Regulatory Affairs: Fw: Proposal regarding the addition of Salvia divinorum and salvinorin A to S

Hi Denis,

Please see the proposed response for your review:

\*\*\*\*\*

Dear [redacted]

The 30-day comment period relating to the Notice to Interested Parties regarding the proposal to add *Salvia divinorum* and salvinorin A to Schedule III of the *Controlled Drugs and Substances Act* (CDSA) began on the date of its publication in the *Canada Gazette*. The comment period is also 30 calendar days. Therefore, it would be appreciated if you could submit all comments regarding this proposal by March 21, 2011.

Sincerely,

Stephanie Chandler  
Regulatory Policy Division

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada  
---- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2011-03-03 02:22 PM ----

**Proposal regarding the addition of Salvia divinorum and salvinorin A to Schedule III to the Controlled Drugs and Substances Act**

[redacted] to: OCS.Policy.and.Regulatory.Affairs

2011-03-03 02:08 PM

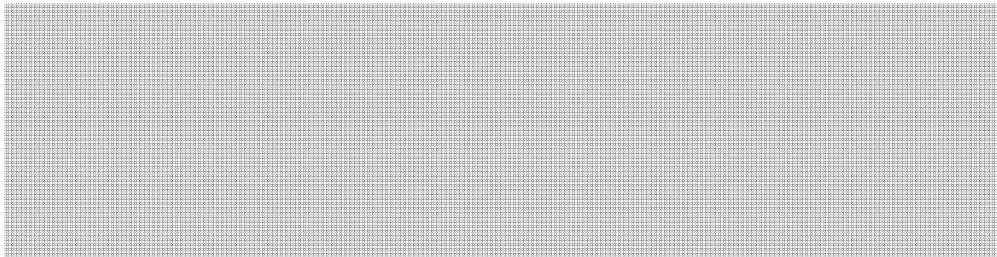
Dear Stephanie Chandler:

Re: Canada Gazette GOVERNMENT NOTICES Vol. 145, No. 8 — February 19, 2011

Could you confirm that the deadline for responding to this proposal is 30 days after the date it was published in the Gazette (February 19, 2011), and not 30 days after the date at the bottom of the notice (Feb 4, 2011).

Also I assume that it is 30 calendar days and not 30 business days, but would also appreciate clarification on this point.

Thanks.





**Fw: Regarding Salvia Divinorum request for comments**

OCS Policy and Regulatory Affairs to: Denis Arsenault

2011-03-03 02:29 PM

Sent by: Stephanie Chandler

Cc: Stephanie Chandler

OCS Policy and Regulatory Affairs: Fw: Regarding Salvia Divinorum request for comments

Hi Denis,

I have slightly revised our original email to stakeholders to notify them of the NOI to answer the attached email. For your approval.

Stephanie

\*\*\*\*\*

Dear [REDACTED]

A *Notice of Intent to Interested Parties* (NOI) regarding the following substances was published in the *Canada Gazette*, Part I on February 19, 2011:

- *Salvia divinorum*
- Salvinorin A

The electronic version of the NOI is available at the following website:

<http://www.gazette.gc.ca/rp-pr/p1/2011/2011-02-19/pdf/g1-14508.pdf> , pages 8-9 in PDF format (pages 438-439 in *Canada Gazette*, Part I).

This NOI outlines Health Canada's proposal to include *Salvia divinorum* and salvinorin A in Schedule III to the *Controlled Drugs and Substances Act* (CDSA). In particular, Health Canada is seeking further information from stakeholders as to whether these substances have any legitimate industrial, scientific or medical uses in Canada. Information received in response to this notice will be instrumental in determining appropriate regulatory controls.

If you are interested in this process or wish to provide us with information for our consideration please do so by March 21, 2011. You may send your comments to Stephanie Chandler, Regulatory Policy Division, Office of Controlled Substances, Address Locator: 3503D, 123 Slater St., Ottawa, Ontario, Canada K1A 1B9, by fax at (613) 946-4224 or by email to [OCS.Policy.and.Regulatory.Affairs@hc-sc.gc.ca](mailto:OCS.Policy.and.Regulatory.Affairs@hc-sc.gc.ca).

Sincerely,

Stephanie Chandler  
Regulatory Policy Division

Office of Controlled Substances/Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada **s.19(1)**  
----- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2011-03-03 02:25 PM -----

**Regarding Salvia Divinorum request for comments**

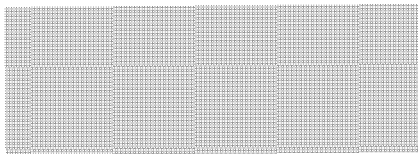
 to: OCS.Policy.and.Regulatory.Affairs

2011-02-23 07:29 PM

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Could you please email me any relevant documents regarding this process as our organization is interested in submitting comments.

Your Truly,



s.19(1)



**Re: Salvia Divinorum**

OCS Policy and Regulatory Affairs to: [REDACTED]

2011-03-03 02:30 PM

Sent by: Stephanie Chandler

Bcc: Stephanie Chandler, Isabel Shanahan

[REDACTED] **Salvia Divinorum**  
OCS Policy and Regulatory Affairs Dear [REDACTED] I am writing to acknowledge receipt of your email with

Dear [REDACTED]

I am writing to acknowledge receipt of your email with regards to the publication of the *Notice to Interested Parties* outlining Health Canada's proposal to add *Salvia divinorum* and salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA).

I thank you for your comments regarding this proposal and can assure you they will be taken into consideration as the federal regulatory process progresses. There will also be additional opportunities for comment should a complete regulatory proposal be pre-published in *Canada Gazette*, Part I.

For your information, Health Canada has developed an *It's Your Health* article about *Salvia divinorum* that aims to inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at: <http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/life-vie/salvia-eng.php>

Thank you for writing.

Sincerely,

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada

[REDACTED] Hello! I recently came across an article about th...

2011-02-20 09:52:59 PM

**Salvia Divinorum**

[REDACTED] to: OCS.Policy.and.Regulatory.Affairs

2011-02-20 09:52 PM

Hello!

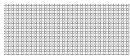
I recently came across an article about the proposed ban on Salvia Divinorum/ Salvinorin A. I was directed to you as the only source of information and contact in the matter. It concerns me, as a citizen of Canada, that the process for deciding these matters is completely inadequate.

**s.19(1)**

Without any research pointing negatively to effects of such a substance, no negative accounts recorded except the only quotable offense of just one threat to police dating 5 years ago, it is claimed a threat to society and youth. Can I ask how many times Canadian police officers have been threatened by sober people? How about under the influence of alcohol? I would wager it will come to a total of more than one but, without a study to find any fault per substance, none can be claimed by me. Without substantial proof of direct cause or even correlation to a negative social affect of anything, let alone substances, no legal precedence should ever occur. Doing so is I direct assault on the freedoms of every Canadian citizen to live their life the way they see fit. It bends people to an opinion driven legal bind with no evidence to support being bound as a positive measure for society. Pardon my being cliché, but there is no better definition of fascism. A massive amount of tax dollars already goes to waste protecting laws produced under this definition. Do not add more without reason above the fact that it is psychoactive, it is an assault on truth.

I would like to request more information on the process incurring, as well as request at least some study into the effects of salvinorin A. The science base of the world deserves such knowledge before a decision is made. We do not know what the plant may hold. Banning it will only increase its use in a negative way due to publicity, make it a black market substance; damaging it's integrity, and destroy any research potential into the positive effects such a substance may hold.

Thanks for your time.



s.19(1)



**Re: Ban on Salvia divinorum**  
OCS Policy and Regulatory Affairs to: [REDACTED]  
Sent by: Stephanie Chandler  
Bcc: Stephanie Chandler, Isabel Shanahan

2011-03-03 02:32 PM

**Ban on Salvia divinorum**  
OCS Policy and Regulatory Affairs Dear [REDACTED] I am writing to acknowledge receipt of your email w

Dear [REDACTED]

I am writing to acknowledge receipt of your email with regards to the publication of the *Notice to Interested Parties* outlining Health Canada's proposal to add *Salvia divinorum* and salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA).

I thank you for your comments regarding this proposal and can assure you they will be taken into consideration as the federal regulatory process progresses. There will also be additional opportunities for comment should a complete regulatory proposal be pre-published in *Canada Gazette*, Part I.

For your information, Health Canada has developed an *It's Your Health* article about *Salvia divinorum* that aims to inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at: <http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/life-vie/salvia-eng.php>

Thank you for writing.

Sincerely,

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada

Hello It has recently come to my attention that H...

2011-02-20 09:56:04 PM

**Ban on Salvia divinorum**

to: ocs.policy.and.regulatory.affairs

2011-02-20 09:56 PM

Hello

It has recently come to my attention that Health Canada intends to impose a ban on the substance *Salvia divinorum*. I request that Health Canada first release the evidence and information used to come to this decision, before the ban itself is put into effect. This ban implies *Salvia* to be more harmful and addictive than legal substances such as alcohol and tobacco and any information regarding this danger should be public knowledge. If in fact *Salvia* can NOT be shown to be as or more harmful than alcohol or tobacco, then logically it must not be banned while the others remain in the open. I hope that you will practice a



consistent, evidence-based, transparent process regarding these matters.  
Thank you for your time.

s.19(1)



**Re: Proposal regarding the addition of Salvia divinorum and salvinorin A to Schedule III to the Controlled Drugs and Substances Act**

OCS Policy and Regulatory Affairs to: Denis Arseneault

2011-03-03 02:35 PM

Sent by: Stephanie Chandler

Cc: Stephanie Chandler

	Conrad Richter	Proposal regarding the addition of Salvia divinorum and salvinorin A to Sch
	OCS Policy and Regulatory Affe	Hi Denis, I spoke to [redacted] earlier, but will still acknowledge receipt

Hi Denis,

I spoke to [redacted] earlier, but will still acknowledge receipt of his email.

\*\*\*\*\*

Dear [redacted]

I am writing to acknowledge receipt of your email with regards to the publication of the *Notice to Interested Parties* outlining Health Canada's proposal to add *Salvia divinorum* and salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA).

It would be appreciated if you could submit all comments regarding this proposal by March 21, 2011.

Thank you for writing.

Sincerely,

Stephanie Chandler  
Regulatory Policy Division

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada

[redacted] Stephanie Chandler We wish to comment on the... 2011-02-21 12:25:21 PM

**Proposal regarding the addition of Salvia divinorum and salvinorin A to Schedule III to the Controlled Drugs and Substances Act**

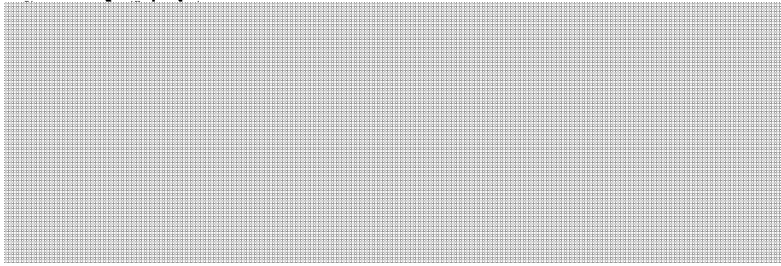
[redacted] to: OCS.Policy.and.Regulatory.Affairs 2011-02-21 12:25 PM

Stephanie Chandler

We wish to comment on the proposal to add *Salvia divinorum* to Schedule III. Also, we would appreciate being added to your mailing list concerning this proposal.

s.19(1)

Thank you.



s.19(1)



**Re: Salvia divinorum**

OCS Policy and Regulatory Affairs to: [REDACTED]

2011-03-03 02:37 PM

Sent by: Stephanie Chandler

Bcc: Stephanie Chandler, Isabel Shanahan

[REDACTED] **Salvia divinorum**  
OCS Policy and Regulatory Affairs Dear [REDACTED] I am writing to acknowledge receipt of your email w

Dear [REDACTED]

I am writing to acknowledge receipt of your email with regards to the publication of the *Notice to Interested Parties* outlining Health Canada's proposal to add *Salvia divinorum* and salvinin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA).

I thank you for your comments regarding this proposal and can assure you they will be taken into consideration as the federal regulatory process progresses. There will also be additional opportunities for comment should a complete regulatory proposal be pre-published in *Canada Gazette*, Part I.

For your information, Health Canada has developed an *It's Your Health* article about *Salvia divinorum* that aims to inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at: <http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/life-vie/salvia-eng.php>

Thank you for writing.

Sincerely,

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada

[REDACTED] To Whom It May Concern, I do not agree with th...

2011-02-21 01:04:58 PM

**Salvia divinorum**

[REDACTED] to: OCS.Policy.and.Regulatory.Affairs

2011-02-21 01:04 PM

To Whom It May Concern,

I do not agree with the proposed ban on *Salvia divinorum*. When used for the purpose that *Salvia divinorum* is use, it is very effective.

In my experience with buying it you had to be 19+ (Ontario) and was asked to show I.D. from the shop I boug

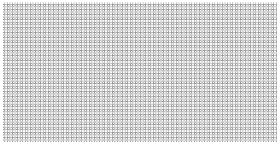
**s.19(1)**

clearly needed like Alcohol & Cigarettes.

Salvia divinorum is not addictive nor can it kill you. If Health Canada was truly concered for the ctizens well  
which kill hundreds of thousands Canadians every year.

Imposing a ban on something is not the answer. We have learned this from the prohibition of Alcohol and cur

Thank you,



s.19(1)



**Re: Proposal to schedule S. divinorum and Salvinorin A**

OCS Policy and Regulatory Affairs to: [redacted]

2011-03-03 02:38 PM

Sent by: Stephanie Chandler

Bcc: Stephanie Chandler, Isabel Shanahan

**Proposal to schedule S. divinorum and Salvinorin A**

OCS Policy and Regulatory Affairs     Dear [redacted]     I am writing to acknowledge receipt of your email with

Dear [redacted]

I am writing to acknowledge receipt of your email with regards to the publication of the *Notice to Interested Parties* outlining Health Canada's proposal to add *Salvia divinorum* and salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA).

I thank you for your comments regarding this proposal and can assure you they will be taken into consideration as the federal regulatory process progresses. There will also be additional opportunities for comment should a complete regulatory proposal be pre-published in *Canada Gazette*, Part I.

For your information, Health Canada has developed an *It's Your Health* article about *Salvia divinorum* that aims to inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at: <http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/life-vie/salvia-eng.php>

Thank you for writing.

Sincerely,

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada

Greetings, I'm interested in commenting about...     2011-02-21 03:56:30 PM

**Proposal to schedule S. divinorum and Salvinorin A**

[redacted] to: OCS.Policy.and.Regulatory.Affairs

2011-02-21 03:56 PM

Greetings,

I'm interested in commenting about the proposal to schedule S. divinorum and Salvinorin A.

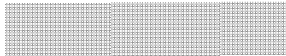
As someone who has experimented with the substances described above, I would ask that the proposal is dropped. Salvia, while known as a legal psychotropic substance, is not one with potential for abuse. While they can be strong, the effects are temporary. The effects are also very

short-lasting and require high grade a potency to achieve. Growing the plant also requires very a specialized environment, and the plant must be grown from clones, which make it very difficult to cultivate and propagate.

According to the Canadian Medical Association Journal (<http://www.cmaj.ca/cgi/content/full/178/2/149>, published January 15, 2008), half of teenagers have used alcohol, and about 20% of those users have used it such that it lead to adverse effects. The article further describes that Marijuana has been used by as many as about 30% of youth in Canada, and most illegal drugs, including Methamphetamine, LSD, and other psychoactive have been used by as few as 5%. Salvia, by Health Canada's survey, has been used at least one time by as few as 7% of teenage users, and frankly the effects, also by Health Canada's description, are not readily enjoyed by users. Prohibiting the possession of salvia will do little to curtail its use, but it will expose the few users to greater possible harms through the few remedies that exist within the legal system.


I implore Health Canada to consider rejecting this proposal. There is no need for it at this time.

Thank you for your consideration.



s.19(1)






**Re: Proposal regarding the addition of Salvia divinorum and salvinorin A to Schedule III to the Controlled Drugs and Substances Act" **

OCS Policy and Regulatory Affairs to: 

2011-03-03 02:40 PM

Sent by: Stephanie Chandler

Bcc: Stephanie Chandler, Isabel Shanahan

  **Proposal regarding the addition of Salvia divinorum and salvinorin A to Sch**  
OCS Policy and Regulatory Affa Dear  I am writing to acknowledge receipt of your email with

Dear 

I am writing to acknowledge receipt of your email with regards to the publication of the *Notice to Interested Parties* outlining Health Canada's proposal to add *Salvia divinorum* and salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA).

I thank you for your comments regarding this proposal and can assure you they will be taken into consideration as the federal regulatory process progresses. There will also be additional opportunities for comment should a complete regulatory proposal be pre-published in *Canada Gazette*, Part I.

For your information, Health Canada has developed an *It's Your Health* article about *Salvia divinorum* that aims to inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at: <http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/life-vie/salvia-eng.php>

Thank you for writing.


Sincerely,

Stephanie Chandler  
Regulatory Policy Division

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada

To: Stephanie Chandler, Regulatory Policy Divis...

2011-02-21 05:48:45 PM

 **Proposal regarding the addition of Salvia divinorum and salvinorin A to Schedule III to the Controlled Drugs and Substances Act"**

 to: ocs.policy.and.regulatory.affairs

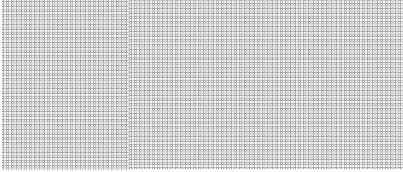
2011-02-21 05:48 PM

To: Stephanie Chandler, Regulatory Policy Division, Office of Controlled Substances,  
Regarding the Governments Proposal to make the Natural Product called "Salvia" illegal; This law will only serve to make more so-called "criminals" out of Canadians. As well, this law will only force the



underground market to take control and sale of this product, in exactly the same way as other so-called "illegal" drugs. The Government never seems to learn anything from past History. One only needs to review history during the time that the USA banned alcohol, to see that even more people died because of the ban. Now that alcohol is legal, we don't see any more drive-by-shootings over beer.

From:



s.19(1)



Re: **Salvia Divinorum**

OCS Policy and Regulatory Affairs to:

2011-03-03 02:41 PM

Sent by: Stephanie Chandler

Bcc: Stephanie Chandler, Isabel Shanahan

**Salvia Divinorum**  
OCS Policy and Regulatory Affe Dear I am writing to acknowledge receipt of your email with re

Dear

I am writing to acknowledge receipt of your email with regards to the publication of the *Notice to Interested Parties* outlining Health Canada's proposal to add *Salvia divinorum* and salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA).

I thank you for your comments regarding this proposal and can assure you they will be taken into consideration as the federal regulatory process progresses. There will also be additional opportunities for comment should a complete regulatory proposal be pre-published in *Canada Gazette*, Part I.

For your information, Health Canada has developed an *It's Your Health* article about *Salvia divinorum* that aims to inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at: <http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/life-vie/salvia-eng.php>

Thank you for writing.

Sincerely,

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada

I am against a proposed ban on salvia Divinoru... 2011-02-21 08:30:39 PM

**Salvia Divinorum**

to: OCS.Policy.and.Regulatory.Affairs 2011-02-21 08:30 PM

I am against a proposed ban on salvia Divinorum.

Salvia is a religious sacrament for many people and is has no potential for abuse as most people who try it do so only once and then never again.

The effects are too weird. Salvia is not a fun drug at all. If you don't believe me try it your self!

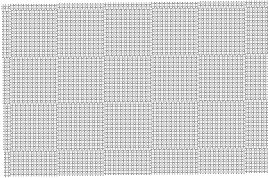
Banning Salvia will only start a black market in it furthering the enrichment of criminal gangs.  
Regulate the sale to adults over 18 or 19 like beer is.

Regulation is the only humane option to controlling drug use.

How many children are you planning to put in jail ?

How many spiritual seekers are you planning to put in jail ?

Thanks for your time.





**Re: Salvia Divinorum needs to be regulated for safety issues and taxed.**

OCS Policy and Regulatory Affairs to: [redacted]

2011-03-03 02:42 PM

Sent by: Stephanie Chandler

Bcc: Isabel Shanahan, Stephanie Chandler

	<b>Salvia Divinorum needs to be regulated for safety issues and taxed.</b>
OCS Policy and Regulatory Affe	<i>Dear Sir/Madam, I am writing to acknowledge receipt of your email with</i>

Dear Sir/Madam,

I am writing to acknowledge receipt of your email with regards to the publication of the *Notice to Interested Parties* outlining Health Canada's proposal to add *Salvia divinorum* and salvinorin A to Schedule III to the *Controlled Drugs and Substances Act (CDSA)*.

I thank you for your comments regarding this proposal and can assure you they will be taken into consideration as the federal regulatory process progresses. There will also be additional opportunities for comment should a complete regulatory proposal be pre-published in *Canada Gazette*, Part I.

For your information, Health Canada has developed an *It's Your Health* article about *Salvia divinorum* that aims to inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at: <http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/life-vie/salvia-eng.php>

Thank you for writing.

Sincerely,

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada

[redacted] The effects of Salvia are very important to kno... 2011-02-21 11:34:59 PM

**Salvia Divinorum needs to be regulated for safety issues and taxed.**

[redacted] to: OCS.Policy.and.Regulatory.Affairs 2011-02-21 11:34 PM

The effects of Salvia are very important to know for people. Salvia is a distinct looking plant that when smoked can provide 5 minutes of elation or nervousness. If salvia was banned no one would have any idea what it does and not have any responsibility if anything bad came out of it.

Savlia Divinorum needs to be regulated and taxed for safety issues, while Salvia Extract is

more potent it generally last less then 5 minutes with a 45 minute afterglow that has more to do with elation and wakefulness. Also people can not drive during the depths of a salvia extract trip, when people come to everything is fine. People need to be aware this goes away or at least not be in a car driving if they smoke a hard variant such as this.

It is not like LSD which last for hours or has a dependence issue like alcohol and tobacco. It won't tax the healthcare system either like diabetes.

Making it illegal will cause the price of it to skyrocket and be sold without any safety net.

s.19(1)



**Re: regarding the addition of Salvia divinorum and salvinorin A to Schedule III to the Controlled Drugs and Substances Act**

OCS Policy and Regulatory Affairs to: [REDACTED]

2011-03-03 02:44 PM

Sent by: Stephanie Chandler

Bcc: Stephanie Chandler, Isabel Shanahan

[REDACTED] regarding the addition of Salvia divinorum and salvinorin A to Schedule III  
OCS Policy and Regulatory Affe Dear [REDACTED] I am writing to acknowledge receipt of your email w

Dear [REDACTED]

I am writing to acknowledge receipt of your email with regards to the publication of the *Notice to Interested Parties* outlining Health Canada's proposal to add *Salvia divinorum* and salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA).

I thank you for your comments regarding this proposal and can assure you they will be taken into consideration as the federal regulatory process progresses. There will also be additional opportunities for comment should a complete regulatory proposal be pre-published in *Canada Gazette*, Part I.

For your information, Health Canada has developed an *It's Your Health* article about *Salvia divinorum* that aims to inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at: <http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/life-vie/salvia-eng.php>

Thank you for writing.

Sincerely,

Stephanie Chandler  
Regulatory Policy Division

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada

[REDACTED] Dear Stephanie Chandler As a tax paying Can...

2011-02-22 01:03:31 AM

regarding the addition of Salvia divinorum and salvinorin A to Schedule III to the Controlled Drugs and Substances Act

[REDACTED] to: OCS.Policy.and.Regulatory.Affairs

2011-02-22 01:03 AM

Dear Stephanie Chandler

As a tax paying Canadian father, I believe that I am a stakeholder and I am taking this opportunity to

provide comments on Health Canada's proposal to add the plant *Salvia divinorum* (*S. divinorum*) and its

main active ingredient salvinorin A to Schedule III to the Controlled Drugs and Substances Act (CDSA).

My intention is not to dispute Health Canadas concern that the ready availability and use of *S. divinorum* poses a risk to the health and safety of Canadians, but rather contend that prohibition is

not the answer & it would in fact exacerbate the situation & be a waste of our finances. Resources

wasted on arrest, processing, prosecuting & incarcerating to enforce prohibition could be used in effective ways instead & have much left over for our betterment.

From what I have read about *Salvia* there is nothing distinguishing such as smell to differentiate it

from any other ground up plant matter. Any culinary artist would be a suspected trafficker. Imagine

the logistic problems & opportunities for abuse by law enforcement. I support LEAP (Law Enforcement

Against Prohibition [www.leap.cc](http://www.leap.cc)), a 5000 member strong organization that would agree with me. In fact I

have yet to find anyone that believes that prohibition works.

To be clear, I do NOT want the plant *Salvia divinorum* (*S. divinorum*) and its main active ingredient

salvinorin A to be added to Schedule III of the Controlled Drugs and Substances Act (CDSA). I believe

that doing so will just create a black market for yet another "controlled" substance. There is no

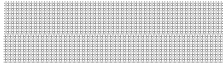
**s.19(1)**

regulation in a black market which poses even more health risks. I feel that education through unbiased

research & freedom of choice are better recieved by a free society than force.

Please feel free to contact me with any questions, concerns, or suggestions regarding my comments.

Sincerely,





s.19(1)



Re: **Salvia divinorum**

OCS Policy and Regulatory Affairs to: [redacted]  
Sent by: Stephanie Chandler  
Bcc: Stephanie Chandler, Isabel Shanahan

2011-03-03 02:47 PM

[redacted] **Salvia divinorum**  
OCS Policy and Regulatory Affairs Dear [redacted] I am writing to acknowledge receipt of your email with

Dear [redacted]

I am writing to acknowledge receipt of your email with regards to the publication of the *Notice to Interested Parties* outlining Health Canada's proposal to add *Salvia divinorum* and salvinin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA).

I thank you for your comments regarding this proposal and can assure you they will be taken into consideration as the federal regulatory process progresses. There will also be additional opportunities for comment should a complete regulatory proposal be pre-published in *Canada Gazette*, Part I.

For your information, Health Canada has developed an *It's Your Health* article about *Salvia divinorum* that aims to inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at: <http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/life-vie/salvia-eng.php>

Thank you for writing.

Sincerely,

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada

[redacted] I am opposed to Health Canada's proposal to ad... 2011-02-22 09:25:55 PM

**Salvia divinorum**

[redacted] to: ocs.policy.and.regulatory.affairs 2011-02-22 09:25 PM

I am opposed to Health Canada's proposal to add salvia to the Controlled Drugs and Substances Act. There are no conclusive studies to indicate that this substance causes anything more than brief hallucinogenic affects. It is not the role of the Canadian government to ban substances simply because they are used recreationally. We need to be very careful when adding further restrictions to the rights of individuals. In a free society, this must not be done casually or arbitrarily.

Salvia has primarily been brought to recent public attention by the RCMP and other police agencies. Canadian police are looking for empowerment so they can take action on controlling this substance. I

have no doubt they see this as their duty in order to protect Canadians. Salvia is a plant that affects perception and mood, and so it naturally draws parallels to marijuana. Police believe they should be authorized to control salvia in the same way they control marijuana.

Adding a substance to the CDSA simply because it resembles other currently controlled substances is not valid reasoning. Each substance should be evaluated on its own risk to human well-being. There is currently no data to support that this substance poses a serious health risk. Anecdotal evidence is not an adequate justification to cut away a piece of Canadian society's freedom. A group of vocal individuals who hold unsupported opinions that something "might be bad" is not an adequate justification to make that thing illegal.

Aside from the lack of evidence to show any significant health risk from salvia, there is the economic and social impact of this decision. If you make this substance illegal, the desire to use it is not going to go away. You are immediately creating a black market where criminals will produce and sell the substance, instead of this being done by legitimate business owners. Police resource will need to increase to control it, requiring additional tax dollars. The criminal element will not be paying taxes on revenues from the sales of this substance. History has shown that a government cannot arbitrarily convince its citizens that a substance is harmful, without evidence to support their claims, and so people will continue using salvia for recreational purposes. These people will be charged and so the drain on our judicial system and our prison costs will increase. The criminals who sell the substance will have no legal recourse to overcome disputes, and street violence will increase.

The only benefit of banning salvia is that some overzealous police, frightened parents, and impressionable government officials will sleep more soundly thinking they have done the right thing. These flippant benefits are greatly outweighed by the overall cost to the country.

I do not want my tax dollars going towards wasted police efforts on controlling a substance that the general population does not want controlled. I do not want criminals profiting on drug revenue without paying taxes. I do not want young people being treated as criminals for experimenting with drugs. I do not want organized crime continuing to create violence in our cities, while our own laws essentially fund their source of revenue.

If you want to perform a study on the effects of salvia, please send my tax dollars there. If you want to promote educational resources to inform young people in Canada about the statistically-supported health risks of recreational substances, send my tax dollars there. If you want to fund services providing rehabilitation to the minority of drug users who are overcome by addiction, send my tax dollars there.

Do not add salvia to the CDSA. There is no logic behind it. This is a knee-jerk decision brought on by our irrational fear of any substance that is used recreationally. This fear has been causing bad political decisions for decades, so please do not add another bad decision to the list.

Thank you.



**Re: Notice to interested parties – Proposal regarding the addition of Salvia divinorum and salvinorin A to Schedule III to the Controlled Drugs and Substances Act**

OCS Policy and Regulatory Affairs to: [redacted] 2011-03-03 02:48 PM  
Sent by: Stephanie Chandler  
Bcc: Stephanie Chandler, Isabel Shanahan

[redacted] Notice to interested parties – Proposal regarding the addition of Salvia divi  
OCS Policy and Regulatory Affe Dear [redacted] I am writing to acknowledge receipt of your email with

Dear [redacted]

I am writing to acknowledge receipt of your email with regards to the publication of the *Notice to Interested Parties* outlining Health Canada's proposal to add *Salvia divinorum* and salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA).

I thank you for your comments regarding this proposal and can assure you they will be taken into consideration as the federal regulatory process progresses. There will also be additional opportunities for comment should a complete regulatory proposal be pre-published in *Canada Gazette*, Part I.

For your information, Health Canada has developed an *It's Your Health* article about *Salvia divinorum* that aims to inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at: <http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/life-vie/salvia-eng.php>

Thank you for writing.

Sincerely,

Stephanie Chandler  
Regulatory Policy Division

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada

[redacted] Dear Stephanie Chandler, I'm would like to be m... 2011-02-22 09:40:02 PM

**Notice to interested parties – Proposal regarding the addition of Salvia divinorum and salvinorin A to Schedule III to the Controlled Drugs and Substances Act**

[redacted] to: OCS.Policy.and.Regulatory.Affairs 2011-02-22 09:40 PM

Dear Stephanie Chandler,

I'm would like to be made aware of any future actions or consultations pursuant to the "Notice to interested parties - Proposal regarding the addition of Salvia divinorum and salvinorin A to Schedule III to the Controlled Drugs and Substances Act". **s.19(1)**

Personally I oppose adding this plant to Schedule III. I do not believe that such an action will increase the safety of the public, or youths. Instead, as is clear from other related Schedule III substances, such action will simply foster an illicit trade in the plant and it's derivatives, which will expose the public and youths to greater threat, and the increased possibility of this substance being contaminated with other drugs and chemicals before hitting the streets. It would be considerably more harmful to the general public if the availability of this plant were to become the sole purview of organized criminals involved in illicit drug trafficking. Moreover such action is likely to increase the strain on the criminal justice system, therefore also the public tax burden, and both needlessly and irreparably tarnish the prospects of any parties, particularly youths who are thus convicted.

Lastly, this plant is a visionary medicine held sacred by many indigenous peoples of Central and North America who have millennia of tradition surrounding it's use in ceremonial/initiatory processes. While I agree that reducing it's availability to minors is desirable, I think that overall, the risks involved in legislating around that, are far greater than any potential harm which the plant poses to the public under current the law. Since it has been clearly cited in the text of this consultation that the effects are both very short-term, and can often be unpleasant, I feel that alone provides sufficient deterrent against it's use. Rather than legislation, what is instead called for is appropriate labeling, and liability on the part of distributors. Together with education concerning the history and appropriate (sacred) context of using this plant, any perceived harm can be easily and readily avoided.

Regards,

--  


s.19(1)



**Re: Proposal regarding the addition of Salvia divinorum and salvinorin A to Schedule III**

OCS Policy and Regulatory Affairs to: [REDACTED]

2011-03-03 02:50 PM

Sent by: Stephanie Chandler

Bcc: Stephanie Chandler, Isabel Shanahan

[REDACTED] Proposal regarding the addition of Salvia divinorum and salvinorin A to Sch  
OCS Policy and Regulatory Affa Dear [REDACTED] I am writing to acknowledge receipt of your email with

Dear [REDACTED]

I am writing to acknowledge receipt of your email with regards to the publication of the *Notice to Interested Parties* outlining Health Canada's proposal to add *Salvia divinorum* and salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA).

I thank you for your comments regarding this proposal and can assure you they will be taken into consideration as the federal regulatory process progresses. There will also be additional opportunities for comment should a complete regulatory proposal be pre-published in *Canada Gazette*, Part I.

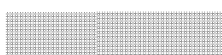
For your information, Health Canada has developed an *It's Your Health* article about *Salvia divinorum* that aims to inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at: <http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/life-vie/salvia-eng.php>

Thank you for writing.

Sincerely,

Stephanie Chandler  
Regulatory Policy Division

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada



Dear Stephanie Chandler, I would like to be ma...

2011-02-22 10:32:18 PM

**Proposal regarding the addition of Salvia divinorum and salvinorin A to Schedule III**



to: OCS.Policy.and.Regulatory.Affairs

2011-02-22 10:32 PM

Dear Stephanie Chandler,

I would like to be made aware of any future actions or consultations pursuant to the "Notice to

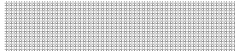
**s.19(1)**

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Personally I oppose adding this plant to Schedule III. I do not believe that such an action will increase the safety of the public, or youths. Instead, as is clear from other related Schedule III substances, such action will simply foster an illicit trade in the plant and it's derivatives, which will expose the public and youths to greater threat, and the increased possibility of this substance being contaminated with other drugs and chemicals before hitting the streets. It would be considerably more harmful to the general public if the availability of this plant were to become the sole purview of organized criminals involved in illicit drug trafficking. Moreover such action is likely to increase the strain on the criminal justice system, therefore also the public tax burden, and both needlessly and irreparably tarnish the prospects of any parties, particularly youths who are thus convicted.

Lastly, this plant is a visionary medicine held sacred by many indigenous peoples of Central and North America who have millennia of tradition surrounding it's use in ceremonial/initiatory processes. While I agree that reducing it's availability to minors is desirable, I think that overall, the risks involved in legislating around that, are far greater than any potential harm which the plant poses to the public under current the law. Since it has been clearly cited in the text of this consultation that the effects are both very short-term, and can often be unpleasant, I feel that alone provides sufficient deterrent against it's use. Rather than legislation, what is instead called for is appropriate labeling, and liability on the part of distributors. Together with education concerning the history and appropriate (sacred) context of using this plant, any perceived harm can be easily and readily avoided.

Thank you,





**Re: From a VERY concerned person...**

OCS Policy and Regulatory Affairs to: [redacted]

Sent by: Stephanie Chandler

Bcc: Stephanie Chandler, Isabel Shanahan

2011-03-03 02:51 PM

[redacted] From a VERY concerned person...  
OCS Policy and Regulatory Affairs Dear Sir/Madam, I am writing to acknowledge receipt of your email with

Dear Sir/Madam,

I am writing to acknowledge receipt of your email with regards to the publication of the *Notice to Interested Parties* outlining Health Canada's proposal to add *Salvia divinorum* and salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA).

I thank you for your comments regarding this proposal and can assure you they will be taken into consideration as the federal regulatory process progresses. There will also be additional opportunities for comment should a complete regulatory proposal be pre-published in *Canada Gazette*, Part I.

For your information, Health Canada has developed an *It's Your Health* article about *Salvia divinorum* that aims to inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at: <http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/life-vie/salvia-eng.php>

Thank you for writing.

Sincerely,

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada

[redacted] Hello, After hearing about the plans to completel...

2011-02-22 10:58:49 PM

[redacted] From a VERY concerned person...

[redacted] to: OCS.Policy.and.Regulatory.Affairs

2011-02-22 10:58 PM

Hello,

After hearing about the plans to completely disregard peoples freedom and spiritual beliefs in Canada my heart began to ache and my emotion flared. I have never heard such unsympathetic closed-minded nonsense. Yes, I'm speaking about *Salvia divinorum* "The Teacher Plant" that has gained a reputation by those who do not take the time to learn about it... For those who are the same people that allow cigarettes and alcohol to destroy the lives and kill millions of people annually, its hard to understand how a plant so useful and entirely harmless when used properly

**s.19(1)**

can become illegal. May I ask why? It IS NOT a burden on society neither financially nor ethically, it is completely non addictive, in fact many can work with the plant once, heal addictions, mental distress and emotional turmoil and then never have the urge to use it again. I feel so unbelievably frustrated and confused by what is happening to Canada... The freedoms of spiritual growth that once were accepted and maybe taken for granted are now being pummeled with fascist thinking and the efforts to put money before societies well-being. Salvia divinorum is not a problem in our country, that is a fact; there are millions of plants that are useful when used properly and i fear that this action to outlaw Salvia divinorum is not only a big mistake because it is such a useful plant but it will also lead to the destruction of all natural products allowing room for the pharmaceutical companies to corner the market in what they call 'healing' which is not healing, it is masking and multiplying the problems for greedy purposes... but that is a different story... my point is; if the Government is allowed to make a judgement call on something they know NOTHING about then we have lost all rights to religious and spiritual freedom and the right to use nature to heal our own bodies both mentally and physically. And to me... That is scary!

My heart is hopeful that someone comes to their senses and remembers that CANADA IS FREE!!!

Thank you,





**Re: Proposal regarding the addition of Salvia divinorum and salvinorin A to Schedule III to the Controlled Drugs and Substances Act**

OCS Policy and Regulatory Affairs to: [REDACTED]

2011-03-03 02:52 PM

Sent by: Stephanie Chandler

Bcc: Stephanie Chandler, Isabel Shanahan

[REDACTED] Proposal regarding the addition of Salvia divinorum and salvinorin A to Sch  
OCS Policy and Regulatory Affs Dear [REDACTED] I am writing to acknowledge receipt of your email w

Dear [REDACTED]

I am writing to acknowledge receipt of your email with regards to the publication of the *Notice to Interested Parties* outlining Health Canada's proposal to add *Salvia divinorum* and salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA).

I thank you for your comments regarding this proposal and can assure you they will be taken into consideration as the federal regulatory process progresses. There will also be additional opportunities for comment should a complete regulatory proposal be pre-published in *Canada Gazette*, Part I.

For your information, Health Canada has developed an *It's Your Health* article about *Salvia divinorum* that aims to inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at: <http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/life-vie/salvia-eng.php>

Thank you for writing.

Sincerely,

Stephanie Chandler  
Regulatory Policy Division

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada

[REDACTED] Dear Ms. Chandler, I am writing you because I a...

2011-02-23 12:42:19 AM

Proposal regarding the addition of Salvia divinorum and salvinorin A to Schedule III to the Controlled Drugs and Substances Act

[REDACTED] to: ocs.policy.and.regulatory.affairs

2011-02-23 12:42 AM

Dear Ms. Chandler,

I am writing you because I am concerned about the proposed ban on Salvia Divinorum. As part of a

s.19(1)

university project, I researched Salvia Divinorum quite extensively. I would be happy to provide you with detailed research and references at your request, but for now I assume you are pressed for time, so here are some brief points and concerns:

-I realize that a very small percent of the population have used Salvia. My research finds that an exceptionally small portion ever use it more than once and an even smaller number use it with any regularity. How many reports of addiction or abuse have you come across? Do you know of any hospitalizations resulting from Salvia use?

-I believe that banning this substance will not reduce use. A small market will still exist for the plant and people will still trade in it, without any taxation. People buying it on the black market may be presented with options to obtain more dangerous substances from the black market suppliers. Banning the plant may also increase the allure of it to some. Some occasional users will use other illegal substances instead, which may or may not have a better safety record, while others may use legal though remarkably dangerous intoxicants such as aerosols.

-I think the social and economic costs of the criminalization of users will far outweigh any benefits. What do your calculations indicate?

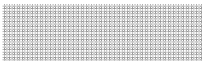
-Though I am not aware of any current research underway in Canada, I do believe this plant should be explored for therapeutic/medicinal potential.

Having mentioned all of this, I must say that I do think sales should be restricted to persons over the age of 19 and perhaps there should be some labeling requirements detailing harm-reduction approaches to use.

I urge you to reconsider this ban.

I eagerly await your response.

Sincerely



s.19(1)



**Re: Formal Protest of adding *S. divinorum* and salvinorin to Controlled Drugs and Substances Act scheduling**

OCS Policy and Regulatory Affairs to: [REDACTED]

2011-03-03 02:54 PM

Sent by: Stephanie Chandler

Bcc: Stephanie Chandler, Isabel Shanahan

[REDACTED] Formal Protest of adding *S. divinorum* and salvinorin to Controlled Drugs a  
OCS Policy and Regulatory Affa Dear [REDACTED] I am writing to acknowledge receipt of your email wi

Dear [REDACTED]

I am writing to acknowledge receipt of your email with regards to the publication of the *Notice to Interested Parties* outlining Health Canada's proposal to add *Salvia divinorum* and salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA).

I thank you for your comments regarding this proposal and can assure you they will be taken into consideration as the federal regulatory process progresses. There will also be additional opportunities for comment should a complete regulatory proposal be pre-published in *Canada Gazette*, Part I.

For your information, Health Canada has developed an *It's Your Health* article about *Salvia divinorum* that aims to inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at: <http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/life-vie/salvia-eng.php>

Thank you for writing.

Sincerely,

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada

[REDACTED] It has come to my attention that the plant known...

2011-02-23 08:27:39 AM

**Formal Protest of adding *S. divinorum* and salvinorin to Controlled Drugs and Substances Act scheduling**

[REDACTED] to: OCS.Policy.and.Regulatory.Affairs

2011-02-23 08:27 AM

It has come to my attention that the plant known as *Salvia Divinorum* (*Salvia*) is being considered to be added to the Controlled Drugs and Substance Act scheduling.

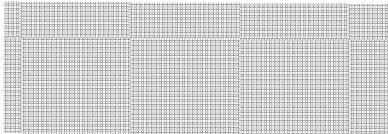
I am lodging a protest against *Salvia* being added to the Controlled Drugs and Substance Act scheduling.

**s.19(1)**

As mistakenly portrayed in the Canada Gazette, salvinorin A is not a substance that is like those found in Schedule III of the CDSA because salvinorin A is not an alkaloid.

Being an adult of sound mind and body, I recognize that Salvia can be potent. The statistics portrayed in Canada Gazette is not scientifically principled because use in of itself does not constitute a threat. The Canada Gazette statistics does not illustrate the potency of the Salvia consumed, nor does it statistically correlate it to any theoretical toxic effects such as organ damage.

Finally, a legal adult substance cannot be banned simply because it is used in a disrespectful manner by troubled youth.





**Fw: Submissions on Salvia**

OCS Policy and Regulatory Affairs to: Denis Arsenault

2011-03-03 02:56 PM

Sent by: Stephanie Chandler

Cc: Stephanie Chandler

OCS Policy and Regulatory Affairs: Submissions on Salvia

Hi Denis,

For your review

\*\*\*\*\*

Dear [redacted]

The 30-day comment period relating to the Notice to Interested Parties regarding the proposal to add *Salvia divinorum* and salvinorin A to Schedule III of the *Controlled Drugs and Substances Act* (CDSA) began on the date of its publication in the *Canada Gazette*. Therefore, it would be appreciated if you could submit all comments regarding this proposal by March 21, 2011.

Sincerely,

Stephanie Chandler  
Regulatory Policy Division

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada  
---- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2011-03-03 02:54 PM ----



**Submissions on Salvia**

[redacted] to: OCS.Policy.and.Regulatory.Affairs

2011-02-23 06:34 PM

Hello:

Is the submission deadline March 4 or March 19?

Best,

[redacted]

**Page(s) 003125 to\à 003125**

**Is(Are) exempted pursuant to section(s)  
est(sont) exemptée(s) en vertu de(s)(l')article(s)**

**19(1)**

**of the Access to Information Act  
de la Loi sur l'accès à l'information**

s.19(1)



**Re: Salvia Ban**

OCS Policy and Regulatory Affairs to: [REDACTED]

2011-03-03 03:01 PM

Sent by: Stephanie Chandler

Bcc: Stephanie Chandler, Isabel Shanahan

[REDACTED] **Salvia Ban**  
OCS Policy and Regulatory Affairs Dear [REDACTED] I am writing to acknowledge receipt of your email with

Dear [REDACTED]

I am writing to acknowledge receipt of your email with regards to the publication of the *Notice to Interested Parties* outlining Health Canada's proposal to add *Salvia divinorum* and salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA).

I thank you for your comments regarding this proposal and can assure you they will be taken into consideration as the federal regulatory process progresses. There will also be additional opportunities for comment should a complete regulatory proposal be pre-published in *Canada Gazette*, Part I.

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Thank you for writing.

Sincerely,

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada

[REDACTED] Hello, I don't have the time to write a lengthy em...

2011-02-23 09:57:15 PM

**Salvia Ban**

[REDACTED] to: OCS.Policy.and.Regulatory.Affairs@hc-sc.gc.ca

2011-02-23 09:57 PM

Hello,

I don't have the time to write a lengthy email with all the information to back up my opinion. But my opinion is this: Banning salvia is unnecessary.

I am speaking for thousands of other people out there as well. The claim of lack of knowledge about long term effects is bogus. "You" simply have a problem with people (and more specifically, youths) experiencing "hallucinations". I may be wrongly assuming this, but I believe that the

people who are making decisions here have never attempted salvia and base much of their "knowledge" on external observations of the affects of salvia. It is a drug that causes no physical harm, and only causes people to learn more about themselves and the world, as well as allowing the people to experience intense wonder and to simply enjoy themselves.



Sincerely,



s.19(1)








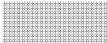




**Re: Dep. of Health Notice. Feb. 4, 2011**   
OCS Policy and Regulatory Affairs to:   
Sent by: Stephanie Chandler  
Bcc: Stephanie Chandler, Isabel Shanahan

s.19(1)

2011-03-03 03:02 PM

  **Dep. of Health Notice. Feb. 4, 2011**  
 OCS Policy and Regulatory Affairs *Dear I  I am writing to acknowledge receipt of your email with re*  
  *Dear Stephanie Chandler,*  
  *Hello again. I realize ou must be busy, but I am wonder*

Dear 

I am writing to acknowledge receipt of your email with regards to the publication of the *Notice to Interested Parties* outlining Health Canada's proposal to add *Salvia divinorum* and salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA).

I thank you for your comments regarding this proposal and can assure you they will be taken into consideration as the federal regulatory process progresses. There will also be additional opportunities for comment should a complete regulatory proposal be pre-published in *Canada Gazette*, Part I.


For your information, Health Canada has developed an *It's Your Health* article about *Salvia divinorum* that aims to inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at: <http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/life-vie/salvia-eng.php>

Thank you for writing.

Sincerely,

Stephanie Chandler  
Regulatory Policy Division

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada

 Dear Ms./Mrs. Stephanie Chandler We write yo... 2011-02-24 03:29:44 PM

**Dep. of Health Notice. Feb. 4, 2011**

 to: ocs.policy.and.regulatory.affairs

2011-02-24 03:29 PM

Dear Ms./Mrs. Stephanie Chandler

We write you today in response to the bulletin posted February 4, 2011 on the Canadian Gazette titled: Notice to interested parties – Proposal regarding the addition of *Salvia divinorum* and salvinorin A to Schedule III to the *Controlled Drugs and Substances Act*

After reviewing your notice and also going through some texts on this particular member of the Sage family I have some serious concerns about it being scheduled in Canada. We have little reason to disagree with somehow controlling the sale of purified psychotropic substances, such as Salvinorin A, we feel it would be against Canada's best interest to further ban and consequently prosecute Canadian citizens for the plant itself.

In the notice, we get the impression that that the health risks were so far not understood, or perhaps misunderstood, and there was concern for youth using psychotropic substances. In studies done in labs on rats, and also through contacting various retailers, it would seem that physical health risk are quite limited, if not completely unheard of. The greatest risk to ones self appears to be harming ones self while intoxicated. Reviewing the reports of people under the influence of Salvinorin A, mobility is greatly impaired, making very dangerous acts such as driving quite impossible. Relative to other psychotropics that last much longer and act on the body in a way that allows one to get around easier, there seems far less room for concern with this particular substance. The fast onset of the effects, and the short duration make it a difficult substance to take to public arenas such as bars, concerts or other common places people may take up such activities.

Reading off the DEA's website in the United states, they claim that "Salvia divinorum most likely will not become widely abused" (DEA 2003). Due to this substance being quite non-addictive (Kappa opioids are negatively reinforcing, which make them very difficult to become addicted to), and the effects of the substance being of a very non popular flavour (which seems to result in people unwilling to continue use), habitual use seems incredibly low by any measure.

In a report testing Salvinorin A on rats, Mowry et al. showed that 6.4 mg/kg/day of salvinorin A by intraperitoneal injection in rats for two weeks produced no fatality or toxicity, and when the rats were autopsied, no changes were noted in their organs or tissues. To our knowledge no such toxicity or damage to the organs, including the brain, have ever been published or mentioned in the literature.

We see in your notice, perhaps the biggest concern is youth using Salvinorin A for its psychotropic effects. This we feel compelled to agree with a controlling of the substance not unlike alcohol and tobacco where there is an age requirement. Or even perhaps just banning the extracted substances, and exempting the plant itself, much like I see the Controlled Substances Act has done with mescaline and exempting the live plants.

We believe, and have found to be the case in many other nations we have traveled to and collected plant species for study, that when any species and any part of that species becomes banned outright, there is a few ill effects placed upon that nation. When actual plants are banned, there are far more people who may be included in the "criminal" category, and indeed in some nations they are imprisoned for having such plants without manufacturing or distributing them. Aside from this being devastating on the citizens of the nation, it also costs quite a Lot to deal with criminals in our society. I have witnessed this in Malaysia and China for example, both of which ave similar policies with banning a species and everything related to it, no matter what. I also notice that nations that tend to ban substances that may be obtained from plants, but leave plants themselves alone, tend to have a far more workable prison system and the costs associated with it are far fewer. One such example would be Portugal.

We have no specific quarrel with protecting youth and keeping substances that intoxicate them away from easy access. We have very deep concerns about making plants outright illegal for the average Canadian citizen to grow in their gardens and on their windowsill, or for a university or medical research centre to be able to cultivate the plant and preform studies on them. It is quite important for us, as citizens of a nation that is such a role model of freedom and human rights, to not be prosecuted for growing Sage and risk imprisonment and loss of freedom and lose the privilege to travel to other nations due to a criminal record based on growing a Salvia species. We urge you to consider the research already done by universities, private researchers and consider our freedoms and rights as Canadians and what may be at stake. We feel very fortunate to live in such an open and free country where we can voice our concerns and be heard by our leaders. It gives us all a great sense of accomplishment and pride to be able to say to people that we do have a say in what freedoms we may enjoy, and that our leaders will listen to us and use their best judgment in deciding what is truly best for the people and does not interfere with what we stand for; Glorious and free.

We are currently in [REDACTED] therefor, we will not return to back Canada for another few months. We would, however, like to be kept informed of any progression of this notice, and anything related to it. If you have a mailing list for this, or some other means of staying informed we would very much appreciate it.

Sincerely,

[REDACTED]

Here is some of the published data we have reviewed

- DEA. 2003. "Information bulletin: Salvia divinorum" Microgram Bulletin 36(6): 122-125.
- Baggott, M.J., E. Erowid, F. Erowid, and J.E. Mendelson. 2004. "Use of Salvia divinorum, an unscheduled hallucinogenic plant: A web-based survey of 500 users"
- Hanes, K.R. 2001. "Antidepressant effects of the herb Salvia divinorum" Journal of Clinical Psychopharmacology 21(6): 634-635.
- Hanes, K.R. 2003. "Salvia divinorum: Clinical and research potential" MAPS 13(1): 18-20.
- Khey, D.N., B.L. Miller, and O.H. Griffin III. 2008. "Salvia divinorum use among a college student sample" Journal of Drug Education 38(3): 297-306.
- Roth, Bryan L. et al. 2002 "Salvinorin A: A potent naturally occurring nonnitrogenous k opioid selective agonist"

s.19(1)



Re:

OCS Policy and Regulatory Affairs to:

2011-03-03 03:04 PM

Sent by: Stephanie Chandler

Bcc: Stephanie Chandler, Isabel Shanahan

OCS Policy and Regulatory Affairs Dear am writing to acknowledge receipt of your email with

Dear

I am writing to acknowledge receipt of your email with regards to the publication of the *Notice to Interested Parties* outlining Health Canada's proposal to add *Salvia divinorum* and salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA).

I thank you for your comments regarding this proposal and can assure you they will be taken into consideration as the federal regulatory process progresses. There will also be additional opportunities for comment should a complete regulatory proposal be pre-published in *Canada Gazette*, Part I.

For your information, Health Canada has developed an *It's Your Health* article about *Salvia divinorum* that aims to inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at: <http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/life-vie/salvia-eng.php>

Thank you for writing.

Sincerely,

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada

dear reader. i have learned that salvia may be s... 2011-02-25 09:50:17 AM



to: ocs.policy.and.regulatory.affairs 2011-02-25 09:50 AM

From:

To: <ocs.policy.and.regulatory.affairs@hc-sc.gc.ca>

dear reader.

i have learned that salvia may be soon regulated. i cant believe Canada is thinking about this, its already a Natural Health Product, that's good enough, don't make salvia illegal that's foolish. shamans using this

magical plant for centuries and soon as us westners get ahold of these plants, they become prohibited.

please, don't make salvia illegal. it doesn't hurt the body or the mind. just keep it as a NHP or put age  
limit on it. DONT make it illegal for canadians, PLEASE!!

peace,



**s.19(1)**

s.19(1)



**Re: Consideration of Salvia Divinorum addition to Schedule III of the CD&S Act**

OCS Policy and Regulatory Affairs to: [REDACTED] 2011-03-03 03:05 PM

Sent by: Stephanie Chandler

Bcc: Stephanie Chandler, Isabel Shanahan

[REDACTED] Consideration of Salvia Divinorum addition to Schedule III of the CD&S Act

OCS Policy and Regulatory Affairs Dear [REDACTED] I am writing to acknowledge receipt of your email with

Dear [REDACTED]

I am writing to acknowledge receipt of your email with regards to the publication of the *Notice to Interested Parties* outlining Health Canada's proposal to add *Salvia divinorum* and salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA).

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Thank you for writing.

Sincerely,

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada

[REDACTED] I wanted to include my opinion as a taxpayer an... 2011-02-25 03:28:39 PM

**Consideration of Salvia Divinorum addition to Schedule III of the CD&S Act**

[REDACTED] to: ocs.policy.and.regulatory.affairs 2011-02-25 03:28 PM

I wanted to include my opinion as a taxpayer and citizen in this issue. Please understand that by reading this, you will be exposed to facts that you may currently be unaware of. Many of these can be substantiated by adults who respect and understand salvia divinorum. Unfortunately, there is a tendency to pigeon-hole such individuals as "users", thereby generalizing them with a pre-established bias and rendering their testimony invalid. This is unfortunate, as they are in actuality the only ones who have a working knowledge of the "other side of the story", and some of the tangible spiritual or symptomatic healings and changes that can occur through responsible and respectful use of this plant (not as some

kind of "legal high", but in keeping with its revered nature in its historical origins).

If one does some respectable online research on the topic of salvia divinorum (i.e.- wikipedia or sagewisdom.org), they will discover that its original use was as a spiritual/religious tool by shamans, who act as intermediaries between the spiritual and physical world. This plant has traditionally been used in healing rituals and vision questing, to restore spiritual balance and promote healing on all levels. However, recent mass-media has drawn attention to the ABUSIVE component ONLY of this plant, which is not balanced by the accounts of those it has helped (since these stories can't compete with the sensationalism of their counterparts). As a result, there is a media-produced subjective bias, where the other side of the story is essentially untold - those who have benefited from salvia - either as a spiritual tool, an herbal treatment for migraine headaches, an antidepressant, or a plant that miraculously delivers people from substance addictions.

Quoting from Wikipedia, " Media stories generally raise alarms over Salvia divinorum's legal status and are sometimes headlined with generally ill-supported comparisons to LSD or other psychoactive substances. Parental concerns are raised by focusing on salvia's usage by younger teens—the emergence of YouTube videos purporting to depict its use being an area of particular concern in this respect."

If you discuss this with mature adults who have some first hand knowledge of salvia divinorum, you'll probably find that they all agree that minors should NOT have access to it. Furthermore, you may learn that the salvia divinorum plant and its leaves are NOT what is being abused - but this fact is rarely brought to light. Salvia divinorum abuse is *entirely* due to "chemical enhancement", creating what is known as "salvia extracts". These are between 5 and 80 times the potency of a naturally occurring salvia plant, and THESE are the problem with the "more is better", "faster is better" mentality of teenagers that have become widely advertised by the media (although granted, many of them find the experience highly unpleasant and don't opt for a second try). The vast majority of people have absolutely no effect when they try "plain" salvia leaves, and this is precisely why the "chemists" set forth to concentrate the active chemical and repackage it for profit. These "extracts" are what NEEDS to be illegal, as there are other health risks that are created when these are produced - potential for contamination during the chemical process, chemical residue, additives, as well as hazards inherent to the process (fire and explosion hazards, harmful vapours). Banning salvia plants and "plain leaves" outright is akin to Health Canada banning coffee beans on the basis of Online Videos that show a highly concentrated dose of caffeine triggering a seizure or a heart attack. Perhaps lemon balm or herbal teas will be next after that. At any rate, it would be severe overkill, and it would be fundamentally wrong to make it illegal for those adults who may use the natural, unaltered form of salvia as a tool in a spiritual context as a meditation aid, violating their freedom to practise a part of their religious beliefs.

Having a large family with a number of children, I am highly in favor of protecting minors, and believe that the sale of salvia, like alcohol, should be regulated - and sale to minors strictly prohibited and enforced. Furthermore, there are SIMPLE additional measures that can be undertaken that promote responsible use of this plant - primarily banning the sale and/or possession of "extracts" (read as concentrated via unregulated chemical processing), which are the actual culprit here. The plant itself, in its unmodified form, is simply not the problem. Subsequent research or polls would demonstrate and substantiate this fact. Creating another "scheduled plant" as a "responsible measure" after a certain media event (who are we kidding here, we all heard about Miley) to alleviate public pressure isn't the kind of insightful and objective leadership that we as Canadians need. What we need is for Health Canada to propose a solution that addresses the real problem, not one that simply panders to public reaction and fear-mongering media hype without statistics that CITE some actual health problems. Objectivity promotes respect. Unchecked fear and misinformation breeds poor decisions and poor legislation (in this case, that the infrastructure likely can't even support and enforce, if it were an across-the-board prohibition).

If you create laws that ban the sale of salvia to minors and the possession/sale of all Salvia Divinorum extracts, and you will SOLVE the problem while preserving something that's sacred to most Canadians -

**s.19(1)**

the right for adults to make informed, self-respecting choices. And while we're at it, let's keep coffee beans legal. Canada is a forward-thinking country - so wouldn't it be best to take the lead and set a global example of "setting the stage for honouring adult choices", instead of returning to the dark ages with knee-jerk reactions that respond to what amounts to nothing more than public ignorance based on media sensationalism?

Thank you for taking the time to consider this information. I would be glad to clarify any points herein, if it would be of assistance in creating an informed and thoughtful background for understanding the facts regarding this issue.





s.19(1)



**Re: Proposal regarding the addition of Salvia divinorum and salvinorin A to Schedule III to the Controlled Drugs and Substances Act**

OCS Policy and Regulatory Affairs to: [REDACTED]

2011-03-03 03:09 PM

Sent by: Stephanie Chandler

Bcc: Stephanie Chandler, Isabel Shanahan

[REDACTED] Proposal regarding the addition of Salvia divinorum and salvinorin A to Sch  
OCS Policy and Regulatory Affz Dear [REDACTED] I am writing to acknowledge receipt of your email with

Dear [REDACTED]

I am writing to acknowledge receipt of your email with regards to the publication of the *Notice to Interested Parties* outlining Health Canada's proposal to add *Salvia divinorum* and salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA).

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Thank you for writing.

Sincerely,

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada

[REDACTED] Hello, I have concerns about the proposal regar...

2011-02-26 05:48:52 AM

**Proposal regarding the addition of Salvia divinorum and salvinorin A to Schedule III to the Controlled Drugs and Substances Act**

[REDACTED] 2011-02-26 05:48 AM

Cc: OCS.Policy.and.Regulatory.Affairs

Hello,

I have concerns about the proposal regarding the addition of Salvia divinorum and salvinorin

A to Schedule III to the Controlled Drugs and Substances Act.

Taken from: Canada Gazette

<http://gazette.gc.ca/rp-pr/p1/2011/2011-02-19/html/notice-avis-eng.html#d109>

"Results from the *Canadian Alcohol and Drug Use Monitoring Survey* (CADUMS) reveal that, in 2009, 1.6% of Canadians aged 15 years and older reported having used *S. divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24 years. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of 15-year-olds have used *S. divinorum* in the past year. Moreover, the *2009 Ontario Student Drug Use and Health Survey* (OSDUHS) indicated that 5.4% of Ontario students in grades 7-12 reported ever using *S. divinorum* and 4.4% of these students reported using this substance in the past year."

When you ban a substance this does not mean the problem will go away. If you look at the same age groups what percentage of population uses highly addictive and dangerous drugs such as alcohol and tobacco? Prohibition has never worked so why do you plan on trying it again?

Another fact from the *Canadian Alcohol and Drug Use Monitoring Survey* (CADUMS) reveal that, in 2009, 76.5% of Canadians aged 15 years and older reported having used Alcohol.

Also in same survey "three quarters of youth (75.5%) reported consuming alcohol in the past year." I do not know of a death from the use of *Salvia divinorum* or *Salvinorin A*. I wish I could say the same for alcohol and tobacco.

Taken from: *Canadian 2008-2009 Youth Smoking Survey*

[http://www.hc-sc.gc.ca/hc-ps/tobac-tabac/research-recherche/stat/survey-sondage\\_2008-2009/result-eng.php](http://www.hc-sc.gc.ca/hc-ps/tobac-tabac/research-recherche/stat/survey-sondage_2008-2009/result-eng.php)

"For youth in grades 10-12 however, the 13% of youth who reported that they were current smokers was a statistically significant increase from 2006-07 when the rate was 11%."

Taken from: *2009 Ontario Student Drug Use and Health Survey*:

[http://www.camh.net/Research/Areas\\_of\\_research/Population\\_Life\\_Course\\_Studies/OSDUS/Highlights\\_DrugReport\\_2009OSDUHS\\_Final\\_Web.pdf](http://www.camh.net/Research/Areas_of_research/Population_Life_Course_Studies/OSDUS/Highlights_DrugReport_2009OSDUHS_Final_Web.pdf)

**Cigarettes:** Cigarette smoking is by far the greatest public health issue impinging on a population's health, as it is the leading preventable cause of disease. Although student smoking has decreased over the decades, there is still a significant proportion (one-in-eight) that does smoke (about 119,600 students). Further, the decline in smoking seen in previous survey cycles ceased in 2009, as the rate remained stable.

Contraband cigarette smoking is reported by 6% of students (about 60,000 students). Among only past year smokers, over half (53%) have smoked contraband cigarettes in the past year.

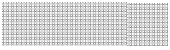
**Alcohol:** Binge drinking still remains at an elevated level, as just over one-quarter (25%) of all students reported drinking at least 5 drinks on the same occasion once in the past month.

**s.19(1)**

When we look at the 12th  
-graders only, this  
proportion becomes half (49%). One-in-five  
students (21%) drink hazardously in that their  
drinking puts them at risk for current or future  
physical and social problems. Indeed, one-in-ten  
(10%) students report being injured or injuring  
someone as a result of their drinking in the past  
year

Lets be honest here. Salvia divinorum is not a problem. If you ban Salvia members of the  
Canadian population will end up with a criminal record for nothing other then an expense to tax  
payers.

Thanks,



s.19(1)



**Re: Salvia legal status**

OCS Policy and Regulatory Affairs to: [REDACTED]

2011-03-03 03:10 PM

Sent by: Stephanie Chandler

Bcc: stephanie.chandler, Isabel Shanahan

**Salvia legal status**

OCS Policy and Regulatory Affairs Dear [REDACTED] I am writing to acknowledge receipt of your email with

Dear [REDACTED]

I am writing to acknowledge receipt of your email with regards to the publication of the *Notice to Interested Parties* outlining Health Canada's proposal to add *Salvia divinorum* and salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA).

I thank you for your comments regarding this proposal and can assure you they will be taken into consideration as the federal regulatory process progresses. There will also be additional opportunities for comment should a complete regulatory proposal be pre-published in *Canada Gazette*, Part I.

For your information, Health Canada has developed an *It's Your Health* article about *Salvia divinorum* that aims to inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at: <http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/life-vie/salvia-eng.php>

Thank you for writing.

Sincerely,

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada

[REDACTED] I hope the following points are part of your deliber... 2011-02-28 01:26:15 PM

**Salvia legal status**

[REDACTED] to: OCS.Policy.and.Regulatory.Affairs

2011-02-28 01:26 PM

I hope the following points are part of your deliberations concerning the proposed criminalization of *salvia divinorum*:

People like myself who have chosen to use this plant will, with the stroke of a pen in Ottawa, become criminals, with all the heavy consequences that entails for the individual, as well as the extra burdens placed on the criminal justice system. While respectful of the law generally, I

**s.19(1)**

will not obey a law that prohibits my use of a plant I consider a godsend.

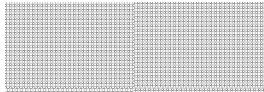
I could argue the virtues of salvinorin, but that would just confuse the issue, as well as possibly confounding the reader who might have no interest in arcane subjects like the nature of reality and how this drug might illuminate such matters. The issue is whether this drug causes harm, and causes enough harm that criminalizing its use is justified, and whether criminalization will achieve the desired aim of eradicating its use.

As the research indicates, there are no known negative health effects in users, and no addictive potential. The only potential safety risk is from the drug's impairment of motor control, but because the drug effect is so short-lived, and doesn't typically motivate people to move around anyway, this risk is moderate at worst. Because the effect is so intensely disorienting, most people will never want to repeat their first experiment with the drug, which places a hard limit on its potential for widespread abuse.

Just as some people will strongly disapprove of any and all "psychedelic" drugs, others will be attracted to their aura of risk and non-conformity. I contend that making this drug illegal will do nothing to dampen that attraction, and isn't likely to reduce its availability. Salvia is easy to grow and easy to transport (as a concentrated extract), and because of its high profile due to widespread media coverage, it would become part of the stock-and-trade of drug dealers, and the state's interest in controlling its use would be thwarted.

Tighter regulations and enforcement governing Salvia's legal sale could do as much or more towards reducing its casual use ( especially by youth ) than criminalization, as opposed to the state issuing a blanket prohibition against personal use, which, apart from its questionable effectiveness, would arguably amount to a denial of individual freedom. This is, above all, the issue that I would hope is uppermost in your review of this, to me, very important legislation.

Thank you for your attention,



s.19(1)



**Re: Proposal To Ban Salvia divinorum**

OCS Policy and Regulatory Affairs to: [REDACTED]

2011-03-03 03:14 PM

Sent by: Stephanie Chandler

Bcc: Stephanie Chandler, Isabel Shanahan

[REDACTED] **Re: Proposal To Ban Salvia divinorum**  
OCS Policy and Regulatory Affairs Dear [REDACTED] I am writing to acknowledge receipt of your email with

Dear [REDACTED]

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Thank you for writing.

Sincerely,

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada

[REDACTED] Greetings! My name is [REDACTED]

2011-02-28 11:04:22 PM

**Re: Proposal To Ban Salvia divinorum**

[REDACTED] to: ocs.policy.and.regulatory.affairs, Jay LeBlanc

2011-02-28 11:04 PM

Greetings!

[REDACTED] I have been working at a full time job since graduating from university and college. I pay my taxes like every law abiding citizen, and I have never faced any legal troubles. I have never been in a fist fight, I have never broken a bone or needed stitches, or had a cavity, nor been hospitalized for any reason. I believe I qualify as a healthy, thoughtful individual. My health can be attributed both to my wonderful country, which has supported my growth, and to my own intelligent choices, which I make every day. The support of my country has allowed me, in turn, to work, so that I may support other honest people in this

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country. Despite my love for my country, Health Canada is recommending that people like me be deemed criminal.

I was deeply saddened to read from the Canadian Gazette, "Proposal regarding the addition of *Salvia divinorum* and salvinorin A to Schedule III to the Controlled Drugs and Substances Act". I have used *Salvia divinorum* for several years and have suffered no negative effects whatsoever. On the contrary, my *Salvia divinorum* use has been one of the few things in my life which has truly been therapeutic on a number of levels; psychologically, socially, and spiritually. The meditative states achieved through unique plants, such as *Salvia divinorum*, have motivated me to be a better worker, to become closer to my family, and be a more caring individual. This is why it saddens me deeply that the people of my country are considering making *Salvia divinorum* a scheduled substance, which would, in effect, make me a criminal... because I use this plant of my own free will for legitimate therapeutic and spiritual purposes. I gave personal background on myself in the first paragraph, in to make clear the type of person that Health Canada is considering criminalizing. I cannot help but feel that Health Canada is considering a proposal that says, "Proposal regarding the addition of [REDACTED] and anyone like [REDACTED] to Schedule III to the Controlled Persons and Citizens Act".

Health Canada does not seem to consider the people who use this plant, or the benefits that some people have gained from its use, nor the consequences of its proposed new legislation. Why is that? The maximum sentence for a person possessing a schedule III substance is three years in prison. Would it really be better to have me in prison than to have me be a working member of society just because I use *Salvia divinorum*, and benefit from it? If convicted of *Salvia divinorum* possession, instead of paying taxes, the people of Canada would pay taxes to pay for me, as I waste away in prison, and use up legal resources. Also, as a fiscally conservative Canadian, I am concerned about the potential costs of enforcing a needless law against *Salvia divinorum*, and as a caring citizen, I am concerned about the lives that would be damaged as a result of the proposed law. This proposed law is coming out at a time when Canada is facing criticism for overcrowded prisons, and overused justice system. Crime rates are reported to be decreasing, yet incarceration rates increasing. This makes no sense and is a very disturbing trend because it suggests that the criminal justice system is beginning to be used in a way that affects non criminals. I would like to think that the justice system should be reserved for those who do harm to others, for those who do harm to their country. No evidence has ever been provided that users of *Salvia divinorum* pose any such threat, certainly not a threat requiring a punishment of three years in prison.

Health Canada suggests that *Salvia divinorum* may be a threat to public health and safety, but do they provide any evidence for this? Has Health Canada also done a study on the threat to health that potential prison time might do to a person? I could not imagine the damage prison would do to my life, and my family's life, if I were to be jailed, or even charged for possessing a schedule III substance. Even a conviction without jail would result in job loss, and make it very difficult to find meaningful employment. That is worse than anything *Salvia divinorum* could ever do. I strongly urge Health Canada and anyone involved in the push to criminalize *Salvia divinorum* users, to consider very carefully the potential harm that the law could impose on honest people.

Yet, despite the severe cost that would accompany being charged with a schedule III substance, I cannot consider the potential penalty as a deterrent. I honestly and truly consider *Salvia divinorum* use to be a personal sacred spiritual practice. It would not matter if the punishment for using *Salvia divinorum* were 3 years, or a hundred years, or death. I would only consider the threat of prison to be a potential disaster to my life, just like a horrible car accident, or being kidnapped or murdered. Yet, I do not allow the possibility that I may be injured by harmful people stop me from living my life. I cannot let those possibilities stop me from being who I am, from living a peaceful and productive life, and expressing my right to freedom of conscience and religion, freedom of thought, belief, opinion, and expression. If arrested for possession of *Salvia divinorum*, the only lesson I would learn is that the people of my country are willing to destroy me for being who I am, and making my own choice. I cannot support such intolerance, nor would I want any young person to support the idea that people should be imprisoned for

making their own choice. There is a threat to youth out there, and it is the promotion of a system of intolerance and inhumane conditions intended for criminals, yet used on non criminals. It would be irresponsible of Health Canada to impose the potential disastrous effects that its proposed law may have on the citizens of Canada.

I beg you to please find an alternative to making *Salvia divinorum* a schedule III substance. I want to continue to be a productive member of society. I wish to reach out to those in power, and try to offer some kind of assurance that not every user of *Salvia divinorum* is a danger to themselves, and many people also use this plant as a spiritual practice. I feel there is a strong negative stereotype against users of a variety of substances. I am just a regular hard working person who doesn't want to go to prison! Please, hear this cry for tolerance and mutual co-operation. I hope to avoid a conflict with the law, and I hope those in power find a way to avoid clashing with its own citizens. Surely, there must be a much less violent way to deal with this *Salvia divinorum* issue than scheduling *Salvia divinorum*. I do not want to be an enemy of the state. I have no desire to break any law. I don't want to be a rebel, nor a martyr. I love my country, and humbly ask for understanding and tolerance.

I have heard blanket arguments against *Salvia divinorum* such as "the effects are unknown", or "the federal government supports families by protecting the children from the hallucinogen, *Salvia divinorum*". Yet I see little in the way of evidence of actual harm done from *Salvia divinorum*, despite its presence in Canada for about twenty years. Does Health Canada and the federal government forget that people who use *Salvia divinorum* have families too? Why is there an assumption that people who use *Salvia divinorum* are somehow anti-family? Why does Health Canada seem to assume that families of people who use *Salvia divinorum* are deserving of punishment and inhumane treatment in the environment of prison? I consider Canada to be one big family. I see no reason why *Salvia divinorum* users and non users can't mutually co-exist without incarcerating each other, or hating each other. I hope Canada chooses to send a message to the world, that while it will do everything in its power to protect underage people from using mind altering substances, Canada will also not destroy the lives of its own citizens, and *their* families by putting more people in prison for meditative plant use. If I want to protect my children from anything, it would be protecting them from becoming hardened, uncaring adults who are willing to imprison any adult who makes their own choice.

I encourage legislators to consider alternatives to scheduling *Salvia divinorum*. According to this CBC article, from October 2010, <http://www.cbc.ca/news/health/story/2010/10/19/salvia-banned.html> "the federal government says products containing *Salvia divinorum* and its active ingredient, salvinorin A, are considered natural health products and, as such, must be authorized by Health Canada before they can be sold."

If that is true, it does not necessarily follow that *Salvia divinorum* must be scheduled. There must be another way. That is to say, just because Health Canada does not approve of a substance being sold as a "natural health product" does not automatically mean the substance should be scheduled. The federal government does not have to classify *Salvia divinorum* as a "natural health product", and the federal government does not have to schedule *Salvia divinorum* just because Health Canada does not approve *Salvia divinorum* as a natural health product. I am sure, or at least I certainly hope, that cigarettes are not approved by Health Canada, yet they are still legally sold in Canada.

The federal government has allegedly chosen to classify *Salvia divinorum* as a natural health product, however, *Salvia divinorum* is not sold as a natural health product. The following is quoted from the "Food and Drugs act: Natural Health Products Regulations", which can be found here, <http://gazette.gc.ca/archives/p2/2003/2003-06-18/html/sor-dors196-eng.html>

"natural health product" means a substance set out in Schedule 1 or a combination of substances in which all the medicinal ingredients are substances set out in Schedule 1, a homeopathic medicine or a traditional medicine, that is manufactured, sold or represented for use in

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
- (b) restoring or correcting organic functions in humans; or



(c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health."

*Salvia divinorum* is not marketed as a "natural health product" and I can prove it. In my letter I have attached a jpg file which shows the cover of a "Salvia Zone" product, which I bought at a local store in Ontario. Salvia Zone is one of the most popular vendors for packaged *Salvia divinorum* sold in stores, which is where people have most easy access to *Salvia divinorum*. The package comes with detailed warning messages. One of those messages expressly states that the salvia product is "not intended to diagnose, treat, cure, or prevent disease". There is also nowhere on the disclaimer that suggests the use of salvia modifies organic function in a way that maintains or promotes health. In fact, the disclaimer warns that all inhaled smoke of any kind may be harmful to health. Therefore, it is incorrect to classify *Salvia divinorum* as a "Natural Health Product" because vendors of Salvia products do not market their product in a way that are represented for use in the diagnosis, treatment, or prevention of disease, as outlined by the "Natural Health Products Regulations". As such, *Salvia divinorum* should not require the approval of Health Canada in order to be sold.

If Health Canada is concerned about *Salvia divinorum* being used by those who are underage, I implore Health Canada and the federal government to devise stricter regulations regarding the selling of *Salvia divinorum*, which would limit its access to minors, while allowing *Salvia Divinorum* to remain legal to possess for consenting adults. Scheduling *Salvia divinorum* potentially places innocent users of *Salvia divinorum* at risk, users, like myself, who have absolutely nothing to do with selling *Salvia divinorum*, nor giving it to anyone, nor promoting it to anyone. I have no interest in promoting *Salvia divinorum* to anyone. People are free to abstain from salvia use, if they are under the impression it is somehow a risk to their health, and *Salvia divinorum* shows low potential for addiction. Charging a person like me for *Salvia divinorum* possession would do absolutely nothing to protect minors from using *Salvia divinorum*, as I have no intention of selling, nor giving *Salvia divinorum* to anyone. Furthermore, scheduling *Salvia divinorum* may pose increased risk to users, including minors. Users who would continue to use *Salvia divinorum*, despite the law, would be forced to acquire salvia from illegitimate sources. This places the user at risk, as they have no idea if they are getting a clean product. Sellers may lace their "salvia" product with any number of other substances, such as pcp. This poses a threat far greater than *Salvia divinorum* on its own.

In the past, Canada has made accommodations for those who use plants as part of their spiritual practice. Mescaline is a controlled substance in Canada, yet Peyote, a plant containing mescaline, has a specific exemption from the Controlled Drugs and Substances Act, found at , <http://laws.justice.gc.ca/eng/C-38.8/page-6.html>  
"17.

Mescaline (3,4,5-trimethoxybenzeneethanamine) and any salt thereof, but not peyote (lophophora) The exemption of Peyote from the Controlled Drugs and Substances act is an appreciated gesture of respect to accommodate those who use the plant ceremonially. There are people, such as myself, who also use *Salvia divinorum* for similar purposes. I ask that if salvinorin A were to become scheduled, please allow for the continued legality of the plant itself, *Salvia divinorum*, in a similar fashion that that Peyote is exempt from the Controlled Drugs and Substances Act.

A similar action with regards to *Salvia divinorum* would be very appropriate and for a number of reasons. First, this would prevent the selling of dried leaf extract in stores, which is the most common place for people to buy *Salvia divinorum* products. The potential strong psychoactive effects of *Salvia divinorum* products are the result of the active compound, salvinorin A being condensed on to plain leaf. This is known as "fortified leaf". This is why salvia products are almost always sold as a value of X, for example, 5x, 10x, or 40x or some claim even high concentrations. A fortified leaf sold as 40x means that the leaf in the 40x product is supposed to contain 40 times the amount of salvinorin A that would be found in plain leaf of the same weight. The amount of salvinorin A in plain leaf is not enough to produce the same type of strong effect that fortified leaf produces. If dried extract were banned in stores, yet the plant, *Salvia divinorum* still permitted, people would still have access to the sacred plant, while not being exposed to

strong concentrations of the active compound salvinorin A, which is concentrated in fortified leaf preparations. The live plant cannot be smoked, and unfortified dried leaf does not produce the same strong effect as fortified leaf.

Furthermore, the traditional use of *Salvia divinorum*, originally used by Mexican natives was to chew the leaves, not smoke the leaves. Chewing the leaves is often referred to as "the quid method", in which *Salvia divinorum* leaf is placed under the tongue, and the active compound is absorbed through membranes under the tongue and mouth. The effect of this method is very different from smoking, and drastically less intense. The reason for the decreased intensity is because only a small amount of the active compound can be absorbed through the mouth for any period of time, thus limiting the amount of inebriation a person can experience. In contrast, inhalation of concentrated amounts of salvinorin A, such as found in fortified leaf, enter the blood stream and reach the brain within a matter of seconds, and is metabolized in a matter of minutes. The result can be a strong alteration of consciousness. However, the traditional use of *Salvia divinorum*, which is to chew the leaves, simply cannot produce such drastic alterations of consciousness. Any person curious about this can easily test this assertion for themselves. The result of chewing *Salvia divinorum* for an hour will result in a mild-medium meditative state in which imagination is stimulated. There will never be a case of videos showing Miley Cyrus acting crazy on chewed *Salvia divinorum* leaf, nor videos of any Saskatchewan dj acting hysterical after chewing *Salvia divinorum* leaf. Chewing *Salvia divinorum* leaf simply does not result in the sudden and strong change of consciousness that results from smoking. However, chewing *Salvia divinorum* is the traditional form of usage, which is used primarily by myself, and in traditional ceremonies. Chewed leaf of *Salvia divinorum* will never be a popular drug of choice for anyone seeking a thrill. The leaf tastes bad and becomes uncomfortable after a few minutes. Chewed *Salvia divinorum* is only useful for those who wish to meditate and learn. For these reasons, the plant *Salvia divinorum* should remain legal. However, if Health Canada believes that inhaling concentrated forms of *Salvia divinorum*, such as the fortified leaf sold in stores, then I see no harm in reducing the availability of fortified leaf to the population by banning the sale of fortified leaf. But I do see harm in banning the plant itself, in criminalizing all users. Please, keep the plant itself legal.

I have seen very little evidence provided from Health Canada that would suggest that *Salvia divinorum* is a dangerous drug. Furthermore, *Salvia divinorum* use has declined from 2008-2009. According to Health Canada's "Canadian Alcohol and Drug Use Monitoring Survey: Summary of Results for 2009", (Health Canada's most recent published Summary of Results) *Salvia divinorum* use declined from 2008-2009. Why is Health Canada choosing this time to propose a ban on *Salvia divinorum* if its use is declining, and the public has not faced significant risk? The following quote is from Health Canada's "Summary of Results for 2009":

"The rate of past year hallucinogen use (including salvia) in 2009 at 0.9% was statistically significantly lower than the rate of 2.1% reported in 2008. Statistically significant declines between 2008 and 2009 in the rate of past 12 month hallucinogen (including salvia) use were also apparent among males (3.3% versus 1.1%, respectively) and youth (10.2% versus 4.4%). Similarly, past-year use of at least one of five illicit drugs excluding cannabis [cocaine or crack, speed, ecstasy, hallucinogens (including salvia), and heroin] at 2.1% in 2009 was statistically significantly lower than the 3.9% rate reported in 2008."

<http://www.hc-sc.gc.ca/hc-ps/drugs-drogués/stat/2009/summary-sommaire-eng.php>

However, after the proposed ban on *Salvia divinorum* has been introduced by Health Canada, sales of *Salvia divinorum* will probably rise, as users fear the substance may become banned, and this will result in people buying quantities in anticipation of the ban. Also, curious people may want to try *Salvia divinorum* after hearing the press that the herb may soon be illegal. The negative press from authority will also make *Salvia divinorum* lucrative to try for "rebels", and everyone knows teens fall in to that category. So, if it was Health Canada's intention to decrease the number of people using *Salvia divinorum*, then proposing this ban was probably not a good idea. However, even if use remains at current levels or increases, there is still a lack of evidence suggesting that *Salvia divinorum* is a dangerous

substance. In fact, evidence suggests that many people who try *Salvia divinorum* do not enjoy it, and thus do not try it again. This may explain the decrease in use from 2008-2009. Making criminals out of users is not an appropriate response to the "possible" threat that Health Canada perceives from *Salvia divinorum*.

Although *Salvia divinorum* is not marketed as a natural health product, there is research being done on the compound, salvinorin A, which suggests that salvinorin A, may be useful in developing medicines helpful in the treatment of Alzheimer's Disease, schizophrenia, chronic pain, addiction, and depression. Scheduling *Salvia divinorum* may prevent important medical research from being done on this potentially helpful substance. Also, current research on the compound salvinorin A, has revealed that salvinorin A is not an addictive compound, not a dangerous compound, and the substance, salvinorin A, may actually be helpful for those wishing to conquer their dependence on truly dangerous and addictive drugs, such as opium and heroin.

Dr. Matthew Johnson, is currently studying salvinorin A at Johns Hopkins Medical School, and submitted a study on *Salvia divinorum* use in November 2010. In this study, Johnson concluded that *Salvia divinorum* and its active compound, salvirnorin A, are relatively non-toxic substances, even in large doses. The compound, salvinorin A activates the kappa opioid receptor in the brain, while other substances, such as heroin and morphine activate the kappa mu receptor. This is an important distinction because while heroin and morphine produce an effect that is euphoric and addictive, activating the kappa opioid receptor via salvinorin A produces an experience that unpleasant for most users, and is thought to have "anti-addictive" qualities. For this reason, it is unlikely that people would become addicted to *Salvia divinorum*, and unlikely to be a substance of repeat use by those simply looking to "get high" because the substance is not pleasant for many people. Furthermore, the anti-addictive qualities of salvirnorin A may be useful in the medical treatment of addiction. The following are quotes from an NPR radio interview between Dr. Matthew Johnson (Johns Hopkins Medical School), Dr. Elena Chartoff (McLean Hospital), and an NPR radio host, Joe Palca. The quotes support the claims I made in this paragraph. The full article can be found here, <http://www.npr.org/2011/01/03/132613641/Scientists-Study-Salvia-Ingredient-As-Medical-Treatment>

"Dr. JOHNSON: Under the conditions of the study, it did appear to be a physiologically safe drug."

"Salvia belongs to a class of drugs that activate something called the kappa opioid receptor. Heroin and morphine also activate opioid receptors, but they activate the mu opioid receptor.

Dr. ELENA CHARTOFF (McLean Hospital): When you activate the mu receptor, like you do with heroin or morphine, you get a euphoric - you get a rush, a high.

PALCA: Elena Chartoff studies opioid receptors at McLean Hospital in Boston.

Dr. CHARTOFF: But when you activate the kappa receptor with a drug, you get kind of the opposite effect, that depressive-like effect.

PALCA: The depressive effect might be used to counteract the mania of manic depression or negate the appealing effects of narcotics as a way to control drug addiction.

"The results suggest that inhaled salvinorin A. was physiologically safe and psychologically well tolerated across the range of doses tested" (doses ranging from low to high).

The full study by Dr. Johnson and Chartoff can be found here,

<http://www.washingtonpost.com/wp-srv/nation/pdfs/salviapaper.pdf>

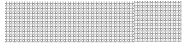
In that study, Dr. Johnson concludes, "The results suggest that inhaled salvinorin A was physiologically safe and psychologically well tolerated across the range of doses tested" (doses ranging from low to high).

*Salvia divinorum* has a long history of use as a method of spiritual and person exploration. Johnson writes, "Shamas of the Mazatec people of Oaxaca, Mexico have used *Salvia divinorum*, a member of the mint family, for at least centuries in ethnomedical practices including divination and spiritual healings". Since this plant has been introduced to other parts of the world, such as Canada, other people have included the use of *Salvia divinorum* in their spiritual practice. I am one such person. It would be very

cold and uncaring of the people of Canada to not take the spiritual practices of users in to account, not to mention, I believe this would also be a violation of the Fundamental Freedoms, under the Charter of Rights, which states, "Everyone has the following fundamental freedoms: (a) freedom of conscience and religion; (b) freedom of thought, belief, opinion and expression".

The scheduling of a substance should be taken very seriously, because people could have their lives destroyed by the proposed law. I would like to think that Canada would only schedule a substance if necessary. Plainly, *Salvia divinorum*, and its users, have not proven worthy of drastic methods of control, such as those proposed by Health Canada, in which possession of *Salvia divinorum* could result in a three years prison sentence. Health Canada provides little evidence as to the dangers of *Salvia divinorum*. Health Canada does suggest that little is known about the effects of *Salvia divinorum*, however, recent studies, such as those by Dr. Matthew Johnson, suggest that *Salvia divinorum* is physiologically safe. Furthermore, anecdotal evidence, such as that provided by myself, suggest no longer term negative effects from regular use.... and frankly, I am much more comfortable making the decision myself, whether I choose to use this plant, rather than having a law deem me as a criminal for making my own decision. In addition, the plant *Salvia divinorum* has been used by Native Americans for at least a hundred years in divination ceremonies, and thus this plant is clearly of spiritual use. It would irresponsible to schedule the plant *Salvia divinorum*, which would result needlessly in arrests and pain for those who possess *Salvia divinorum*, and the law also discriminates against people who use *Salvia divinorum* for spiritual purposes. For these reasons, Canada must consider alternatives to adding *Salvia divinorum* to the Controlled Drugs and Substances Act.

Thank you,



s.19(1)



**Re: Citizen Input: Salvia**

OCS Policy and Regulatory Affairs to: [REDACTED]

2011-03-03 03:16 PM

Sent by: Stephanie Chandler

Bcc: Stephanie Chandler, Isabel Shanahan

[REDACTED] **Citizen Input: Salvia**  
OCS Policy and Regulatory Affairs Dear [REDACTED] I am writing to acknowledge receipt of your email with  
[REDACTED] Thank you for the note Mr. or Ms. Office of Controlled Substances

Dear [REDACTED]

I am writing to acknowledge receipt of your email with regards to the publication of the *Notice to Interested Parties* outlining Health Canada's proposal to add *Salvia divinorum* and salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA).

I thank you for your comments regarding this proposal and can assure you they will be taken into consideration as the federal regulatory process progresses. There will also be additional opportunities for comment should a complete regulatory proposal be pre-published in *Canada Gazette*, Part I.

For your information, Health Canada has developed an *It's Your Health* article about *Salvia divinorum* that aims to inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at: <http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/life-vie/salvia-eng.php>

Thank you for writing.

Sincerely,

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada

[REDACTED] I am very interested in contributing to the di...

2011-03-01 01:33:33 AM

**Citizen Input: Salvia**

[REDACTED] to: OCS.Policy.and.Regulatory.Affairs

2011-03-01 01:33 AM

I am very interested in contributing to the discussion of this proposed legal change.

I have noted for some years that Salvia has been available for sale in reputable shops and at a reasonable price in its natural forms.

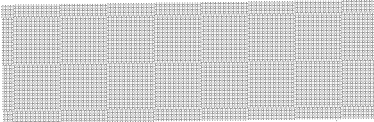
I am a film maker and TV producer. My extensive research on the subject follows nearly 2000 years of recorded use of Salvia and no clearly documented problem, injuries or ill effects directly attributable to the drug.

liquor is controlled (both verified to be infinitely more dangerous and addictive substances).

As a practical matter, the plant is among the most easily grown and cultivated on any windowsill and almost impossible to pick out from any common plantain. It seems to me the pursuit of making the drug illegal now that its place in popular culture is set and widely known would be to make criminals out of thousands of middle-class teenagers and deny people with a genuine spiritual interest an inalienable right to their personal beliefs while costing millions of dollars to solve a non-existent problem.

I am happy to speak on this issue any time.

Sincerely,

A rectangular area of the document is redacted with a dense grid pattern, obscuring the signature and any text that might have been present.

s.19(1)



**Re: Concerns regarding Salvia divinorum proposal**

OCS Policy and Regulatory Affairs to: [REDACTED]

2011-03-03 03:17 PM

Sent by: Stephanie Chandler

Bcc: Stephanie Chandler, Isabel Shanahan

[REDACTED] Concerns regarding Salvia divinorum proposal

OCS Policy and Regulatory Affairs Dear [REDACTED] I am writing to acknowledge receipt of your email with

Dear [REDACTED]

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Thank you for writing.

Sincerely,

Stephanie Chandler  
Regulatory Policy Division

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada

[REDACTED] Ms. Chandler, I would like to take this opportunit...

2011-03-02 08:55:43 PM

**Concerns regarding Salvia divinorum proposal**

[REDACTED] to: OCS.Policy.and.Regulatory.Affairs

2011-03-02 08:55 PM

Ms. Chandler,

I would like to take this opportunity as a concerned citizen of Canada to express my objections to the addition of the plant *Salvia divinorum*, its primary active compound salvinorin A, and their

associated unenhanced and enhanced herbal products (hereafter collectively referred to as salvia) to schedule three of the Controlled Drugs and Substances Act. In my view, this is an unfortunate overreaction to legitimate concerns about the use and abuse of salvia by Canadian (and global) youth which, if followed through, will become a serious case of uninvestigated lost potential. I will not pretend that regulation of some kind is not necessary in order to mitigate risk to the public, but I would argue that what amounts to a prohibition is not a good fit for the substance in question.

The article published in Canada Gazette addresses three main concerns with regards to the unregulated status of salvia as follows: "the hype", or salvia's reputation for being sold as a legal alternative to illegal products (notably lysergic acid diethylamide and cannabis, colloquially known as "acid" and "pot"); the similarity of salvia's psychoactive effects to those of substances already controlled under schedule three, specifically citing LSD and psilocybin; rapidly rising use by Canadian school-age youth. (The article also lists ten countries (i.e. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain, and Sweden) that have already regulated salvia, apparently as justification for Canada's proposed ban, though this hardly seems adequate support for any action by a legislative body.) I will discuss these three issues in the context of why the proposed addition to schedule three is a bad fit given these concerns.

Before discussing the above issues in detail, I would like to establish the variance in the profiles of people who make use of this substance today. The group that is obviously of the greatest concern to Health Canada and the citizenship of this and other countries consists of a growing number of youths who abuse this potent hallucinogenic drug. These are kids who are entering into an overwhelming experience ill-informed and ill-prepared. The videos on YouTube depicting teenagers stumbling about and engaging in dangerous behaviour are clearly not depicting safe and cautious use of this powerful substance. I would argue that because such videos are clearly representing substance abuse, it is a fallacy to use them as a gauge for (or source of any information on) the *proper* use of salvia, just as a series of clips on YouTube depicting drunken exploits cannot be used to represent a group of responsible adults enjoying a few beers on a summer afternoon; they can, however, be used to loosely represent the drunks. Along those lines, what we can glean from these much talked about videos is that unsafe abuse of salvia by youth is unsafe, but little else.

It is crucial to recognise that reckless teenagers looking for new ways to get high are not the only demographic making use of salvia. Much unlike their teenage counterparts (who, in my opinion, should be classed as abusers of this drug rather than users), there are people who make use of this substance for medicinal reasons. These are sometimes referred to as being deeply spiritual, or a way of connecting with the world that surrounds us. This is easily dismissed offhand as hippy nonsense and not to be seriously considered, but given that the *Canadian Charter of Rights and Freedoms* stipulates the following fundamental freedoms: "freedom of conscience and religion", and "freedom of thought, belief, opinion and expression", I believe that even these abstract perspectives merit discussion as legitimate considerations. Furthermore, "Every individual is equal before and under the law and has the right to the equal benefit of the law without discrimination", even hippies; to put things another way, even those whose positions may be marginalised, stigmatised, or simply uncommon have a right to be taken into consideration in the making of this new law on salvia. It is for this reason that I feel the government of Canada has a self-imposed obligation to consider the citizens who make honest use of this drug in a safe way for their personal benefit, and I implore you personally to ensure that that obligation be



honoured. Were it not for these individuals, I would wholly support a ban on salvia (excluding availability upon approved request for legitimate research on new uses) as it has proven its potential for abuse by the youth of our country, but because such a ban would thoroughly railroad such individuals, I cannot view it as anything but a way to cut corners.

Other than already marginalised potential for near unquantifiable spiritual use, exploratory research reveals promising results for a variety of treatments with this herb. Because salvinorin A is, at the very least, a relatively nonaddictive opioid receptor agonist, it shows great promise for the treatment of addiction to a very dangerous class of drugs known as the opiates, which include such narcotics as heroin, morphine, oxycontin and other derivatives of opium. In addition, because it acts on these receptors, it has also been touted as having potential for pain management. Preliminary research has also shown salvinorin A to have an antidepressant effect in rats and mice; this research would seem to corroborate surveys which have found that salvia has potential as an antidepressant in human populations. It has even been suggested that salvia could be an effective treatment for certain gastrointestinal illnesses. These are not shady, unfounded theories with potential for alternative treatments that reek of the placebo effect, these are real opportunities that ought to be fully explored for the real opportunity for mainstream use. Far more controversial remedies (homeopathy, for example) have already been approved by Health Canada; one investigation showed that common homeopathic remedies do not contain sufficient quantities of the active ingredient to conventionally explain their effect. Although salvia has its origins in the traditional medicine of the Mazatecs of Mexico, its uses and mechanisms of action are very much conventional medicine, the only thing missing is more thorough research.

Similarly, this lack of knowledge leads to efforts to explain salvia's action in terms we are familiar with, namely as an LSD analogue. Salvia is oft compared to LSD and other similar hallucinogenic substances such as psilocybin which have long been outlawed; almost as a matter of course these comparisons have led to salvia being sold erroneously as legal LSD. Some people will do anything if it means easy money. It is well known and well accepted within the scientific community that the molecular structure of salvinorin A is unique within the domain of hallucinogens, as well as its mechanism of action. Whereas LSD and psilocybin act upon serotonin receptors in the brain and have a more or less typical mechanism of action for hallucinogens, salvinorin A works upon a completely separate set of receptors. LSD and psilocybin are structurally similar (both loosely resembling a serotonin molecule), work in similar ways, and have similar effects of similar duration (twelve hours for LSD, six for psilocybin), so it makes sense to treat them similarly in terms of legislation. Salvinorin A, on the other hand, structurally resembles neither of these nor any other hallucinogen regulated or not, works in a completely separate manner, and has effects which at best are loosely comparable and usually of far shorter duration (around fifteen minutes, given the western habit of consumption by smoking rather than the seldom used traditional methods which give longer lasting but much milder effects, if any). Claims that salvia is a legal LSD are ill founded and at best are founded on claims made by people who aim to directly make a profit off of them, or else are searching for a legal equivalent to LSD, and upon finding something that can perhaps be described as vaguely comparable claim to have found it.

The article published by Health Canada specifically mentions concerns about use of this substance by youth, and proposes a ban to manage risks towards all age groups. As Health Canada's own paper expresses concern almost exclusively for youth, it seems both an

s.19(1)

overreaction and counterintuitive to prohibit this substance across the board. Even if placed in the context of justifiable concern for people of all ages, but especially youth, it does not make sense to add salvia to schedule three as such a ban would be impossible to enforce to anywhere near its full reach and would actually push salvia into the hands of youth and away from responsible adults, researchers, and medical professionals. Numerous sources have agreed that cannabis would actually prove far more difficult for youth to obtain if it were partially legalised, because restricting sale to people aged eighteen or older would be far easier and could be enforced far more effectively than the current ban as well as providing incentive to follow the constraints of legitimacy in selling the substance. Although not comparable in their effects, I believe that this model of inadequacy in legislation can be applied with a considerable degree of accuracy to salvia, which would make the proposed ban counterproductive if anything.

If any risks exist surrounding salvia (and they do), at this point, they stem from ignorance.

Teenagers who abuse this powerful substance do so because they do not fully understand the hazards associated with the kind of dissociative feelings and odd sensations it can produce.

Valid concerns about the long term effects of this substance are due only to a lack of effort on the part of the scientific community to find out what those are, or if indeed there are any at all.

Furthermore, the main worries of the public at large and associated legislative bodies seem have at their heart ill-supported comparisons to drugs like LSD. It seems a waste to me to create a blanket prohibition based solely on a deficiency of good information.

As has been set out in the article in Canada Gazette, “[the proposed ban] is not intended to interfere with the use and availability of *S. divinorum* and/or salvinorin A for legitimate medical, scientific or industrial purposes”. My hope is only that Health Canada will honour its words wholly and without bias or discrimination. If I may be of any more assistance in this process, please direct any further correspondence to this e-mail address [REDACTED]

[REDACTED]

Sincerely,

[REDACTED]



**Re: Salvia Law**

OCS Policy and Regulatory Affairs to: [REDACTED]

2011-03-03 03:17 PM

Sent by: Stephanie Chandler

Bcc: Stephanie Chandler, Isabel Shanahan

[REDACTED] **Salvia Law**  
OCS Policy and Regulatory Affairs Dear [REDACTED] I am writing to acknowledge receipt of your email with

Dear [REDACTED]

I am writing to acknowledge receipt of your email with regards to the publication of the *Notice to Interested Parties* outlining Health Canada's proposal to add *Salvia divinorum* and salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA).

I thank you for your comments regarding this proposal and can assure you they will be taken into consideration as the federal regulatory process progresses. There will also be additional opportunities for comment should a complete regulatory proposal be pre-published in *Canada Gazette*, Part I.

For your information, Health Canada has developed an *It's Your Health* article about *Salvia divinorum* that aims to inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at: <http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/life-vie/salvia-eng.php>

Thank you for writing.

Sincerely,

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada

[REDACTED] As a salvia user I would like to see that it contin... 2011-03-03 02:11:44 AM

**Salvia Law**

[REDACTED] to: OCS.Policy.and.Regulatory.Affairs

2011-03-03 02:11 AM

As a salvia user I would like to see that it continues to remain legal. This herb has a lot of potential. Furthermore it is harmless. The effects are 5-10 minutes or less. One would have to be inhaling the smoke whilst doing an activity to have an accident. If protecting the youth is the goal here I propose a law restricting it's sale and use to minors below 18.


Sincerely,

[REDACTED]

s.19(1)



**Re: Salvia Divinorum Ban is very concerning** 

OCS Policy and Regulatory Affairs to: 

2011-03-03 02:05 PM

Sent by: Stephanie Chandler

Bcc: Stephanie Chandler, Isabel Shanahan

Dear 

I am writing to acknowledge receipt of your email with regards to the publication of the *Notice to Interested Parties* outlining Health Canada's proposal to add *Salvia divinorum* and salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA).

I thank you for your comments regarding this proposal and can assure you they will be taken into consideration as the federal regulatory process progresses. There will also be additional opportunities for comment should a complete regulatory proposal be pre-published in *Canada Gazette*, Part I.

For your information, Health Canada has developed an *It's Your Health* article about *Salvia divinorum* that aims to inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at: <http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/life-vie/salvia-eng.php>

Thank you for writing.

Sincerely,

Stephanie Chandler  
Regulatory Policy Division

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada

 Hello, I am very concerned the proposed ban on...

2011-02-19 04:45:03 PM

**Salvia Divinorum Ban is very concerning**

 to: OCS.Policy.and.Regulatory.Affairs

2011-02-19 04:45 PM

Please respond to 

Hello,

I am very concerned the proposed ban on *Salvia Divinorum* will do more harm than good, as well as take away the choice of adults.

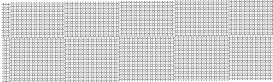
I can certainly understand the concerns about it getting to young people, which is why it makes sense for a ban, such as with cigarettes, to sell to people under the age of majority. However, having taken the substance myself one time, I can assure you that it is not an addictive substance nor one that does anything but commands respect from the user. With responsible use, it can have profound spiritual meaning and depth and allow for insight.

003155

This isn't a party drug. By making it a schedule III substance, it will provide the perfect opportunity for the criminal underworld to take over the trade in salvia divinorum and make sure it gets to young people and is used irresponsibly.

Instead, I would suggest talking with adults versed in both responsible and effective drug policy, as well as those who have a holistic understanding of entheogens. The best way to minimize harm from salvia is to treat it with respect and take appropriate steps that responsible adults are the ones who can make the choice to use it.

Sincerely,

A rectangular area of the document is redacted with a grey grid pattern, obscuring the signature.

s.19(1)

*Added we are not replying to second enquiries from some persons.*

*RPD March 15, 2011*



Re: Salvia

to: OCS Policy and Regulatory Affairs

2011-03-03 04:25 PM

This is exactly what I was writing **against**:

*Canadians should not use products containing S. divinorum and/or salvinorin A because they are hallucinogenic and little is known about the long-term effects of these substances on the brain and body.*

Little is known about the long-term effects. *Little* . Why is it being banned when we don't know about it? Again, please support an evidence based drug policy.

I see that my comment was simply not read at all.

On Thu, Mar 3, 2011 at 2:13 PM, OCS Policy and Regulatory Affairs <[ocs.policy.and.regulatory.affairs@hc-sc.gc.ca](mailto:ocs.policy.and.regulatory.affairs@hc-sc.gc.ca)> wrote:

Dear [redacted]

I am writing to acknowledge receipt of your email with regards to the publication of the *Notice to Interested Parties* outlining Health Canada's proposal to add *Salvia divinorum* and salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA).

I thank you for your comments regarding this proposal and can assure you they will be taken into consideration as the federal regulatory process progresses. There will also be additional opportunities for comment should a complete regulatory proposal be pre-published in *Canada Gazette*, Part I.

For your information, Health Canada has developed an *It's Your Health* article about *Salvia divinorum* that aims to inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at:

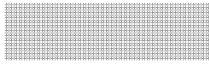
<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/life-vie/salvia-eng.php>

Thank you for writing.

Sincerely,

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada

Salvia



to: OCS.Policy.and.Regulatory.Affairs

2011-02-20 05:50 PM

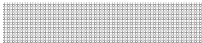
s.19(1)

Hello

As a citizen of Canada, I want an evidence based drug control policy. In order for Salvia divinorum to become a controlled substance in Canada, it should first be shown by Health Canada to be more harmful and addictive than other legal substances like alcohol and tobacco. If a drug cannot be proven to be more harmful and addictive than *legal* substances in Canada, that substance should remain legal. Regardless of personal philosophies, this is merely just logical consistency.

I am not a drug user - I even avoid alcohol. But personal freedoms in Canada should not be under siege without strong scientific evidence. Please support an evidence based drug control policy.

Thanks



*Refused not to respond to second enquiries from same person. RPLD March 15, 2011*

s.19(1)



Re: Citizen Input: Salvia

to: OCS Policy and Regulatory Affairs

2011-03-03 06:39 PM

Thank you for the note Mr. or Ms. Office of Controlled Substances, I think the article you've shared with me is a fair brief assessment of the current situation. People who have used psychotropic drugs often report that drugs, like salvia, free your mind to think any thoughts you want.

To people who haven't had this experience that sentiment seems absurd because everyone likes to believe we already have the freedom to think anything we want. But that's not true. Certain drug experiences do expand a person's scope and freedom of thought just as repeated exposure to certain images narrow our scope of thought... like too much TV, video games or porn.

What the legislation seems to be proposing is that this plant causes a set of experiences that the article summarizes (assume simply for the sake of brevity) as hallucinations. It is well established science that the experience is much more complex and complicated than that but as a matter of public policy the Government of Canada is saying Canadians should never under any circumstances have those experiences.

My position is that it is a proven fact that if we take that route we will be a poorer (spiritually and commercially), less creative and less enlightened society.

On 2011-03-03, at 4:16 PM, OCS Policy and Regulatory Affairs wrote:

Dear [REDACTED]

I am writing to acknowledge receipt of your email with regards to the publication of the *Notice to Interested Parties* outlining Health Canada's proposal to add *Salvia divinorum* and salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA).

I thank you for your comments regarding this proposal and can assure you they will be taken into consideration as the federal regulatory process progresses. There will also be additional opportunities for comment should a complete regulatory proposal be pre-published in *Canada Gazette*, Part I.

For your information, Health Canada has developed an *It's Your Health* article about *Salvia divinorum* that aims to inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at:

<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/life-vie/salvia-eng.php>

Thank you for writing.

Sincerely,

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch



Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada

Citizen Input: Salvia

[REDACTED] to: OCS.Policy.and.Regulatory.Affairs

2011-03-01 01:33 AM

I am very interested in contributing to the discussion of this proposed legal change.

I have noted for some years that Salvia has been available for sale in reputable shops and at a reasonable price in its natural forms.

[REDACTED]  
follows nearly 2000 years of recorded use of Salvia and no clearly documented problem, injuries or ill effects directly attributable to the drug.

My single personal experience with the plant was very meaningful and I believe contributed to spiritual and cultural insights that I have been writing about and contemplating for several years.

I understand the proliferation of YouTube clips give the appearance of something sinister but consider what is really happening in these clips which are now being deleted from YouTube. With very few exceptions these are teenagers trying something one time that is the equivalent of spinning around on a swing until they are very very dizzy then trying to walk. Lots of people have done this. Is it good or bad? Who is to say. Is addictive? No. Could anything bad come of it? It's possible, but would it be rational to then ban spinning in circles. No.

The plant is natural, not part of any criminal supply chain, anti-addictive in the extreme and a very reasonable substitute for other illegal, manufactured and crime-related psychotropic drugs. It's effects are very brief yet powerful and - to many people throughout the last couple thousand years - very meaningful as part of religious experiences, spiritual quests and personal searches for deeper meaning in life.

It is undeniable that some of those who have used psychotropic drugs have gained from it greatly and added invaluable to our culture, art, music and understanding of ourselves and the world around us. From native shamans to the Beatles we can see that the world would be a much poorer place without psychotropics and the amazing people who have used them to explore our spiritual world.

After all this time and not a single direct causal injury to anyone or anything from Salvia (a remarkable feat that beer, wine cigarettes and spirits certainly couldn't boast or even aspirin or sugar for that matter) the knee jerk reaction, as if this were the days of opium addicts sprawled around bongos, is for the Government of Canada to ban,

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outright, Salvia simply because they became aware of its existence.

We have vast and terrible knowledge of what happens next if that happens. The substance leaves the shelves of normal commerce and heads in to the realm of the criminal; the price goes up, the purity becomes tainted and it is just added to the list of illegal drugs separating the most vulnerable form civil society and filling our prisons with young poor uneducated citizens. It becomes the very thing the government, with this proposed ban is trying to stop. It becomes accessible only to those who would break the law, those who would abuse and misuse. It becomes inaccessible to all those who might use it to expand all of our cultural spiritual and personal understanding of ourselves and the natural world around us - as it has been used for thousands of years.

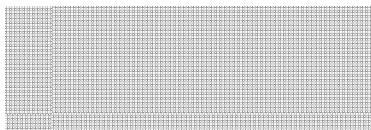
I also understand that the ban could be considered required for consistency with other drugs. I would point out however that by that same logic we would certainly ban tobacco, alcohol, caffeine and probably sugar. We just can't ban our way to the society we think we want.

I know I am only one voice but what I want to do is propose a reasonable alternative: Don't criminalize the plant in one step and risk destroying the cultural and spiritual meaning of the plant. Respect it for what it is and what it offers all society, particularly those responsible and interested in exploring what it offers without wanting to break the laws of their country. Set a rule that the plant should not be sold to anyone under 18. Monitor the situation for a year. If a single injury, misadventure or ill-effect is verifiably reported by a single Canadian, or anybody anywhere in the world, then set the laws such that it is controlled in the same way cigarettes or liquor is controlled (both verified to be infinitely more dangerous and addictive substances).

As a practical matter, the plant is among the most easily grown and cultivated on any windowsill and almost impossible to pick out from any common plantain. It seems to me the pursuit of making the drug illegal now that its place in popular culture is set and widely known would be to make criminals out of thousands of middle-class teenagers and deny people with a genuine spiritual interest an inalienable right to their personal beliefs while costing millions of dollars to solve a non-existent problem.

I am happy to speak on this issue any time.

Sincerely,





**Re: Fw: Standard Reply to Salvia NOI Comments**

Jocelyn Kula  
Cc: Stephanie Chandler  
Cc: Denis Arsenault

2011-03-04 10:19 AM

Follow Up: Normal Priority.

all good; I just didn't remember that that para was in there

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

Stephanie Chandler Hi Jocelyn, In regards to our conversation a fe... 2011-03-04 09:40:07 AM

---

From: Stephanie Chandler/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2011-03-04 09:40 AM  
Subject: Fw: Standard Reply to Salvia NOI Comments

Hi Jocelyn,

In regards to our conversation a few minutes ago, I just want to let you know that we had already sent out versions of the standard response from the OCS PRAD email account that also include the IYH link yesterday.

This is the version that we sent out which Denis and I were under the impression was approved.



Standard Reply to Salvia NOI Comments\_EN.wpd

Regards,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

----- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2011-03-04 09:33 AM -----

From: Brenda Paine/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: CSTD-DGO, Denis Arsenault/HC-SC/GC/CA@HWC, Michael Assad/HC-SC/GC/CA@HWC,  
stephanie.chandler@hc-sc.gc.ca  
Date: 2011-02-24 02:53 PM  
Subject: Re: Fw: Standard Reply to Salvia NOI Comments

---

Good note .. and good strategy. Will you handle ADMO or do you want us to?

.. and yes, I hope that they understand the flexibility for the first line of the response .. may not always be by e-mail!!

B

Jocelyn Kula Brenda I am attaching what we propose to send... 2011-02-24 02:08:42 PM

From: Jocelyn Kula/HC-SC/GC/CA  
To: brenda.paine@hc-sc.gc.ca  
Cc: Michael Assad/HC-SC/GC/CA@HWC, CSTD-DGO, stephanie.chandler@hc-sc.gc.ca, Denis  
Arsenault/HC-SC/GC/CA@HWC  
Date: 2011-02-24 02:08 PM  
Subject: Fw: Standard Reply to Salvia NOI Comments

---

Brenda

I am attaching what we propose to send out in response to all the emails RPD has received in response to the NOI on salvia. It is consistent with emails we have used for the same purpose but in relation to other regulatory files, and is also akin to what we typically send in response to respondents who file comments during a prepublication comment period. As you will see, it is very generic and does not seek to respond to any particular issue(s) raised by the correspondent, and this is on purpose as it avoids us having to get into long defensive letters where we have to keep explaining our actions in acknowledging every set of comments received.

In conversation with Jesse yesterday, she mentioned that ADMO has already received a few letters re salvia directly, and she asked what our process was in terms of responding to them. If you are OK with this, I would like to advise her that they should forward any correspondence they receive to OCS, and we will acknowledge it in exactly the same way, adding, if necessary, a line that says the letter was forwarded to us from ADMO for the purposes of a direct reply.

Please advise (and happy to discuss of course).

Jocelyn

---

Jocelyn Kula  
Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224  
----- Forwarded by Jocelyn Kula/HC-SC/GC/CA on 2011-02-24 01:58 PM -----

From: Stephanie Chandler/HC-SC/GC/CA

To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC  
Date: 2011-02-24 01:40 PM  
Subject: Standard Reply to Salvia NOI Comments

---

Hi Jocelyn,

Revised as requested.



Standard Reply to Salvia NOI Comments.wpd

Denis has also suggested that we have this translated (once approved) in case we receive any French comments.

Regards,

Stephanie

Stephanie Chandler  
Junior Regulatory Project Officer  
Regulatory Policy Division/ Division de la politique réglementaire  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 946-0124, Fax: (613) 946-4224  
E-Mail: stephanie.chandler@hc-sc.gc.ca

**Standard Reply to Comments Received Regarding the Salvia Notice to Interested Parties**

Dear Mr./Ms. [insert name],

I am writing to acknowledge receipt of your email with regards to the publication of the *Notice to Interested Parties* outlining Health Canada's proposal to add *Salvia divinorum* and salvinorin A to Schedule III to the *Controlled Drugs and Substances Act (CDSA)*.

I thank you for your comments regarding this proposal and can assure you they will be taken into consideration as the federal regulatory process progresses. There will also be additional opportunities for comment should a complete regulatory proposal be pre-published in *Canada Gazette*, Part I.

For your information, Health Canada has developed an *It's Your Health* article about *Salvia divinorum* that aims to inform the general public about the risks associated with the use of this plant. The article can be found on the Health Canada website at:  
<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/life-vie/salvia-eng.php>

Thank you for writing.

Sincerely,

s.19(1)

*Advised not to respond to second enquiries from same person*

*AKC  
APD April 15, 2011*



RE: Dep. of Health Notice. Feb. 4, 2011

to: ocs.policy.and.regulatory.affairs

2011-03-04 11:21 AM

History: This message has been forwarded.

Dear Stephanie Chandler,

I very much appreciate your getting back to me on this subject. I also thank you for providing me the link to Salvia divinorum page on Health Canada's website.

I am now quite concerned, however, that this species might be made outright illegal based on, more or less, uncertainty. It would seem the tone of that page is already set against scheduling this plant species without requiring much additional study.

I realize that a big issue at hand is the issue of youth gaining access to prepared Salvia material for purposes of intoxication. For this I do not differ from Health Canada's view on the need to act in some form to prevent such activities. I recently was reading that dried preparations of Salvia are being sold packaged and labeled as intoxicants, or legal highs, in convenient stores and the like. Much like tobacco and alcohol products, I am in full favour of implementing control measures to prevent underage use of such things. Also like tobacco, Salvia divinorum is hallucinogenic. But unlike tobacco (*Nicotiana glauca*), which is well studied and showed to be lethal at high doses and cause numerous health risks in prolonged use, Salvia is not known. It seems quite premature to make such drastic decisions affecting our rights as Canadian citizens based on "unknown data".

Once again, the main thing I am very much concerned with is the banning of any living species for purposes of cultivation and related activities to cultivation. I think that it is very much important for any free country to limit the amount of living species, nature if you will, that is made illegal. Banning an entire species outright can cause untold problems for future study, developments and even freedoms according to our charter of rights.

In relation to the link you kindly provided me, I would like to perhaps discuss this issue, topic by topic, if you would be so kind as to read through my lengthy emails.

### **The Issue**

Websites promoting use as legal hallucinogen. I have no disagreement with such a case, and might even add that it is likely marketed in "marijuana shops" as well. On the link provided it states: "Scientific reports also suggest that it has the potential for abuse." There have also been reports to the contrary. Such organizations as the DEA in the United States, which are quite against the use of hallucinogenic plants, state that this plant is not likely to be abused. The chemical Salvinorin A is simply not addictive as it works in quite the opposite way. It is just not possible to get addicted to it. Abuse will simply lie within the "party" crowd that will find any number of ways to intoxicate themselves, in which there is no shortage of methods to do so, from quite legal sources.

In the third paragraph of "The Issue", it states: "Canadians should not use products containing *S. divinorum* and/or salvinorin A because they are hallucinogenic and little is known about the long-term effects of these substances on the brain and body. There is also no way to predict how it will affect you with each use."

This paragraph seems at odds with the original statement of protecting youth. Although I do not particularly agree with the use of hallucinogenic compounds for recreational use, this paragraph seems to imply that Canadians of mature age do not have the mental capacity to decide for themselves to use a product that is only known to produce hallucinations. Much like the native people of Canada and the US using peyote in their religious ceremonies, people have also traditionally used *Salvia divinorum* for their religious reasons and it seems very non-Canadian to limit one's religious freedoms or belief system based

on the fact Health Canada does not know of any long term health problems. Surely there are more health concerns well documented with the use of tobacco products, and those such products have an age limit and do not get limited by any such scheduling such as Salvia divinorum is now facing.

I do not intend on comparing Salvia divinorum to Nicotiana tobacum as Nicotiana has a far lower concentration of its hallucinogenic compounds than does Salvia divinorum, however S. divinorum in low doses does not produce hallucinations and has by some proven to show anti-depressant activities without any form of intoxication. Much like N. tobacum doesn't show any form of hallucinatory effects until a certain threshold has been reached.

### **Risks Associated with the Use of Salvia divinorum**

I happen to agree with much of this, but again Health Canada seems to be treading on thin ice by implementing restrictions on Canadians based on something they have not studied. I also feel that all this is based on prepared material, and has little to do with the live plants. The point: "The purity of the product (products that contain S. divinorum may be mixed with other substances) " The purity of any single product is completely unknown to the consumer, even medicine and food products. Consumers rely totally on the person manufacturing it. This alone shows that perhaps a ban of prepared material is wise, as live plants are not likely to be tainted, or even used, by the common party goer that just wants something to intoxicate themself with.

The risks listed here can be applied to any number of things, even some vegetables, and pose little reasoning for the prosecution (such as tainting ones record or imprisonment) of citizens cultivating this species.

### **Minimizing Your Risk**

Again, i have little to disagree with, however the way this is written implies the decision is already decided to schedule the entire S. divinorum complex and products without any more thought.

Paragraph 1 states: "Health Canada recommends that you should not use S. divinorum because little is known about the long-term effects it may have on your body and/or brain functions. There is also no way to predict how it will affect you with each use. Just because a drug is plant-based or "natural", does not mean that it is safe. "

This holds true for all sorts of chemicals, not just this one. New medicines that have undergone extensive testing still cannot accurately explain long term effects, as Health Canada well knows from past experiences. This is more of a common sense thing with every single type of chemical that has not gone observation for extended periods. The last sentence claiming natural, or plant based, drugs are not always safe is also a matter of common sense. There is nothing to say it is unsafe either, at least physically, at this point. This point is also relevant to any other plant species and drug derived from. Take Atropa and Brugmansia, super hallucinogenic plants that are also used to obtain certain chemicals form for eye medicine and drops. The plant is quite dangerous to use, but has useful products in them. These advancements would not have been possible if various nations scheduled the entire species.

### **Legal Status of Salvia divinorum In Canada**

I totally and whole heartedly agree with making any prepared part of salvia a "Natural Health Product" and controlling it as such. But again, this has nothing to do with a living plant.

The article states: "The sale of unauthorized natural health products containing S. divinorum or its main active ingredient salvinin A may be subject to compliance and enforcement action by Health Canada under the Food and Drugs Act."

That seems quite logical, and I cannot think of any reason to disagree with such a reasoning of controlling the prepared plant material. Though I feel it would be quite against the good of the Canadian people to add the species, Salvia divinorum, to the Controlled Drugs and Substances Act, I can accept the reasoning behind adding the active chemical salvinin A to the act. This makes sense seen as it is the "Controlled



s.19(1)

Drugs and Substances Act" and not the "Controlled Species Act".

### **In Other Countries**

This is perhaps one of the most worry some aspects of the article. The lack of actual study and research and the willingness to "follow along" is truly frightening and a sign of Canada's depreciation as an independent nation capable of extensively investigating matters before willing to risk its own freedoms. I feel that certain countries, especially Australia and the United States, are particularly poor examples to follow in regards to rights and freedoms of the people, as is quite apparent in recent years. Though even the US DEA has reported little risk of abuse fo this substance simply due to its lack of addictiveness and relatively unpleasantness of the effects at hallucinogenic levels.

### **Background**

Here reveals the lack of independent research done, which I hope brings about some reasoning. *Salvia divinorum* is known to rarely produce seeds, and is next to impossible to get to set seed. Some very few people, through exhaustive work, have managed to produce seed. Health Canada's website has stated: "The products are sold in a number of forms, including fresh or dried leaves, liquids or seeds and plant cuttings for growing purposes."

Seeds are just not a normal thing, and though true they have been produced, are by no means a way of multiplying. IN fact most plants sold on the internet get tagged with names for clones taken as they are almost exclusively multiplied via vegetative methods.

In closing, I strongly urge Health Canada to seriously consider teh ramifications of threatening it's citizens with punishment for cultivating the species *Salvia divinorum*, and instead rely on facts, study and common sense to perhaps control the production of refined compounds and marketing strategies that promote recreational hallucinogen use. I feel that the prosecution of any Canadian citizen for cultivating a plant goes against our basic rights and freedoms which we claim to hold so dear. Jailing our own people for gardening is quite a big leap in teh wrong direction from our previous happy, easy going Canadian lifestyle, and I sincerely hope we can remain as free as we have been in previous years.

I really appreciate your willingness to hear people out and be open to communication on matters that may greatly affect our rights and freedoms as Canadians.

Once again, thank you.

From: ocs.policy.and.regulatory.affairs@hc-sc.gc.ca

To: [REDACTED]

Subject: Re: Dep. of Health Notice. Feb. 4, 2011

Date: Thu, 3 Mar 2011 15:02:49 -0500

Dear [REDACTED],

I am writing to acknowledge receipt of your email with regards to the publication of the *Notice to Interested Parties* outlining Health Canada's proposal to add *Salvia divinorum* and salvinorin A to Schedule III to the *Controlled Drugs and Substances Act* (CDSA).

I thank you for your comments regarding this proposal and can assure you they will be taken into consideration as the federal regulatory process progresses. There will also be additional opportunities for comment should a complete regulatory proposal be pre-published in *Canada Gazette*, Part I.

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scheduling of *Salvia divinorium*

to: OCS.Policy.and.Regulatory.Affair

2011-03-04 01:29 PM

Please respond to

Hi

I'm a Canadian and an amateur botanist.

I have a large collection of exotic foreign plants, some of which may contain alkaloids.

I hope we're not going down a path of wholesale criminalization of plants, here.

If in fact there is a serious *Salvia* abuse problem, I'm all for resolving it. However, do you solve a problem of kids huffing gasoline by banning gasoline? Thankyou for taking the time to read this and have a nice day.

Regards,

*Replied to with std msg.  
It did not save/print.*

*Angela*

*March 15, 2011  
RPD*



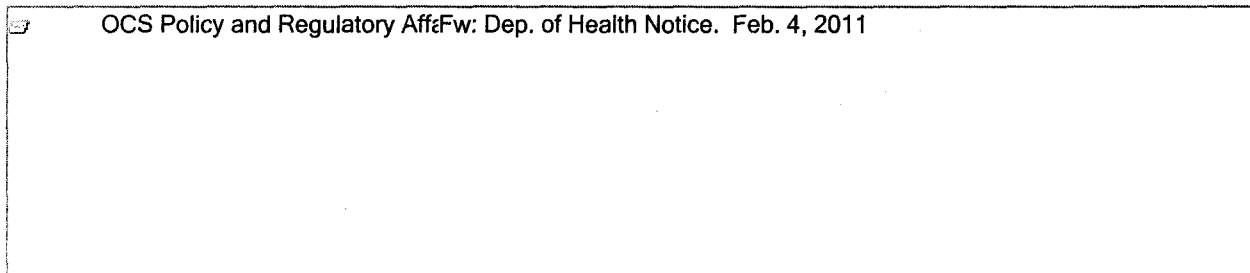
**Fw: Dep. of Health Notice. Feb. 4, 2011**

OCS Policy and Regulatory Affairs to: Denis Arsenault

2011-03-04 01:33 PM

Sent by: Stephanie Chandler

Cc: Stephanie Chandler



Hi Denis,

There have been a couple of responses to the acknowledgement email sent out yesterday. Do you think its necessary to acknowledge again or reply in some way?

Thanks,

Stephanie

Office of Controlled Substances/Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch  
Health Canada/Santé Environnementale et Sécurité des Consommateurs/Santé Canada  
----- Forwarded by Stephanie Chandler/HC-SC/GC/CA on 2011-03-04 01:22 PM -----

**RE: Dep. of Health Notice. Feb. 4, 2011**

 to: ocs.policy.and.regulatory.affairs

2011-03-04 11:21 AM

Dear Stephanie Chandler,

I very much appreciate your getting back to me on this subject. I also thank you for providing me the link to Salvia divinorum page on Health Canada's website.

I am now quite concerned, however, that this species might be made outright illegal based on, more or less, uncertainty. it would seem teh tone of that page is already set against scheduling this plant species without requiring much additional study.

I realize that a big issue at hand is the issue of youth gaining access to prepared Salvia material for purposes od intoxication. For this I do not differ from Health Canada's view on teh need to act in some form to prevent such activities. I recently was reading that dried preparations of Salvia are being sold packaged and labeled as intoxicants, or legal highs, in convenient stores and the like. Much like tobacco and alcohol products, I am in full favour of implementing control measures to prevent underage use of such things. Also like tobacco, Salvia divinorum is hallucinogenic. But unlike tobacco (Nicotiana tobacum), which is well studied and showed to be lethal at high doses and cause numerous health risks in prolonged us, Salvia is not known. It seems quite premature to make such drastic decisions affecting our rights as Canadian citizens based on "unknown data".

s.19(1)

Re: For approval: Media query - INTERVIEW - Niagara Falls review - [REDACTED]

[REDACTED] - Salvia [REDACTED]

Jocelyn Kula Nicole Prentice

2011-03-07 12:03 PM

Chantal Routhier-Garner, Christine Roush, CSTD-OCS-DO, Denis  
Arsenault, Stephanie Chandler, Suzanne Desjardins

I will write something new for Q3 as I don't think referring to A1 will cut it...

JK

---

Jocelyn Kula

Acting Director/ Directrice par intérim

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs

Health Canada/ Santé Canada

Tel: (613) 952-2177 Fax: (613) 946-4224

Nicole Prentice

Hi Jocelyn and Suzanne, Below is a media enq...

2011-03-07 11:57:27 AM

From: Nicole Prentice/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC, Christine Roush/HC-SC/GC/CA@HWC, CSTD-OCS-DO, Chantal Routhier-Garner/HC-SC/GC/CA@HWC  
Date: 2011-03-07 11:57 AM  
Subject: For approval: Media query - INTERVIEW - Niagara Falls review - [REDACTED] - Salvia

Hi Jocelyn and Suzanne,

Below is a media enquiry for your approval please by 2pm today please. We are recommending written responses.

**Suzanne** - I believe only A1 is for your approval.

Thanks,  
Nicole

This reporter did a story on Salvia back in 2008; , where he wrote; At the time "... HC is researching salvia and "may" take action ... " He's following up on this story and asking pretty standard Questions - seeking interview ideally (for Tuesday), but willing to receive written responses by Monday COB.

**Q1** - Has / is HC studying this issue? What have been the results?

A1 - Health Canada has reviewed information and reports from a variety of sources regarding the use and dangers of salvia and has assessed its findings against several key factors involved in the determination of the scheduling of a substance, including

- its pharmacological similarity to other substances already regulated under the CDSA;
- its potential for abuse related to its hallucinogenic properties, and the fact that about 7% of youth 15-24 years of age have used it - this represents about 300,000 youth;
- the health risks associated with this substance as shown from some reports of adverse incidents, for example, an article in the Journal of Emergency Medicine in 2009 indicates that 39 adverse neurological, cardiovascular and gastrointestinal events associated with the use of salvia were reported to a statewide (California) poison control system over the span of a decade.
- Health Canada is also aware of other cases where suicide and psychotic symptoms were linked to use of *Salvia divinorum*.

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Health Canada is continuing to survey the prevalence of salvia use and in 2009, Health Canada started including questions on salvia use in both the Youth Smoking Survey and the Canadian Alcohol and Drug Use Monitoring Survey. The Centre for Addiction and Mental Health in Toronto similarly included questions on salvia use in the Ontario Student Drug Use and Health Survey. As results from these surveys became available in 2009-2010, the Department was able to include Canadian surveillance data in its ongoing assessment of salvia.

Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *Salvia divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of students grades 7-12 have used *Salvia divinorum* in the past year. This represents about 123,000 Canadian high-school students. The 2009 *Ontario Student Drug Use and Health Survey (OSDUHS)* indicated that 5.4% of Ontario students in grades 7-12 reported ever using *Salvia divinorum* and 4.4% of these students reported using this substance in the past year.

**Q2a - What evidence has been brought forward to support / refute the Gov't position on salvia?**

A2a- See A1

**Q2b - Does Health Canada deem salvia divinorum to be dangerous to the public?**

A2b- *S. divinorum* is known to have both physical and mental effects. The effects of *S. divinorum*, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

There is no way to predict what effect these substances may have on an individual. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product;
- how much is used;
- the purity of the product (products that contain *S. divinorum* may be mixed with other substances);
- how it is taken, for example, whether the product is chewed, swallowed or smoked; and
- the user's mood and expectations.

While scientists know which brain receptors are targeted by the main active ingredient, salvinorin A, very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or if it can cause permanent damage;
- how it interacts with other substances, including other drugs, natural health products and alcohol;
- the potential of *S. divinorum* to produce physical dependence and/or addiction.

For more information on *Salvia divinorum* and the risks associated with its use, please see *It's Your Health* at: (<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/life-vie/salvia-eng.php>)

**Q3 - Have stakeholders / who has been consulted in order to arrive at this decision?**

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A3 - See A1.

**Q4 - Has the recent publicity around recreational uses of salvia been a factor in the Government proposing a ban on salvia?**

A4 - Scheduling these products will reduce the potential risks to the health and safety of Canadians associated with their ready availability, with their increased use and their unknown effects. The scheduling of *Salvia divinorum* and salvinorin A will also eliminate the current misconception that these substances are a safe alternative to other illegal drugs. Furthermore, the scheduling will also enable law enforcement agencies to take action against suspected illegal activities involving these substances.

**Q5 - What is the likely timeline for salvia to be added to the Controlled subs list? When will it be official?**

A5 - Health Canada considers several factors in determining whether the scheduling of a substance under the Controlled Drugs and Substances Act (CDSA) is warranted. These include:

- Overall risk to public health and safety posed by the substance.
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- International requirements and trends in international control.

Health Canada recently concluded its assessment of *Salvia divinorum* and salvinorin A against these factors and proposes to include both substances in Schedule III to the CDSA. The first step in the process of scheduling a substance under the CDSA is the publication of a *Notice to Interested Parties* (NOI) in *Canada Gazette*, Part I, which was published on February 19, 2011 for a 30-day comment period (<http://canadagazette.gc.ca/rp-pr/p1/2011/2011-02-19/html/notice-avis-eng.html#d109>). This notice provides interested stakeholders with the opportunity to provide comments on Health Canada's proposal to add *Salvia divinorum* and its main active ingredient salvinorin A to Schedule III to the CDSA. Any comments received are considered during the preparation of a regulatory proposal. There will be additional opportunities for comment as the federal regulatory process progresses, which usually takes about 18 to 24 months to complete.

### **Nicole Prentice**

Junior Communications Officer | Agente junior des Communications  
Regulatory Communications and Media Relations Division | Division des communications réglementaires et des relations avec les médias  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la consultation et des communications  
Health Canada | Santé Canada  
Tel: 613.941.3107  
Fax: 613.948.8085

----- Forwarded by Nicole Prentice/HC-SC/GC/CA on 2011-03-07 11:38 AM -----

From: Christine Roush/HC-SC/GC/CA  
To: Nicole Prentice/HC-SC/GC/CA@HWC  
Date: 2011-03-07 11:37 AM  
Subject: Re: For your review: Media query - INTERVIEW - Niagara Falls review - [REDACTED] - Salvia

OK to go - I changed the answer to Q1, and made some other changes. thx. .

Christine Roush

Senior Communications Advisor/

Nicole Prentice

For your review, This reporter did a story on Sal...

2011-03-07 10:42:42 AM

s.19(1)

Re: For approval: Media query - INTERVIEW - Niagara Falls review - [REDACTED]  
[REDACTED] - Salvia [REDACTED]

Jocelyn Kula to Nicole Prentice

2011-03-07 12:10 PM

Chantal Routhier-Garner, Christine Roush, CSTD-OCS-DO, Denis

Arsenault, Stephanie Chandler, Suzanne Desjardins

Approved for OCS with new response to Q3 below and concomitant changes to A5.

---

Jocelyn Kula

Acting Director/ Directrice par intérim

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs

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Tel: (613) 952-2177 Fax: (613) 946-4224

Nicole Prentice

Hi Jocelyn and Suzanne, Below is a media enq...

2011-03-07 11:57:27 AM

From: Nicole Prentice/HC-SC/GC/CA

To: Jocelyn Kula/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC

Cc: Denis Arsenault/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC, Christine Roush/HC-SC/GC/CA@HWC, CSTD-OCS-DO, Chantal Routhier-Garner/HC-SC/GC/CA@HWC

Date: 2011-03-07 11:57 AM

Subject: For approval: Media query - INTERVIEW - Niagara Falls review - [REDACTED] - Salvia

Hi Jocelyn and Suzanne,

Below is a media enquiry for your approval please by 2pm today please. We are recommending written responses.

**Suzanne** - I believe only A1 is for your approval.

Thanks,  
Nicole

This reporter did a story on Salvia back in 2008; , where he wrote; At the time "... HC is researching salvia and "may" take action ... " He's following up on this story and asking pretty standard Questions - seeking interview ideally (for Tuesday), but willing to receive written responses by Monday COB.

**Q1 - Has / is HC studying this issue? What have been the results?**

A1 - Health Canada has reviewed information and reports from a variety of sources regarding the use and dangers of salvia and has assessed its findings against several key factors involved in the determination of the scheduling of a substance, including

- its pharmacological similarity to other substances already regulated under the CDSA;
- its potential for abuse related to its hallucinogenic properties, and the fact that about 7% of youth 15-24 years of age have used it - this represents about 300,000 youth;
- the health risks associated with this substance as shown from some reports of adverse incidents, for example, an article in the Journal of Emergency Medicine in 2009 indicates that 39 adverse neurological, cardiovascular and gastrointestinal events associated with the use of salvia were reported to a statewide (California) poison control system over the span of a decade.
- Health Canada is also aware of other cases where suicide and psychotic symptoms were linked to use of *Salvia divinorum*.



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A2a- See A1

**Q2b - Does Health Canada deem salvia divinorum to be dangerous to the public?**

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A3 - ~~See A1.~~ The first step in the process of scheduling a substance under the CDSA is the publication of

a *Notice to Interested Parties* (NOI) in *Canada Gazette*, Part I, which was published on February 19, 2011 for a 30-day comment period (<http://canadagazette.gc.ca/rp-pr/p1/2011/2011-02-19/html/notice-avis-eng.html#d109>). This notice provides interested stakeholders with the opportunity to provide comments on Health Canada's proposal to add *Salvia divinorum* and its main active ingredient salvinorin A to Schedule III to the CDSA. Any comments received are considered during the future preparation of a related regulatory proposal.

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Junior Communications Officer | Agente junior des Communications  
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----- Forwarded by Nicole Prentice/HC-SC/GC/CA on 2011-03-07 11:38 AM -----

From: Christine Roush/HC-SC/GC/CA

s.19(1)

Re: For approval: Media query - INTERVIEW - Niagara Falls review - [REDACTED]

[REDACTED] - Salvia [REDACTED]

Suzanne Desjardins to Nicole Prentice

2011-03-07 12:13 PM

Chantal Routhier-Garner, Christine Roush, CSTD-OCS-DO, Denis Arsenault, Jocelyn Kula, Stephanie Chandler

I am fine with the proposed answer A1

Thanks

Suzanne

Nicole Prentice

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2011-03-07 11:57:28 AM

From: Nicole Prentice/HC-SC/GC/CA  
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- its potential for abuse related to its hallucinogenic properties, and the fact that about 7% of youth 15-24 years of age have used it - this represents about 300,000 youth;
- the health risks associated with this substance as shown from some reports of adverse incidents, for example, an article in the Journal of Emergency Medicine in 2009 indicates that 39 adverse neurological, cardiovascular and gastrointestinal events associated with the use of salvia were reported to a statewide (California) poison control system over the span of a decade.
- Health Canada is also aware of other cases where suicide and psychotic symptoms were linked to use of *Salvia divinorum*.

Health Canada is continuing to survey the prevalence of salvia use and in 2009, Health Canada started including questions on salvia use in both the Youth Smoking Survey and the Canadian Alcohol and Drug Use Monitoring Survey. The Centre for Addiction and Mental Health in Toronto similarly included questions on salvia use in the Ontario Student Drug Use and Health Survey. As results from these surveys became available in 2009-2010, the Department was able to include Canadian surveillance data

in its ongoing assessment of salvia.

Results from the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)* reveal that, in 2009, 1.6% of Canadians aged 15 years and older have reported using *Salvia divinorum* at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15-24. The results from the *Canadian 2008-2009 Youth Smoking Survey* also show that 5% of students grades 7-12 have used *Salvia divinorum* in the past year. This represents about 123,000 Canadian high-school students. The 2009 *Ontario Student Drug Use and Health Survey (OSDUHS)* indicated that 5.4% of Ontario students in grades 7-12 reported ever using *Salvia divinorum* and 4.4% of these students reported using this substance in the past year.

**Q2a - What evidence has been brought forward to support / refute the Gov't position on salvia?**

A2a- See A1

**Q2b - Does Health Canada deem salvia divinorum to be dangerous to the public?**

A2b- *S. divinorum* is known to have both physical and mental effects. The effects of *S. divinorum*, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

There is no way to predict what effect these substances may have on an individual. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product;
- how much is used;
- the purity of the product (products that contain *S. divinorum* may be mixed with other substances);
- how it is taken, for example, whether the product is chewed, swallowed or smoked; and
- the user's mood and expectations.

While scientists know which brain receptors are targeted by the main active ingredient, salvinorin A, very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or if it can cause permanent damage;
- how it interacts with other substances, including other drugs, natural health products and alcohol;
- the potential of *S. divinorum* to produce physical dependence and/or addiction.

For more information on *Salvia divinorum* and the risks associated with its use, please see *It's Your Health* at: (<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/life-vie/salvia-eng.php>)

**Q3 - Have stakeholders / who has been consulted in order to arrive at this decision?**

A3 - See A1.

**Q4 - Has the recent publicity around recreational uses of salvia been a factor in the Government proposing a ban on salvia?**

A4 - Scheduling these products will reduce the potential risks to the health and safety of Canadians

associated with their ready availability, with their increased use and their unknown effects. The scheduling of *Salvia divinorum* and salvinorin A will also eliminate the current misconception that these substances are a safe alternative to other illegal drugs. Furthermore, the scheduling will also enable law enforcement agencies to take action against suspected illegal activities involving these substances.

**Q5 - What is the likely timeline for salvia to be added to the Controlled subs list? When will it be official?**

A5 - Health Canada considers several factors in determining whether the scheduling of a substance under the Controlled Drugs and Substances Act (CDSA) is warranted. These include:

- Overall risk to public health and safety posed by the substance.
- Chemical and pharmacological similarity to other substances already regulated under the CDSA;
- Legitimate uses of the substance (i.e., therapeutic, industrial or commercial);
- Potential for abuse and risk of addiction associated with the substance;
- Extent of actual abuse of the substance in Canada and internationally; and
- International requirements and trends in international control.

Health Canada recently concluded its assessment of *Salvia divinorum* and salvinorin A against these factors and proposes to include both substances in Schedule III to the CDSA. The first step in the process of scheduling a substance under the CDSA is the publication of a *Notice to Interested Parties* (NOI) in *Canada Gazette*, Part I, which was published on February 19, 2011 for a 30-day comment period (<http://canadagazette.gc.ca/rp-pr/p1/2011/2011-02-19/html/notice-avis-eng.html#d109>). This notice provides interested stakeholders with the opportunity to provide comments on Health Canada's proposal to add *Salvia divinorum* and its main active ingredient salvinorin A to Schedule III to the CDSA. Any comments received are considered during the preparation of a regulatory proposal. There will be additional opportunities for comment as the federal regulatory process progresses, which usually takes about 18 to 24 months to complete.

**Nicole Prentice**

Junior Communications Officer | Agente junior des Communications  
Regulatory Communications and Media Relations Division | Division des communications réglementaires et des relations avec les médias  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la consultation et des communications  
Health Canada | Santé Canada  
Tel: 613.941.3107  
Fax: 613.948.8085

----- Forwarded by Nicole Prentice/HC-SC/GC/CA on 2011-03-07 11:38 AM -----

From: Christine Roush/HC-SC/GC/CA  
To: Nicole Prentice/HC-SC/GC/CA@HWC  
Date: 2011-03-07 11:37 AM  
Subject: Re: For your review: Media query - INTERVIEW - Niagara Falls review - [REDACTED] Salvia

OK to go - I changed the answer to Q1, and made some other changes. thx. .

Christine Roush  
Senior Communications Advisor/

Nicole Prentice

For your review, This reporter did a story on Sal...

2011-03-07 10:42:42 AM

s.19(1)



Re: For approval: Media query - INTERVIEW - Niagara Falls review - [redacted]

[redacted] - Salvia [redacted]

Nicole Prentice Jocelyn Kula

2011-03-07 12:19 PM

Chantal Routhier-Garner, Christine Roush, Denis Arsenault,  
Stephanie Chandler, Suzanne Desjardins

Normal Priority.

Thanks Jocelyn. We will wait for Suzanne to send to DGO.

FYI - There is anothe Salvia enquiry on its way, however, we are waiting for clarification on a question.

**Nicole Prentice**

Junior Communications Officer | Agente junior des Communications  
Regulatory Communications and Media Relations Division | Division des communications  
réglementaires et des relations avec les médias  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires  
publiques, de la consultation et des communications  
Health Canada | Santé Canada  
Tel: 613.941.3107  
Fax: 613.948.8085

Jocelyn Kula

Approved for OCS with new response to Q3 bel...

2011-03-07 12:10:51 PM

From: Jocelyn Kula/HC-SC/GC/CA  
To: Nicole Prentice/HC-SC/GC/CA@HWC  
Cc: Chantal Routhier-Garner/HC-SC/GC/CA@HWC, Christine Roush/HC-SC/GC/CA@HWC,  
CSTD-OCS-DO, Denis Arsenault/HC-SC/GC/CA@HWC, Stephanie  
Chandler/HC-SC/GC/CA@HWC, Suzanne Desjardins/HC-SC/GC/CA@HWC  
Date: 2011-03-07 12:10 PM  
Subject: Re: For approval: Media query - INTERVIEW - Niagara Falls review - [redacted] - Salvia

Approved for OCS with new response to Q3 below and concomitant changes to A5.

**Jocelyn Kula**

Acting Director/ Directrice par intérim  
Office of Controlled Substances/ Bureau des substances contrôlées  
Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et  
de la sécurité des consommateurs  
Health Canada/ Santé Canada  
Tel: (613) 952-2177 Fax: (613) 946-4224

Nicole Prentice

Hi Jocelyn and Suzanne, Below is a media enq...

2011-03-07 11:57:27 AM

Nicole Prentice

For your review, This reporter did a story on Sal...

2011-03-07 10:42:42 AM

s.19(1)



For input/approval: Media query - INTERVIEW - Gauntlet Newspaper - [redacted]

[redacted] - Salvia [redacted]

Nicole Prentice to Jocelyn Kula

2011-03-08 10:30 AM

Denis Arsenault, Stephanie Chandler, CSTD-OCS-DO, Christine Roush

Subject: [redacted]

Normal Priority.

Hi Jocelyn,

Below is the other salvia media enquiry for your input and approval by 2pm please. We are recommending written responses again.

Thanks,

Nicole

\*\*\*\*\*

Another request for information - INTERVIEW - with the following questions (link to the Salvia news release has been provided to requestor):

**Q1 - Info please: the legal status of salvia in canada right now.**

A1 - After reviewing available information and reports that suggest these substances have the potential for abuse, especially among young people, Health Canada is proposing to schedule both *Salvia divinorum* and its main active ingredient salvinorin A as controlled substances.

The first step in the process of scheduling a substance under the CDSA is the publication of a *Notice to Interested Parties* (NOI) in *Canada Gazette*, Part I, which was published on February 19, 2011 for a 30-day comment period. This notice provides interested stakeholders with the opportunity to provide comments on Health Canada's proposal to add *Salvia divinorum* and its main active ingredient salvinorin A to Schedule III to the CDSA. Any comments received are considered during the preparation of a regulatory proposal. There will be additional opportunities for comment as the federal regulatory process progresses, which usually takes about 18 to 24 months to complete.

The Government of Canada is taking these steps in order to protect the health and safety of Canadians, particularly youth, from the potentially harmful effects of *Salvia divinorum* and/or salvinorin A. The proposed inclusion of *Salvia divinorum* and salvinorin A in Schedule III to the Controlled Drugs and Substances Act would make possession, trafficking, importation, exportation, production (or cultivation), possession for the purpose of trafficking or possession for the purposes of exporting illegal unless authorized by regulation.

The move to schedule *Salvia divinorum* and salvinorin A as controlled substances is based on surveillance data from surveys such as the *Canadian Alcohol and Drug Use Monitoring Survey* (CADUMS), *Youth Smoking Survey* (YSS) and the *Ontario Student Drug Use and Health Survey* (OSDUHS), some of which only became available in 2010.

In the interim, as *Salvia divinorum* is a plant with hallucinogenic properties, it currently meets the definition of a natural health product under the *Natural Health Products Regulations* (NHPR). The sale of unauthorized natural health products may be subject to compliance and enforcement action in accordance with the *Food and Drugs Act* and its associated regulations.

To date, Health Canada has not authorized for sale any natural health products which contain *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products containing *Salvia divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health

Canada under the *Food and Drugs Act and its associated regulations*.

**Q2 - Is there anything that has been taking place that has recently changed the legal status of salvia in Canada?**

A2 - See A1.

**Q3 - Is there a lot known about the effects (long term and otherwise)?**

A3 - *S. divinorum* is known to have both physical and mental effects. The effects of *S. divinorum*, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

There is no way to predict what effect these substances may have on an individual. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product;
- how much is used;
- the purity of the product (products that contain *S. divinorum* may be mixed with other substances);
- how it is taken, for example, whether the product is chewed, swallowed or smoked; and
- the user's mood and expectations.

While scientists know which brain receptors are targeted by the main active ingredient, salvinorin A, very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or if it can cause permanent damage;
- how it interacts with other substances, including other drugs, natural health products and alcohol;
- the potential of *S. divinorum* to produce physical dependence and/or addiction.

For more information on *Salvia divinorum* and the risks associated with its use, please see *It's Your Health* at: (<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/life-vie/salvia-eng.php>)

**Q4 - Many people say that a change in the legal status would be a preventative measure, can you talk about this?**

A4 - Scheduling these products will reduce the potential risks to the health and safety of Canadians associated with their ready availability, with their increased use and their unknown effects. The scheduling of *Salvia divinorum* and salvinorin A will also eliminate the current misconception that these substances are a safe alternative to other illegal drugs. Furthermore, the scheduling will also enable law enforcement agencies to take action against suspected illegal activities involving these substances.

**Q5 - are there any other drugs that have the same status as salvia? (Interpret as... Are there any other substances currently awaiting to be placed on the Controlled Substances List)**

A5 - For OCS input?

**Q6 - How has the media affected our perception of the drugs danger? (Interpret as...was it because of**



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the media that there is now a push to schedule this substance)

A6- See A4.

**Nicole Prentice**

Junior Communications Officer | Agente junior des Communications  
Regulatory Communications and Media Relations Division | Division des communications réglementaires et des relations avec les médias  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la consultation et des communications  
Health Canada | Santé Canada  
Tel: 613.941.3107  
Fax: 613.948.8085

Christine Roush      OK with changes below. Christine Roush Senio...      2011-03-07 11:18:17 AM

From:            Christine Roush/HC-SC/GC/CA  
To:                Nicole Prentice/HC-SC/GC/CA@HWC  
Date:             2011-03-07 11:18 AM  
Subject:         Re: For your review: Media query - INTERVIEW - Gauntlet Newspaper - [REDACTED] - Salvia

OK with changes below.

Christine Roush  
Senior Communications Advisor/  
Conseillère principale en communications  
Public Affairs, Consultation and Communications Branch/  
Direction générale des affaires publiques,  
de la consultation et des communications  
Health Canada/Santé Canada  
Tel/Tél : (613) 954-0712/Cell: (613) 219-7194  
Fax/Facsimile : 948-8085  
E-mail / courriel : christine\_roush@hc-sc.gc.ca

Nicole Prentice      Another request for information - INTERVIEW -...      2011-03-07 10:54:11 AM

From:            Nicole Prentice/HC-SC/GC/CA  
To:                Christine Roush/HC-SC/GC/CA@HWC  
Date:             2011-03-07 10:54 AM  
Subject:         For your review: Media query - INTERVIEW - Gauntlet Newspaper - [REDACTED] - Salvia

Another request for information - INTERVIEW - with the following questions (link to the Salvia news release has been provided to requestor):

**Q1 - Info please: the legal status of salvia in canada right now.**

A1 - After reviewing available information and reports that suggest these substances have the potential for abuse, especially among young people, Health Canada is proposing to schedule both *Salvia divinorum* and its main active ingredient salvinorin A as controlled substances.

The first step in the process of scheduling a substance under the CDSA is the publication of a *Notice to*

*Interested Parties* (NOI) in *Canada Gazette*, Part I, which was published on February 19, 2011 for a 30-day comment period. This notice provides interested stakeholders with the opportunity to provide comments on Health Canada's proposal to add *Salvia divinorum* and its main active ingredient salvinorin A to Schedule III to the CDSA. Any comments received are considered during the preparation of a regulatory proposal. There will be additional opportunities for comment as the federal regulatory process progresses, which usually takes about 18 to 24 months to complete.

The Government of Canada is taking these steps in order to protect the health and safety of Canadians, particularly youth, from the potentially harmful effects of *Salvia divinorum* and/or salvinorin A. The proposed inclusion of *Salvia divinorum* and salvinorin A in Schedule III to the Controlled Drugs and Substances Act would make possession, trafficking, importation, exportation, production (or cultivation), possession for the purpose of trafficking or possession for the purposes of exporting illegal unless authorized by regulation.

~~Health Canada is continuing to survey the prevalence of salvia use and have based our proposed scheduling on available information and reports that suggest these substances have the potential for abuse, especially among young Canadians. The risks of salvia use include hallucinations, loss of consciousness and short-term memory loss.~~

The move to schedule *Salvia divinorum* and salvinorin A as controlled substances is based on surveillance data from surveys such as the *Canadian Alcohol and Drug Use Monitoring Survey* (CADUMS), *Youth Smoking Survey* (YSS) and the *Ontario Student Drug Use and Health Survey* (OSDUHS), some of which only became available in 2010.

In the interim, as *Salvia divinorum* is a plant with hallucinogenic properties, it currently meets the definition of a natural health product under the *Natural Health Products Regulations* (NHPR). The sale of unauthorized natural health products may be subject to compliance and enforcement action in accordance with the *Food and Drugs Act* and its associated regulations.

To date, Health Canada has not authorized for sale any natural health products which contain *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products containing *Salvia divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act* and its associated regulations.

**Q2 - Is there anything that has been taking place that has recently changed the legal status of salvia in Canada?**

A2 - See A1.

**Q3 - Is there a lot known about the effects (long term and otherwise)?**

A3 - *S. divinorum* is known to have both physical and mental effects. The effects of *S. divinorum*, which vary from person to person, are often described as unpleasant and may include the following:

- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

There is no way to predict what effect these substances may have on an individual. In addition, the effects may differ from one use to the next, depending on factors such as:

s.19(1)

- the potency of the product;
- how much is used;
- the purity of the product (products that contain *S. divinorum* may be mixed with other substances);
- how it is taken, for example, whether the product is chewed, swallowed or smoked; and
- the user's mood and expectations.

While scientists know which brain receptors are targeted by the main active ingredient, salvinorin A, very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or if it can cause permanent damage;
- how it interacts with other substances, including other drugs, natural health products and alcohol;
- the potential of *S. divinorum* to produce physical dependence and/or addiction.

For more information on *Salvia divinorum* and the risks associated with its use, please see *It's Your Health* at: (<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/life-vie/salvia-eng.php>)

**Q4 - Many people say that a change in the legal status would be a preventative measure, can you talk about this?**

A4 - Scheduling these products will reduce the potential risks to the health and safety of Canadians associated with their ready availability, with their increased use and their unknown effects. The scheduling of *Salvia divinorum* and salvinorin A will also eliminate the current misconception that these substances are a safe alternative to other illegal drugs. Furthermore, the scheduling will also enable law enforcement agencies to take action against suspected illegal activities involving these substances.

**Q5 - are there any other drugs that have the same status as salvia?**

A5 - Waiting for clarification....currently? going through the same process? etc

**Q6 - How has the media affected our perception of the drugs danger? (Interpret as...was it because of the media that there is now a push to schedule this substance)**

A6- See A4.

### **Nicole Prentice**

Junior Communications Officer | Agente junior des Communications  
Regulatory Communications and Media Relations Division | Division des communications réglementaires et des relations avec les médias  
Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la consultation et des communications  
Health Canada | Santé Canada  
Tel: 613.941.3107  
Fax: 613.948.8085

----- Forwarded by Nicole Prentice/HC-SC/GC/CA on 2011-03-07 10:43 AM -----

From: Gary Holub/HC-SC/GC/CA  
To: Christine Roush/HC-SC/GC/CA@HWC, Nicole Prentice/HC-SC/GC/CA@HWC  
Cc: Dave Stephens/HC-SC/GC/CA@HWC  
Date: 2011-03-07 10:39 AM  
Subject: Media query - INTERVIEW - Gauntlet Newspaper - [REDACTED] - Salvia

Good morning,

Another request for information - INTERVIEW - with the following questions (link to the Salvia news

s.19(1)

release has been provided to requestor):

- Q1 - Info please: the legal status of salvia in canada right now.
- Q2 - Is there anything that has been taking place that has recently changed the legal status of salvia in Canada?
- Q3 - Is there a lot known about the effects (long term and otherwise)?
- Q4 - Many people say that a change in the legal status would be a preventative measure, can you talk about this?
- Q5 - are there any other drugs that have the same status as salvia?
- Q6 - How has the media affected our perception of the drugs danger?

Deadline: TBD

\*\*\*

Thanks,  
Gary

Gary Scott Holub  
 Media Relations Officer | Agent des relations avec les médias  
 Regulatory Communications and Media Relations Division | Division des communications réglementaires et des relations avec les médias  
 Health Canada | Santé Canada  
 (t) 613.954.4807  
 (e) gary.holub@hc-sc.gc.ca  
 Government of Canada | Gouvernement du Canada  
 ----- Forwarded by Gary Holub/HC-SC/GC/CA on 2011-03-07 10:37 AM -----



### Media Enquiry - Demande médiatique

Name/Nom : [REDACTED]	Media/Média : Gauntlet newspaper
Telephone/Téléphone : [REDACTED]	Language/Langue : English-anglais
Cell Telephone/Téléphone cellulaire : [REDACTED]	Fax/Télécopieur :
Email/Courriel : [REDACTED]	

Date and Time Received	Date Completed
Date et Heure de réception : 2011-03-04 10:03:47 AM	Date d'achèvement :

Subject/Objet : Controlled Substances/Substances contrôlées

**Question:**

Add to the Question/ajouter a la question  
 2011-03-04 10:03:49 AM (Gary Holub)

From: [REDACTED]  
 To: Legault, Christelle  
 Sent: Thu Mar 03 22:11:25 2011  
 Subject: Salvia

Hi Christelle,

My name is [REDACTED] and I am from the Gauntlet newspaper. I am doing an article next week about the legal status of salvia in Canada. I just had a few questions I would like to ask if you have time. It

s.19(1)

should not take more than 10 minutes, if you would prefer I could email you the questions.

Thanks so much,

2011-03-07 10:32:27 AM (Gary Holub)

Q1 - Info please: the legal status of salvia in canada right now.

Q2 - Is there anything that has been taking place that has recently changed the legal status of salvia in Canada?

Q3 - Is there a lot known about the effects (long term and otherwise)?

Q4 - Many people say that a change in the legal status would be a preventative measure, can you talk about this?

Q5 - are there any other drugs that have the same status as salvia?

Q6 - How has the media affected our perception of the drugs danger?

Q7 - and is there anything else that you think is important to know?

Deadline: TBD

**Response/Réponse :**

Add to the Response/ajouter a la réponse

2011-03-07 10:36:55 AM (Gary Holub)

Good morning

Thank you for the questions. What is your deadline?

In the meantime, please review the news release on the Minister's announcement, and the associated information available at the link below:

Harper Government Takes Action to Protect Families

[http://www.hc-sc.gc.ca/ahc-asc/media/nr-cp/\\_2011/2011\\_29-eng.php](http://www.hc-sc.gc.ca/ahc-asc/media/nr-cp/_2011/2011_29-eng.php)

Regards,  
Gary

**Action Taken/Mesures prises :**

Add to the Action Taken/ajouter au mesures prises

2011-03-04 11:17:21 AM (Gary Holub)

TCB

2011-03-07 10:36:58 AM (Gary Holub)

Sent to Christine, Nicole, cc'd Dave ste

Interview with spokesperson granted/Entrevue avec porte-parole accordé:  Yes-Oui  No-Non

Branch/Direction générale : HECS - Controlled Substances & Drug Analysis/DGSESC - Direction de la sécurité des substances chimiques et des produits de consommation

Spokesperson/Porte-parole :

Reporter's Deadline

Heure de tombée du journaliste :

Priority/Priorité : Regular

Telephone/Téléphone :

Story Run Date

Date de parution de l'article :

Status/Rapport de situation : Follow-up

**Comment/Commentaire :**

**Attachments/Pièces jointes :**

**Related Clippings/Coupures connexes :**

**Media Relations Officer/Agente de relations avec les médias :** Gary Holub

**Edit History / Historique des révisions**

Send To / Transmettre à : Suzanne Desjardins; Stephanie Szick; Christine von Arx; Ken Moore; Christine Roush; Nicole  
Prentice; Dave Stephens; Jeannine Ritchot; Paul Spendlove; Louise Bertrand; Jesse  
Arnup-Blondin; Tim Vail/HC-SC/GC/CA; Jenny VanAlstyne/HC-SC/GC/CA; Warren  
Braun/HC-SC/GC/CA;

**Branch Recipient:**

Suzanne Desjardins, Stephanie Szick, Christine von Arx, Ken Moore, Christine Roush, Nicole Prentice, Dave Stephens, Jeannine  
Ritchot, Paul Spendlove, Louise Bertrand, Jesse Arnup-Blondin

**Mail Recipients:**

CN=Tim Vail/OU=HC-SC/O=GC/C=CA, CN=Jenny VanAlstyne/OU=HC-SC/O=GC/C=CA, CN=Warren  
Braun/OU=HC-SC/O=GC/C=CA

s.19(1)



Re: For input/approval: Media query - INTERVIEW - Gauntlet Newspaper -

[REDACTED] - Salvia

Jocelyn Kula to: Nicole Prentice

2011-03-08 02:39 PM

cc: Denis Arsenault, Stephanie Chandler, Christine Roush, CSTD-OCS-DO

denis sent me edits and I am just reviewing

Jocelyn Kula

Acting Director/ Directrice par intérim

Office of Controlled Substances/ Bureau des substances contrôlées

Healthy Environments and Consumer Safety Branch/ Direction générale de la santé environnementale et de la sécurité des consommateurs

Health Canada/ Santé Canada

Tel: (613) 952-2177 Fax: (613) 946-4224

Nicole Prentice

Hello, This is just a friendly reminder...can I get...

2011-03-08 02:31:22 PM

From: Nicole Prentice/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC, Denis Arsenault/HC-SC/GC/CA@HWC  
Cc: Stephanie Chandler/HC-SC/GC/CA@HWC, Christine Roush/HC-SC/GC/CA@HWC, CSTD-OCS-DO  
Date: 2011-03-08 02:31 PM  
Subject: Re: For input/approval: Media query - INTERVIEW - Gauntlet Newspaper - [REDACTED] - Salvia

Hello,

This is just a friendly reminder...can I get a response asap. Media Relations wants to close this call by COB today.

Thanks!

**Nicole Prentice**

Junior Communications Officer | Agente junior des Communications

Regulatory Communications and Media Relations Division | Division des communications réglementaires et des relations avec les médias

Public Affairs, Consultation and Communications Branch | Direction générale des affaires publiques, de la consultation et des communications

Health Canada | Santé Canada

Tel: 613.941.3107

Fax: 613.948.8085

Nicole Prentice

Hi Jocelyn, Below is the other salvia media enq...

2011-03-08 10:30:33 AM

From: Nicole Prentice/HC-SC/GC/CA  
To: Jocelyn Kula/HC-SC/GC/CA@HWC  
Cc: Denis Arsenault/HC-SC/GC/CA@HWC, Stephanie Chandler/HC-SC/GC/CA@HWC, CSTD-OCS-DO, Christine Roush/HC-SC/GC/CA@HWC  
Date: 2011-03-08 10:30 AM  
Subject: For input/approval: Media query - INTERVIEW - Gauntlet Newspaper - [REDACTED] - Salvia

Hi Jocelyn,

003190

Below is the other salvia media enquiry for your input and approval by 2pm please. We are recommending written responses again.

Thanks,  
Nicole

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Another request for information - INTERVIEW - with the following questions (link to the Salvia news release has been provided to requestor):

**Q1 - Info please: the legal status of salvia in canada right now.**

A1 - After reviewing available information and reports that suggest these substances have the potential for abuse, especially among young people, Health Canada is proposing to schedule both *Salvia divinorum* and its main active ingredient salvinorin A as controlled substances.

The first step in the process of scheduling a substance under the CDSA is the publication of a *Notice to Interested Parties* (NOI) in *Canada Gazette*, Part I, which was published on February 19, 2011 for a 30-day comment period. This notice provides interested stakeholders with the opportunity to provide comments on Health Canada's proposal to add *Salvia divinorum* and its main active ingredient salvinorin A to Schedule III to the CDSA. Any comments received are considered during the preparation of a regulatory proposal. There will be additional opportunities for comment as the federal regulatory process progresses, which usually takes about 18 to 24 months to complete.

The Government of Canada is taking these steps in order to protect the health and safety of Canadians, particularly youth, from the potentially harmful effects of *Salvia divinorum* and/or salvinorin A. The proposed inclusion of *Salvia divinorum* and salvinorin A in Schedule III to the Controlled Drugs and Substances Act would make possession, trafficking, importation, exportation, production (or cultivation), possession for the purpose of trafficking or possession for the purposes of exporting illegal unless authorized by regulation.

The move to schedule *Salvia divinorum* and salvinorin A as controlled substances is based on surveillance data from surveys such as the *Canadian Alcohol and Drug Use Monitoring Survey* (CADUMS), *Youth Smoking Survey* (YSS) and the *Ontario Student Drug Use and Health Survey* (OSDUHS), some of which only became available in 2010.

In the interim, as *Salvia divinorum* is a plant with hallucinogenic properties, it currently meets the definition of a natural health product under the *Natural Health Products Regulations* (NHPR). The sale of unauthorized natural health products may be subject to compliance and enforcement action in accordance with the *Food and Drugs Act* and its associated regulations.

To date, Health Canada has not authorized for sale any natural health products which contain *Salvia divinorum* as an ingredient. The sale of unauthorized natural health products containing *Salvia divinorum* or its active ingredient salvinorin A may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act and its associated regulations*.

**Q2 - Is there anything that has been taking place that has recently changed the legal status of salvia in Canada?**

A2 - See A1.

**Q3 - Is there a lot known about the effects (long term and otherwise)?**

A3 - *S. divinorum* is known to have both physical and mental effects. The effects of *S. divinorum*, which vary from person to person, are often described as unpleasant and may include the following:



- hallucinations
- dysphoria (feeling anxious, depressed or restless)
- out-of-body experiences
- uncontrollable laughter
- loss of consciousness
- short-term memory loss
- lack of physical coordination
- slurred speech and awkward sentence patterns

There is no way to predict what effect these substances may have on an individual. In addition, the effects may differ from one use to the next, depending on factors such as:

- the potency of the product;
- how much is used;
- the purity of the product (products that contain *S. divinorum* may be mixed with other substances);
- how it is taken, for example, whether the product is chewed, swallowed or smoked; and
- the user's mood and expectations.

While scientists know which brain receptors are targeted by the main active ingredient, salvinorin A, very little is known about the following:

- how it affects the brain overall, including whether there are any long-term effects or if it can cause permanent damage;
- how it interacts with other substances, including other drugs, natural health products and alcohol;
- the potential of *S. divinorum* to produce physical dependence and/or addiction.

For more information on *Salvia divinorum* and the risks associated with its use, please see *It's Your Health* at: (<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/life-vie/salvia-eng.php>)

**Q4 - Many people say that a change in the legal status would be a preventative measure, can you talk about this?**

**A4 -** Scheduling these products will reduce the potential risks to the health and safety of Canadians associated with their ready availability, with their increased use and their unknown effects. The scheduling of *Salvia divinorum* and salvinorin A will also eliminate the current misconception that these substances are a safe alternative to other illegal drugs. Furthermore, the scheduling will also enable law enforcement agencies to take action against suspected illegal activities involving these substances.

**Q5 - are there any other drugs that have the same status as salvia? (Interpret as... Are there any other substances currently awaiting to be placed on the Controlled Substances List)**

**A5 -** For OCS input?

**Q6 - How has the media affected our perception of the drugs danger? (Interpret as...was it because of the media that there is now a push to schedule this substance)**

**A6- See A4.**

### **Nicole Prentice**

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Christine Roush	OK with changes below. Christine Roush Senio...	2011-03-07 11:18:17 AM
Nicole Prentice	Another request for information - INTERVIEW -...	2011-03-07 10:54:11 AM