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CONTROLLED DRUGS AND SUBSTANCES ACT

### **Order Amending Schedule IV to the Controlled Drugs and Substances Act (Salvia Divinorum)**

P.C. 2015-1173 July 31, 2015

His Excellency the Governor General in Council, on the recommendation of the Minister of Health, pursuant to section 60 of the *Controlled Drugs and Substances Act* ([see footnote a](#)), deeming that it is necessary in the public interest, makes the annexed *Order Amending Schedule IV to the Controlled Drugs and Substances Act (Salvia Divinorum)*.

#### **ORDER AMENDING SCHEDULE IV TO THE CONTROLLED DRUGS AND SUBSTANCES ACT (SALVIA DIVINORUM)**

##### **AMENDMENT**

1. Schedule IV to the *Controlled Drugs and Substances Act* ([see footnote 1](#)) is amended by adding the following after item 26:

27. *Salvia divinorum* (*S. divinorum*), its preparations and derivatives, including:

(1) Salvinorin A ((2S,4aR,6aR,7R,9S,10aS,10bR)-9-(acetyloxy)-2-(3-furanyl)dodecahydro-6a,10b-dimethyl-4,10-dioxo-2H-naphtho[2,1-c]pyran-7-carboxylic acid methyl ester)

##### **COMING INTO FORCE**

2. This Order comes into force 180 days after the day on which it is published in the *Canada Gazette*, Part II.

#### **REGULATORY IMPACT ANALYSIS STATEMENT**

*(This statement is not part of the Regulations and the Order.)*

#### **Issues**

*Salvia divinorum* (*S. divinorum*) is a species of sage belonging to the mint family, and which is found in the form of dried leaves, extracts and plant cuttings. Also called “diviner’s sage,” the plant is known to induce hallucinations when chewed or smoked. *S. divinorum*’s pharmacological effects are similar to other hallucinogens regulated under the *Controlled Drugs and Substances Act* (CDSA), such as dimethyltryptamine and ketamine.

There are no therapeutic or natural health products containing *S. divinorum* authorized by Health Canada. While the sale of unauthorized natural health products containing *S. divinorum* may be subject to compliance and enforcement

action by Health Canada under the *Food and Drugs Act* and its associated regulations, this has not restricted its availability to Canadian youth. *S. divinorum* is widely touted as a legal hallucinogen on the Internet, and has also been reported to be used as an alternative to illicit drugs among adolescents and young adults. *S. divinorum* may be purchased in Canada over the Internet and at head shops or alternative life style stores.

In the 2012–2013 Youth Smoking Survey, approximately 41 000 Canadian youth in grades 7 to 12 reported using “salvia to get high” in the previous 12 months (2%). This compares to 3% of youth reporting past-12 month use of ecstasy and 1% of youth reporting past-12 month use of “bath salts.”

There is no way for individual users to predict what effect *S. divinorum* may have on them. The effects differ depending on factors such as the potency of the product, how much is used, the purity of the product, how it is taken, and the user's mood and expectations. *S. divinorum* products sold in Canada do not conform to any specific quality or safety standards.

## Background

The CDSA provides a legislative framework for the control of substances that can alter mental processes and that may cause harm to the health of an individual or to society when diverted or misused. Currently, over 300 such substances are expressly listed in Schedules I to IV to the CDSA. Entries in the schedules may include plants that are smoked, chewed, or ingested for recreational purposes, and the psychoactive substances contained in such plants. Substances are scheduled to the CDSA based on criteria including their pharmacological activity, considerations for approved therapeutic use, and evidence of the extent of their abuse in Canada.

*S. divinorum* leaves are known to be chewed or smoked to obtain psychotropic effects. Active psychoactive ingredients in *S. divinorum* may also be extracted, concentrated, and sold as a concentrate or mixed with or sprayed onto plant material. The use of these substances may have effects including hallucinations, out-of-body experiences, unconsciousness and short-term memory loss. Adverse reactions associated with salvia use include abdominal distension, confusion, hallucination, aggression, and/or self-injurious ideation. Some public health and safety risks associated with the known effects of *S. divinorum* include the potential for accidents caused by impaired driving, and injuries caused by dissociation with one's surroundings or loss of consciousness.

*S. divinorum* is not currently scheduled to the CDSA. The sale of unauthorized natural health products containing *S. divinorum* may be subject to compliance and enforcement action by Health Canada under the *Food and Drugs Act* and its associated regulations. No natural health products containing *S. divinorum* have been approved by Health Canada.

*S. divinorum* has traditionally been used for spiritual and medicinal purposes by the Mazatec people in Oaxaca, Mexico. An infusion of the leaves has been traditionally ingested to treat gastrointestinal problems. However, its main use in Mexico today is believed to be for its psychedelic properties in the aid of producing “mystical” or hallucinogenic experiences as part of spiritual rituals. There are no known industrial or commercial uses for *S. divinorum* in Canada. *S. divinorum* could be cultivated for horticultural purposes, but retailers and gardening centres typically sell other species of *Salvia*, and not *S. divinorum*. A few retailers who specialize in herbal products are selling *S. divinorum*. Dozens of other species of salvia seeds and plants are commonly sold by other retailers for horticultural and/or gardening purposes.

Internationally, *S. divinorum* is controlled in some countries (e.g. Australia and European countries) and at least 33 U.S. States. The degree of control varies widely throughout these jurisdictions. Some only impose restrictions on the sale of *S. divinorum* to minors (e.g. Maine, California), some restrict sale and distribution with a range of penalties from fines to prison terms (e.g. Wisconsin, Spain, Russia) and still others prohibit the possession, sale and distribution of this substance (e.g. Australia, Germany, Sweden). Although *S. divinorum* is not controlled federally in the United States under the *Controlled Substances Act*, the United States Drug Enforcement Administration has listed salvia as a “drug of concern.”

## Objective

The objective of this Order and these Regulations is to protect the health and safety of Canadians, particularly

youth, by setting out controls under the CDSA on activities with *S. divinorum*, including its sale. This Order and these Regulations will align the controls for *S. divinorum*, with those for other hallucinogenic drugs scheduled to the CDSA, in light of the health and safety risks associated with its use.

## Description

First, this Order will add *S. divinorum* and its preparations and derivatives to Schedule IV to the CDSA. This will prohibit the production, trafficking, possession for the purposes of trafficking, importation and exportation and possession for the purposes of exportation of these substances, unless as authorized under the regulations or a section 56 exemption. Simple possession will not be prohibited under the CDSA. The maximum penalties associated with conducting the activities listed above will range from one year of imprisonment for a person found guilty of an offence prosecuted by summary conviction, to three years of imprisonment for a person found guilty of an offence prosecuted by indictment.

Secondly, these Regulations will make amendments to Part J of the *Food and Drug Regulations* in order to add these substances to its Schedule. As a result, test kits containing this substance could be registered to authorize their use by forensic/analytical laboratories, and access to the substances for scientific research could be authorized.

Requests for exemptions under section 56 of the CDSA authorizing the use of these substances for traditional medical or spiritual purposes will be evaluated by the Minister on a case-by-case basis.

## “One-for-One” Rule

This Order and these Regulations will not impose new administrative costs to business; consequently, the “One-for-One” Rule does not apply.

## Small business lens

The small business lens does not apply, as the overall costs are less than \$1M, and there is no indication that small businesses will be affected disproportionately.

## Consultation

Health Canada published on February 19, 2011, a Notice to Interested Parties (NTIP) in the *Canada Gazette*, Part I, to notify stakeholders and the general public regarding a proposal to add *S. divinorum* to Schedule III to the CDSA. In addition, background information about *S. divinorum* and the regulatory proposal was added to the Health Canada Web site in February 2011.

Three comments were received supporting the scheduling proposal, on the basis of the hallucinogenic properties of these substances. Health Canada has also received correspondence from Canadians supporting the control of *S. divinorum* under the CDSA. Three additional comments received were neutral in nature and simply sought further clarification on the scheduling proposal.

Seventy-five comments were received that were not supportive of the proposal, as outlined in the NTIP. The most common comments received referred to a lack of scientific evidence to indicate that *S. divinorum* use causes harm and/or addiction. Some additional concerns were that drug prohibition in itself is ineffective, and that scheduling would restrict personal choice.

Among those respondents opposed to the scheduling proposal outlined in the NTIP were two retailers of *S. divinorum*. One explicitly sold the plant in question for its psychoactive effects, while the other asserted that it sold the plant for its horticultural significance. It should be noted that Health Canada is aware of at least three other retailers of herbal products in Canada that sell *S. divinorum*. None of the above-noted respondents to the NTIP specifically identified potential impacts of lost sales that would result from the scheduling of *S. divinorum* under the CDSA.

In response to public input received during the consultation process and subsequent analysis of this proposal, Health Canada has amended the original proposal to add *S. divinorum* to Schedule IV of the CDSA instead of to

Schedule III of the CDSA. This change eliminates the prohibition on the simple possession of these substances and reduces the maximum penalties for a number of offenses, such as trafficking and import, from 10 years to 3 years of imprisonment.

## Rationale

*S. divinorum* is a psychoactive plant that induces hallucinations and dissociative experiences that range widely in severity and implications for each individual user. There are no approved therapeutic uses of *S. divinorum* in Canada. The current status of *S. divinorum* as a substance that is not controlled under the CDSA has resulted in widespread availability of *S. divinorum* to youth, and a false perception of safety concerning the recreational use of this hallucinogen. This Order and these Regulations will further protect the health and safety of Canadians, particularly youth, by prohibiting unauthorized activities with *S. divinorum* in Canada.

## Implementation, enforcement and service standards

Health Canada will notify stakeholders as well as provincial/ territorial ministries of health of this regulatory amendment and provide relevant links on Health Canada's Web site at <http://www.hc-sc.gc.ca/ahc-asc/legislation/acts-reg-lois/acts-reg-lois-eng.php>.

Health Canada is responsible for authorizing (for example through licences, permits, and exemptions) activities with substances scheduled under the CDSA and its regulations and for monitoring compliance with the CDSA and its regulations.

Health Canada will communicate with known stakeholders and the public regarding the steps to take prior to the coming into force of these scheduling amendments in order to ensure compliance with the Act and its regulations. The amendments in question will come into force 180 days following their publication in the *Canada Gazette*, Part II. For retailers of *S. divinorum* and gardeners cultivating the plant in question, compliance will involve ceasing the sale of *S. divinorum*, as well as its cultivation, given that cultivation is captured under the prohibited activity of production. Health Canada will provide guidance as appropriate to stakeholders and members of the public with respect to dealing with *S. divinorum* plants under cultivation.

Federal, provincial and local law enforcement agencies are responsible for taking enforcement action in response to contraventions of the CDSA and its regulations. The prosecution of contraventions under the CDSA is the responsibility of the justice system. Law enforcement agencies have indicated their support for scheduling salvia, and Health Canada will assist them as required in responding to questions from any impacted individuals.

These regulatory amendments will come into force 180 days after the day on which they are published.

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### [Footnote a](#)

S.C. 1996, c. 19

### [Footnote 1](#)

S.C. 1996, c. 19

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