



Address Locator 0300B
Ottawa ON K1A 0T6

2023-07-04

21-114291-595
HC6-53-140-139



QC

Dear [redacted]:

Pursuant to subsection 56(1) of the *Controlled Drugs and Substances Act* (CDSA) and subject to the terms and conditions set out herein, you, the Facility Operator of the Companionship of the Sacred Vine Inc. (CSV) and the members of Companionship of the Sacred Vine Inc. (CSV) are hereby exempted from the application of Part J of the *Food and Drug Regulations* (FDR) and certain provisions of the CDSA.

Definitions

Except as defined below, the terms used in this exemption have the same meaning as those provided in the CDSA and its regulations.

Ayahuasca means a mixture prepared with *Banisteriopsis caapi* and *Psychotria viridis* that contains N,N-Dimethyltryptamine (DMT), harmaline, or harmalol, which are controlled substances listed in Schedule III to the CDSA and in the Schedule to Part J of the FDR.

Companionship of the Sacred Vine Inc. means the non-distributing corporation constituted under the *Canada Business Corporations Act* that holds the corporation number 12244045-8 and is located at 50 St. Peters Rd, Charlottetown, Prince Edward Island.

Designated criminal offence means

- (a) an offence involving the financing of terrorism against any of sections 83.02 to 83.04 of the *Criminal Code*;
- (b) an offence involving fraud against any of sections 380 to 382 of the *Criminal Code*;
- (c) the offence of laundering proceeds of crime against section 462.31 of the *Criminal Code*;
- (d) an offence involving a criminal organization against any of sections 467.11 to 467.13 of the *Criminal Code*; or
- (e) a conspiracy or an attempt to commit, being accessory after the fact in relation to, or any counselling in relation to an offence referred to in any of paragraphs (a) to (d);

Designated substance offence means

- (a) an offence under Part I of the CDSA, except subsection 4(1), or
- (b) a conspiracy or an attempt to commit, being an accessory after the fact in relation to, or any counselling in relation to, an offence referred to in paragraph (a);

Facility Operator means the Facility Operator of Companionship of the Sacred Vine Inc.

Member means a person who is registered with the Companionship of the Sacred Vine Inc. to attend a Session.

Designated Member means a person, including the Facility Operator, who is a member of the Companionship of the Sacred Vine Inc. and is listed in Appendix 1, as amended from time to time.

Session means a ceremony or ritual carried out as part of the Companionship of the Sacred Vine Inc.'s practice.

Scope of the Exemption

Designated Members are exempt from the following provisions of the CDSA:

- a. Subsections 4(1), 5(1), 5(2), and 6(1) of the CDSA with respect to the possession, provision, and importation of Ayahuasca;

Members are exempt from the following provisions of the CDSA:

- a. Subsection 4(1) of the CDSA with respect the possession of Ayahuasca.

This exemption provides the aforementioned Designated Members with the authority to possess, provide, import, administer and destroy Ayahuasca, as applicable, when carrying out activities related to the delivering of a Session and the participation in a Session, subject to the terms and conditions of this exemption.

Terms and Conditions

The exemption is applicable only if the following conditions are met:

General

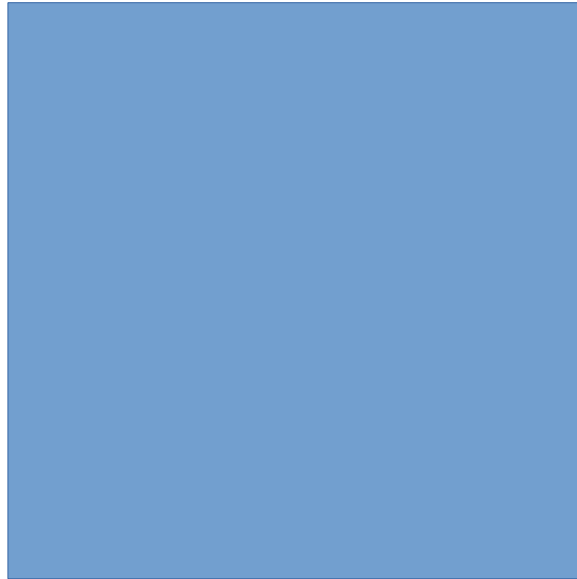
1. With the reasonable exception of activities associated with the importation of Ayahuasca, this exemption is only valid at the Companionship of the Sacred Vine Inc. site located at [REDACTED], Québec. The activities with Ayahuasca authorized by this exemption may only be conducted at the Companionship of the Sacred Vine Inc. site.

2. The Designated Members and Members must follow the below relevant policies and procedures of the Companionship of the Sacred Vine Inc. regarding the possession, provision, importation, destruction and administration of Ayahuasca in Canada:
 - a. policies and procedures described in the application to Health Canada submitted on January 27, 2021, unless otherwise specified in the terms and conditions, and
 - b. policies and procedures described in the email correspondence for additional information provided to the Office of Controlled Substances (OCS) on June 30, 2021 to June 6, 2023, unless otherwise specified in the terms and conditions.
3. Designated Members and Members must be at least eighteen (18) years of age.
4. Designated Members and Members may only possess Ayahuasca that was imported from Peru.
5. Designated Members may not possess more than 10 kilograms of Ayahuasca paste, or the equivalent of 40 litres of Ayahuasca tea, collectively at one time.
6. Designated Members may provide Ayahuasca to a Member within the context of a Session.

Importing

7. To apply for an import certificate to import Ayahuasca, a Designated Member shall submit an application to Office of Controlled Substances containing:
 - a. the Designated Member's full name and date of birth,
 - b. the Designated Member's contact information including mailing address and phone number,
 - c. the name and address of the supplier,
 - d. method of importation,
 - e. if imported by shipment, the
 - i. proposed port of entry;
 - ii. proposed mode of transport, i.e. air, land, ;
 - iii. name of the proposed carrier; and
 - iv. name and address of the proposed customs broker, if applicable;
 - v. proposed date of entry into Canada;
 - vi. name of any proposed country of transit or transshipment, and
 - f. if imported on a Designated Member's person, the
 - vii. date of arrival;
 - viii. proposed port of arrival; and
 - ix. name of any proposed country of transit.

8. An application for an import certificate shall be signed by the applicant and indicate that all information submitted in support of the application is correct and complete to the best of their knowledge.
9. A Designated Member may only import Ayahuasca from Peru, from the following individuals:



10. The Designated Member may not import more than 10 kilograms of Ayahuasca paste, or the equivalent of 40 litres of Ayahuasca tea, collectively at any one time. The imports of Ayahuasca must not exceed a total of 10 kilograms of Ayahuasca paste, or the equivalent of 40 litres of Ayahuasca tea, in a calendar year.
11. A valid import certificate issued to a Designated Member by the OCS must accompany each shipment of Ayahuasca.
12. Within 10 days after the date of release of shipment in Canada, or the arrival of the Ayahuasca imported, the Designated Member named on the importation certificate shall provide the OCS with a declaration that contains the following information:
 - a. the name of the courier on the importation certificate and the certificate number;
 - b. the date of release of the shipment or the date the courier named on the certificate imported the Ayahuasca into Canada; and
 - c. the quantity of the Ayahuasca imported.
13. The Designated Member named on the import certificate shall make a record of the information submitted to the OCS and provide such a record to the Facility Operator, for record-keeping purposes. The Facility Operator must retain all records with respect to the importation of Ayahuasca for a period of two years from the date of the making of such records. All records made regarding the importation of

Ayahuasca must be made available to the Minister or an inspector designated under section 30 of the CDSA upon request.

14. A Designated Member that becomes aware of a theft or loss of an import certificate must provide a written report to the OCS within 72 hours after becoming aware of it.
15. An import certificate issued on the basis of false or misleading information, or false or falsified document is invalid.
16. An import certificate may be revoked where it is necessary to protect the security, safety or health of the public, if there are reasonable grounds to believe that the holder has failed to comply with any terms and conditions of this exemption.
17. An import certificate shall be revoked at the request of the holder, or when the holder notifies the OCS that the import certificate has been lost or stolen.
18. A new Designated Member may not apply for an import certificate without the Facility Operator receiving a confirmation of notification from the OCS that the new Designated Member has been included in Appendix 1. A list of approved Designated Members is enclosed as Appendix 1, and will be amended as necessary.

Disposal

19. A Designated Member must be responsible for the destruction of any unused or expired Ayahuasca. The destruction must be witnessed by another Designated Member of the Companionship of the Sacred Vine Inc. The method of destruction used must alter or denature Ayahuasca to such an extent that its use or future use is rendered impossible or improbable.
20. The Designated Member destroying the Ayahuasca must make a record with the following information:
 - the quantity of any Ayahuasca to be destroyed;
 - the date of destruction;
 - the method of destruction; and
 - the reason for destruction.

Immediately following the destruction, the Designated Member and the witness are required to sign and print their names on a joint statement indicating that they have witnessed the destruction and that the Ayahuasca destroyed has been altered or denatured to such an extent that its consumption has been rendered impossible or improbable.

21. The destruction of Ayahuasca must be carried out in accordance with a method that complies with all federal, provincial and municipal environmental protection legislation applicable to the place of destruction.

22. A Designated Member destroying any unused or expired Ayahuasca shall provide any records of destruction to the Facility Operator, for record-keeping purposes. The Facility Operator must retain all records with respect to the destruction of Ayahuasca for a period of two years from the date of the making of such records. All records made regarding the destruction of Ayahuasca must be made available to the Minister or an inspector designated under section 30 of the CDSA upon request.

Record-Keeping

23. Designated Members are required to record the following information with respect to their possession, and provision of Ayahuasca:
- the date and quantity of any Ayahuasca imported or received;
 - the name of the supplier from whom the Ayahuasca was received;
 - the quantity of Ayahuasca consumed at a given Session;
 - the name of the Designated Members and members of Companionship of the Sacred Vine Inc. who consume Ayahuasca during a Session;
 - the location at which the Session was held; and
 - the quantity of Ayahuasca in the Companionship of the Sacred Vine Inc.'s possession remaining after each Session.

The Designated Members must provide such records to the Facility Operator, for record keeping purposes. The Facility Operator must keep and retain records for a period of two years from the making of the record. These records must be made available to the Minister or an inspector designated under section 30 of the CDSA upon request.

Physical Security and Loss and Theft

24. A Designated Member must take necessary steps to ensure the safe-keeping of any Ayahuasca stored to minimize the risk of loss or theft.
25. A Designated Member must report immediately to the Facility Operator when they become aware of any loss or theft of Ayahuasca in storage or in their possession.
26. The Facility Operator, upon becoming aware of a theft or loss of Ayahuasca, must:
- a. provide a written report to a member of a police force within 24 hours after becoming aware of the theft or loss; and
 - b. provide a written report to the OCS within 72 hours after becoming aware of the theft or loss and include a confirmation that the report under paragraph (a) has been provided.

Written reports may be submitted to the Compliance and Monitoring Division, OCS, by email: ocs.reporting-rapporter.bsc@hc-sc.gc.ca.

27. Ayahuasca will be stored by the Companionship of the Sacred Vine Inc. at the following location:

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Labelling

28. Designated Members must, at the border, label every package that contains Ayahuasca with the following information:
 - a. the words “Ayahuasca” or another synonym for Ayahuasca,
 - b. the quantity of Ayahuasca contained in the package,
 - c. the words “Restricted Drug”, and
 - d. the name and address of the supplier.
29. Designated Members must ensure that every package that contains Ayahuasca shall be accompanied by documentation that indicates the package contains N,N-Dimethyltryptamine (DMT), harmaline, and harmalol.

Changes in Information

30. The Facility Operator must inform the OCS should any of the information which has been provided by the Companionship of the Sacred Vine Inc. within the context of this exemption change. This includes any changes to Companionship of the Sacred Vine’s Inc. policies and procedures and to the list of Designated Members of the Companionship of the Sacred Vine Inc. found in Appendix 1. In particular, the Facility Operator must notify the OCS if they are no longer the Facility Operator of the Companionship of the Sacred Vine Inc. within 10 days of the change, so that responsibilities for the Ayahuasca may be formally transferred to another individual and this exemption may be amended.
31. Where a Designated Member is convicted of a “designated substance offence” or a “designated criminal offence”, the Facility Operator must advise the OCS, and will be removed from the list of approved Designated Members (Appendix 1).
32. The Facility Operator must advise the OCS of the removal of a Designated Member within 10 days of the removal, so that the OCS may remove the individual from Appendix 1.
33. The Facility Operator must provide the following information to the OCS in order to amend Appendix 1 to include a new Designated Member:
 - a. the name of the new Designated Member;
 - b. contact information of the new Designated Member;
 - c. a document issued by a Canadian police force in relation to each Designated Member, indicating whether, during the 10 years before the day on which the application was made, in respect of a designated substance offence or a

designated criminal offence or a designated offence as defined in subsection 2(1) of the *Cannabis Act*

- (i) the individual was convicted as an adult, or
 - (ii) was a young person who received an adult sentence, as those terms are defined in subsection 2(1) of the *Youth Criminal Justice Act*; and
- d. if any new Designated Member has ordinarily resided in a country other than Canada in the 10 years before the day on which the application was made, a document issued by a police force of that country stating whether, in respect of an offence committed outside Canada that, if committed in Canada, would have constituted a designated substance offence or a designated criminal offence or a designated offence as defined in subsection 2(1) of the *Cannabis Act*
- (i) the individual was convicted as an adult, or
 - (ii) if they committed the offence when they were at least 14 years old but less than 18 years old, the individual received a sentence that was longer than the maximum youth sentence, as that term is defined in subsection 2(1) of the *Youth Criminal Justice Act*, that could have been imposed under that Act for such an offence.

Period of Validity

34. This exemption expires on the earliest of the following three dates:
- the date on which this exemption is replaced by another exemption,
 - the date of revocation, or
 - December 23, 2025.

Health Canada has not approved the sale of Ayahuasca as a drug under the *Food and Drugs Act* and the *Food and Drug Regulations*. That is, there are no products containing DMT, Harmaline, or Harmalol approved as therapeutic drugs in Canada.

This exemption does not constitute an opinion from Health Canada on the safety, effectiveness, or quality of Ayahuasca.

This exemption is being provided with the understanding that you and the Members of the Companionship of the Sacred Vine Inc. acknowledge these facts, and that you and the Members of Companionship of the Sacred Vine Inc. voluntarily assume the risks and dangers associated with the use of Ayahuasca.

You are strongly encouraged to report any adverse reactions that may be related to the use of Ayahuasca (including adverse food and drug interactions) to Health Canada through MedEffect Canada. Information regarding the reporting of adverse reactions can be obtained on the MedEffect Canada website at www.healthcanada.gc.ca/medeffect or by telephoning the Canada Vigilance Regional Office at 1-866-234-2345.

If you have any further questions regarding this exemption, please do not hesitate to contact the Exemptions Section at exemption@hc-sc.gc.ca.

Sincerely,

**Saxe,
Jennifer**



Digitally signed by Saxe, Jennifer
DN: C=CA, O=GC, OU=HC-SC,
CN="Saxe, Jennifer"
Reason: I am the author of this
document
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Date: 2023.07.04 11:05:26-0400'
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Jennifer Saxe
Director General
Controlled Substances Directorate

Attachments

Appendix 1 – Designated Members of the Companionship of the Sacred Vine Inc.

Appendix 2 – Application for Certificate to Import