

DRAFT December 12, 2007
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Issue Analysis Summary (DRAFT)

Office of Controlled Substances

Exemption under Section 56 of the *Controlled Drugs and Substances Act* (Public Interest) Regarding the Use of Daime Tea for Religious Purposes

CONTENTS:

- **ISSUE**
- **PURPOSE**
- **CONTEXT**
- **IDENTIFICATION OF OPTIONS**
- **ASSESSMENT OF OPTIONS**
- **CONSULTATIONS**
- **CONSIDERATIONS**
- **SELECTED STRATEGY**
- **IMPLEMENTATION AND EVALUATION**

1. ISSUE

The sacramental drinking of Daime tea is central to the practice of the Santo Daime religion. While Daime tea itself is not listed in the schedules to the *Controlled Drugs and Substances Act* (CDSA), some of its active ingredients include substances listed in Schedule III to the CDSA, i.e. harmaline and N,N-dimethyltryptamine (DMT), and therefore, activities including the importation, possession, and administration of Daime tea are prohibited. The Cému do Montréal has claimed that this prohibition infringes on its right to religious freedom and on April 24, 2001, requested an exemption under section 56 (s.56) of the CDSA that would allow them to import, possess and administer Daime tea for use in their religious ceremonies.

2. PURPOSE

The purpose of this issue analysis summary is to examine what is currently known about the pharmacology, dependence potential, and abuse potential associated with Daime Tea and the controlled substances contained within it, with a view to determining whether the importation, possession and administration of Daime Tea for the purposes of use in religious ceremonies to be carried out by the Cému de Montréal poses any undue health and safety risks to the members of the Church and/or the general public. This assessment will form the basis on which the decision as to whether it is appropriate for the Minister of Health to issue an exemption under s.56 of the CDSA (in the public interest) to the Cému de Montréal.

DRAFT December 12, 2007
UPDATED February 2008

3. CONTEXT

Freedom of Religion

In Canada, freedom of religion is a fundamental right enshrined in the *Charter of Rights and Freedoms*. As with all rights under the Charter however, freedom of religion is subject to limitations as can be justified in a free and democratic society. Freedom of religion also exists in a matrix of other, sometimes competing rights, such as the right to live in a peaceful society, etc.

Daime Tea

Daime tea is prepared by boiling the bark and stems of *Banisteriopsis caapi* and the leaves of *Psychotria viridis*, two plant species of the Amazon forest. The bark of *Banisteriopsis caapi* contains harmala alkaloids (harmine, harmaline, tetrahydroharmine and other similar alkaloids), which inhibit the enzyme monoamine oxidase (MAO). The leaves of *Psychotria viridis* contain DMT.

The psychoactive ingredients in Daime tea include three substances listed in Schedule III of CDSA, namely, harmaline, harmalol and N,N-dimethyltryptamine (DMT). The tea, known as ayahuasca, hoasca and other names in South America, is unique in that its pharmacological activity is dependent on a synergistic interaction between the active alkaloids in both plants.

Most samples of the preparation contain high levels of DMT, harmine and tetrahydroharmine (THH), and lesser amounts of harmaline, harmalol, harmol and related alkaloids¹. A typical dose of Daime tea (200 ml) would contain 25 mg of DMT and 40 mg of harmala alkaloids².

The traditional preparation of Daime tea is strenuous and time-consuming as sections of the vine and bark of *B. caapi* are cut and beaten for hours to facilitate the extraction of Harmala alkaloids. The brew is boiled for many hours and the leaves of *P. viridis* are added at the end of the boiling process, causing the DMT to dissolve into the concoction³.

Most samples of Daime tea contain high levels of DMT, harmine and tetrahydroharmine (THH), and lesser amounts of harmaline, harmalol, harmol and related alkaloids⁴. As might be

¹Pomilio, A. B., Vitale, A.A., Ciprian,-Ollivier, J., Cetkovich-Bakmas, M., Gomez, R., Vazquez, G., (1999). Ayahuasca: an experimental psychosis that mirrors the transmethylation hypothesis of schizophrenia. *J Ethopharmacol* 65: 29-51

²Rivier, L., & Lindgren, J.-E., (1972). Ayahuasca, the South American hallucinogenic drink: an ethnobotanical and chemical investigation. *Econ Botany* 26: 101-129

³Source: Videos and information provided by Céu do Montréal: A 17 Minute History of the Santo Daime Church of Brazil, The Wisdom of the Serpent NTSC, and Santo Daime NTSC

⁴Pomilio, A. B., Vitale, A.A., Ciprian,-Ollivier, J., Cetkovich-Bakmas, M., Gomez, R., Vazquez, G., (1999). Ayahuasca: an experimental psychosis that mirrors the transmethylation hypothesis of schizophrenia. *J Ethopharmacol* 65: 29-51

DRAFT December 12, 2007
UPDATED February 2008

expected, however, concentrations of active ingredients can vary widely depending on the specimens collected, region of harvest, variation in climates and in the case of *P. viridis* the time of day, DMT being found in highest concentration within the leaves of *P. Viridis* at 6pm⁵.

Mechanism of Action of DMT

DMT is the prototype of the tryptamine subclass of indole derivatives. It is a powerful psychedelic agent⁶, not unlike LSD. DMT fits rather well into certain subsets of serotonin receptors within the brain⁷, where it is believed to modify the flow of information. It has been identified as a natural component of the mammalian brain⁸ and is found in many plant species⁹. Although a function for its presence has not been demonstrated, the production of visions in dream sleep has been suggested as a role for endogenous DMT¹⁰. Under normal physiological conditions, endogenous DMT would be quickly degraded by the monamine oxidase (MAO) and aldehyde dehydrogenase present in the human body¹¹.

On its own, DMT is not active orally. It is rapidly metabolized by MAO, the same enzyme that metabolizes serotonin. After MAO is inhibited by harmala alkaloids, DMT becomes orally active and intricate visual displays of colored patterns are often achieved through this combination. The onset of DMT begins after 20 minutes and typically lasts up to 90 minutes, and the psychic effects tend to be integrated while awareness of the physical environment is typically intact¹².

The effects of DMT once it becomes orally active are qualitatively different from either injected

⁵Callaway, J.C., Brito, G., Neves, E., (2005). Phytochemical Analyses of Banisteriopsis Caapi and Psychotria Viridis. *Journal of Psychoactive Drugs*. 37(2): 145-150.

⁶Szara, S., (1956). Dimethyltryptamine: its metabolism in man; the relation of its psychotic effect to serotonin metabolism. *Experientia* 12: 441-442

⁷Callaway, J.C., & McKenna, D.J., (1998). Neurochemistry of psychedelic drugs. *Drug Abuse Handbook*, chapter 6.6, et. S.B. Karch, 485-498. Boca Raton: CRC Press

⁸Callaway, J.C., (1994a). Another warning about harmala alkaloids and other MAO inhibitors. *MAPS newsletter* 4(4): 58.

⁹Ott, J., (1994). *Ayahuasca Analogues: Pangoean Enthogens*. Kennewick, WA: Natural Products Co.

¹⁰Callaway, J.C., & McKenna, D.J., (1998). Neurochemistry of psychedelic drugs. *Drug Abuse Handbook*, chapter 6.6, et. S.B. Karch, 485-498. Boca Raton: CRC Press

¹¹Nichols, D. E., (2000). Declaration for Centro Espirita Benefiente Uniao do Vegetal.

¹²Callaway, J.C., McKenna, D.J., Grob, C.S., Brito, G.S., Raymon, L.P., Poland, R.E., Andrade, E.N., Andrade, E.O., Mash, D.C., (1999). Pharmacokinetics of haosca alkaloids in healthy humans. *Journal of Ethnopharmacology* 65: 243-256.

DRAFT December 12, 2007
UPDATED February 2008

or smoked DMT in the absence of MAO inhibition¹³. The difference is partly due to the route of administration, the amount of time involved, and almost certainly due to the influence of increased serotonin in the brain after MAO inhibition¹⁴. Unlike instances where DMT is smoked or injected, DMT that is ingested must compete with serotonin for receptor binding sites in order to have an effect. Thus serotonin serves to moderate the effects of Daime tea ingestion. Lowering the intensity and increasing the duration of Daime tea effects in this way allows for more cognitive functions to engage in the experience¹⁵.

Mechanism of Action of Harmala Alkaloids

Harmala alkaloids, known as beta-carbolines, include harmine, harmaline, and tetrahydroharmine. They are reversible inhibitors of monoamine oxidase (MAO), that is MAO returns to its original state after the inhibiting molecule has been removed by other metabolic processes¹⁶. Basically, when MAO is inhibited, levels of serotonin in the brain begin to increase, producing noticeable psychoactive effects as the brain becomes hyper-activated with its own neurotransmitters. The primary action of harmine is to temporarily inhibit the action of MAO¹⁷. Harmaline is slightly more potent than harmine in its ability to inhibit MAO, although it is not highly concentrated in Daime tea. Both harmine and harmaline also have CNS stimulant properties.

Early effects produced by harmala alkaloids include lowered body temperature, nausea and vomiting, sweating, weakness, dizziness, tremors and numbness of the limbs. Users then become physically relaxed and experience long dreamlike sequences of vivid images and

¹³Strassman, R.J., Qualls, C.R., Uhlenhuth, E.H., Kellner, R., (1994). Dose response study of N,N-dimethyltryptamine in humans II. Subjective effects and preliminary results of a new rating scale. *Archives of General Psychiatry* 51: 98-108.

Callaway, J.C., & McKenna, D.J., (1998). Neurochemistry of psychedelic drugs. *Drug Abuse Handbook*, chapter 6.6, et. S.B. Karch, 485-498. Boca Raton: CRC Press

¹⁴Callaway, J.C., McKenna, D.J., Grob, C.S., Brito, G.S., Raymon, L.P., Poland, R.E., Andrade, E.N., Andrade, E.O., Mash, D.C., (1999). Pharmacokinetics of haosca alkaloids in healthy humans. *Journal of Ethnopharmacology* 65: 243-256.

¹⁵Callaway, J.C., McKenna, D.J., Grob, C.S., Brito, G.S., Raymon, L.P., Poland, R.E., Andrade, E.N., Andrade, E.O., Mash, D.C., (1999). Pharmacokinetics of haosca alkaloids in healthy humans. *Journal of Ethnopharmacology* 65: 243-256.

¹⁶Callaway, J.C., McKenna, D.J., Grob, C.S., Brito, G.S., Raymon, L.P., Poland, R.E., Andrade, E.N., Andrade, E.O., Mash, D.C., (1999). Pharmacokinetics of haosca alkaloids in healthy humans. *Journal of Ethnopharmacology* 65: 243-256.

¹⁷Udenfriend S. Witkop, B., Reifield, B., Weissbach, H., (1958). Studies with the reversible inhibitors of monoamine oxidase: Harmaline and related compounds. *Biochemical Pharmacology* 1: 160-165.

Buckholtz, N.S., & Boggan, W.O., (1977). Monoamine oxidase inhibition in brain and liver β -carbolines: Structure-activity relationships and substrate specificity. *Biochemical Pharmacology* 26: 1991-1996.

DRAFT December 12, 2007
UPDATED February 2008

fantasies, dominated by specific intense colors. Perceptions of the external environment are usually not as greatly affected as with other hallucinogens, and delusions and feelings of unreality generally do not occur¹⁸.

There is also no published evidence suggesting that DMT causes significant physiological toxicity. Hallucinogens, in general, do not produce life-threatening changes in blood pressure, cardiovascular, renal or hepatic function because they have little or no affinity for the biological receptors and targets that mediate vital vegetative functions¹⁹.

Likewise, there is very little published evidence concerning the toxicity of harmine and harmaline. One report indicates that harmaline produces neurotoxicity in rats, causing high frequency tremors lasting about 12 hours²⁰. However, such effects have not been observed in humans.

Indeed, there is no anecdotal evidence of any neurological or physiological damage among members of religious groups that have consumed Daime tea for over 30 years²¹. In addition, individuals taking antidepressants and Daime tea could experience a condition called serotonin syndrome which is caused by the presence of excess serotonin in the blood, and which causes elevated temperature, tremor and confusion²².

Dependence Potential

The psychoactive substances in Daime tea are not known to cause physiological dependence. Very little is known about the tolerance and dependence producing properties of harmine and harmaline, and the repeated use DMT appears to produce neither physical dependence nor tolerance to its subjective effects. The absence of tolerance makes DMT unique among hallucinogens. Evidence suggests that DMT does not produce cross-tolerance with LSD²³. Chronic users may develop psychological dependence to DMT.

Likelihood of Abuse/Misuse

¹⁸Drugs and Drugs of Abuse (1998) 3rd ed., ch 4: 513-520

¹⁹Nichols, D. E., (2000). Declaration for Centro Espirita Beneficente Uniao do Vegetal.

²⁰O'Hearn, E., & Molliver, M.E., (1993). Degeneration of Purkinje cells in parasagittal zones of the cerebellar vermis after treatment with ibogaine and harmaline. *Neuroscience* 55: 303-310.

²¹Pomilio, A. B., Vitale, A.A., Ciprian,-Ollivier, J., Cetkovich-Bakmas, M., Gomez, R., Vazquez, G., (1999). Ayahosca: an experimental psychosis that mirrors the transmethylation hypothesis of schizophrenia. *J Ethopharmacol* 65: 29-51

²²Callaway, J.C., & Grob, C.S., (1998). Ayahuasca preparations and serotonin uptake inhibitors: a potential combination for severe adverse reactions. *Journal of Psychoactive Drugs* 30: 367-369.

²³Drugs and Drugs of Abuse (1998) 3rd ed., ch 4: 513-520

DRAFT December 12, 2007
UPDATED February 2008

There is a significant difference between the abuse liability associated with smoking or injecting DMT and that associated with the oral ingestion of Daime tea²⁴. While the former presents serious abuse potential, the latter produces a less intense and psychologically safer altered state of consciousness. Also, the fact that ingestion induces vomiting seriously limits the amount ingested and the abuse liability of Daime tea²⁵.

The context in which drug use takes place is also an important determinant of abuse liability. Members of the Santo Daime Church believe that Daime tea is a sacrament (not a drug) requiring tight controls over both the quality of the sacrament and the use of it. The ceremony during which the tea is consumed is a highly structured church service.

Extent of Abuse in Canada

There is some evidence of abuse of DMT in Canada and the United States. Sometimes, parsley is soaked in a solution of DMT and then dried and smoked. A typical dose would be 40-100mg²⁶.

Daime tea is relatively unknown in Canada however, and there is no evidence of its abuse in North America. In Brazil, where Daime tea has been used for centuries, the Federal Council on Narcotics (CONFEN) has conducted a comprehensive review of the use of Daime tea in religious ceremonies and has concluded that ...“there is no objectively verified record containing an unequivocal demonstration of social harm caused by the use of ayahuasca ...There is no reason, to date, for said beverage, in the way it is being prepared and used, to be included in DIMED, the list of illicit substances.”²⁷

Risk to Public Health and Safety

There is no evidence of illicit production or traffic of Daime tea in Canada or elsewhere in North

²⁴Strassman, R.J., Qualls, C.R., Uhlenhuth, E.H., Kellner, R., (1994). Dose response study of N,N-dimethyltryptamine in humans II. Subjective effects and preliminary results of a new rating scale. *Archives of General Psychiatry* 51: 98-108.

Callaway, J.C., & McKenna, D.J., (1998). Neurochemistry of psychedelic drugs. *Drug Abuse Handbook*, chapter 6.6, ed. S.B. Karch, 485-498. Boca Raton: CRC Press

Callaway, J.C., McKenna, D.J., Grob, C.S., Brito, G.S., Raymon, L.P., Poland, R.E., Andrade, E.N., Andrade, E.O., Mash, D.C., (1999). Pharmacokinetics of haosca alkaloids in healthy humans. *Journal of Ethnopharmacology* 65: 243-256.

²⁵Halpern, John H., (2004). Hallucinogens and dissociative agents naturally growing in the United States. *Pharmacology & Therapeutics* 102(2): 131-138.

²⁶Halpern, John H., (2004). Hallucinogens and dissociative agents naturally growing in the United States. *Pharmacology & Therapeutics* 102(2): 131-138.

²⁷ CONFEN Working Group Final report 1985

DRAFT December 12, 2007
UPDATED February 2008

America²⁸. There also does not appear to be any evidence of attempts to extract DMT or other psychoactive constituents from preparations of Daime tea, and this is likely because the potential for such extraction is very limited due to the small amounts of DMT contained in Daime tea preparations and the significant volume of tea required in order to generate enough DMT that would produce the required psychoactive effect.

The greatest risk to public health and safety is therefore due to the possibility of serious adverse drug and food interactions due to the MAO inhibitor effect of the harmala alkaloids contained in Daime tea. In particular, if a person has ingested certain foods, typically certainly meats and cheeses, some elements of those foods which would normally be digested can become potentially lethal. Similarly, taking Daime tea concurrently with certain foods containing tyramine (aged cheeses, chocolate, red wine) can also produce severe increases in blood pressure²⁹.

Legitimate Use in Canada

None of the psychoactive ingredients of Daime tea are currently used for medical purposes in North America, although harmaline was experimentally employed for a short period as an adjunct to psychotherapy³⁰.

There are no known industrial uses for any substances contained in Daime tea.

Regulation of Daime Tea and its Component Substances in Canada

Passed in 1996, the CDSA is Canada's federal drug control statute in that it provides control over the possession, import, export, production, distribution and sale of narcotics, controlled drugs, targeted substances, and precursor chemicals used in the manufacture of illegal drugs. The CDSA, which contains eight schedules of controlled substances (including two classes of precursors), also specifies the penalties associated with unauthorized activities involving substances listed in the Schedules to the CDSA.

The Act is also the means by which Canada honours its obligations under the 1961 Single Convention on Narcotic Drugs, the 1971 Convention on Psychotropic Substances, and the 1988 United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances. These conventions require Canada to control certain activities related to certain drugs and substances.

In Canada, DMT and harmaline are listed in Schedule III of CDSA. Moreover, under section 2 (2) of the CDSA, anything that contains a controlled substance including "...all synthetic and natural forms of the substance" is governed by the Act. Thus, Daime tea is subject to all of the

²⁸E-mail correspondence Feb 26, 2004 with RCMP

²⁹Drugs and Drugs of Abuse (1998) 3rd ed., ch 4: 513-520

³⁰Drugs and Drugs of Abuse (1998) 3rd ed., ch 4: 513-520

DRAFT December 12, 2007
UPDATED February 2008

provisions of CDSA. In this context, individuals who have not been authorized to carry out activities with Daime Tea under the CDSA or its Regulations would be committing an offence and would be subject to potential prosecution. As there are no specific regulations under the CDSA that allow non-licensed individuals to deal in Daime Tea, nor are there any other specific provisions relating to Daime Tea in the CDSA, the only way for the Santo Daime Church in Canada to legally import, transport and provide Daime Tea during its church services, is via a s.56 exemption issued under the authority of the Minister of Health.

The Santo Daime Church

The Santo Daime religion is a Christian syncretic religion originating in Brazil, where CEFLURIS (the mother Church in Brazil) is officially recognized by the Brazilian government. Practice of the Santo Daime faith involves upholding many elements of Christian beliefs and yet also practices with ancient indigenous religious and healing practices.

The ritual drinking of the sacramental Daime tea is a central practice of the Santo Daime religion and church members believe the tea helps them to directly experience the divine. The practice is analogous to the Christian Eucharist³¹ and the consumption of peyote (mescaline) as a sacramental ritual of the Native American Church.

The Santo Daime Church in Canada

In Canada, the Santo Daime religion is practised by approximately 80 persons located in Montreal, Quebec (Céu do Montréal), Tilsonburg, Ontario and Toronto, Ontario. The Céu do Montréal, to which this issue analysis applies, was incorporated by Letters Patent on March 9, 2000.

Use of Daime Tea by the Céu do Montréal

The sacrament is only served during Church services and between services, because the Céu do Montréal is not yet in a position to purchase or build its own Church and is currently holding services in a rented facility, unused Daime Tea is kept in locked cupboard in the Church leader's home. Keys to the Church leader's home are held by designated elders, who are also responsible for transporting the Daime tea between the Church leader's home and the location of church services, and then return any remaining tea to the Church leader's home.

Only adults over the age of 18 may participate in Church services where Daime tea is consumed, and participation in these services is also subject to a rigorous screening process that includes the

³¹McKenna, Dennis J., J.C.Callaway, and Charles S. Grob., (1998). The Scientific Investigation of Ayahuasca: A Review of Past and Current Research. The Heffter Review of Psychedelic Research. 1:65-76.

DRAFT December 12, 2007
UPDATED February 2008

review of a Visitors Information Package³², the completion of forms identifying any medical contra-indications, and signing of a waiver absolving Céu do Montréal of any responsibility in the case of adverse effects. Interested persons must then be interviewed by a member of the Medical and Scientific Advisory Committee and/or Counselling Committee of the Céu do Montréal in order to ensure that there is full understanding concerning the challenges of the Daime Tea rituals itself and the required preparations. If any information provided cannot be validated and/or there is suspicion that a newcomer does not fully understand the risks associated with the service, Céu do Montréal would ask the individual to speak to their physician and/or family members prior to determining whether that individual can attend a service or not.

The Céu do Montréal estimates that it would require 35L of Daime tea per month, where this is based on the consumption of 30 mL for a church with 40 people attending one monthly church service, and a sufficient quantity for use in two special types of services that involve the ingestion of three or five services of decreasing quantities of Daime Tea. In order to track who has ingested Daime Tea, the Céu do Montréal keeps a log documenting the names of people attending each service and the amount of Daime tea served to them.

Church elders are also responsible for importing the required Daime tea from CEFLURIS in Brazil, i.e., collecting the tea from customs upon arrival, completing all required paperwork and transporting it to the church leader's residence. According to the Céu do Montréal, Daime tea would be shipped in leak-proof 10-12 L plastic containers, clearly marked as to their contents (tea, with all substances listed). The containers will also be marked with the following information:

- name of Specific Church of Origin, e.g., Ceu do Mapia or Ceu do Jurua;
- the phase of the moon and the date the Daime tea was made;
- the CEFLURIS logo;
- a contact address and telephone number ofr CEFLURIS; and
- the registration number for CEFLURFIS.

Study Groups of the Céu do Montréal

Study group are groups of at least two committed individuals who follow the same principles and guidelines as the main church, but who do not follow the full church calendar and therefore only have permission to conduct certain works. Permission for the formation of a study group is granted through CEFLURIS in Brazil, and because only designated church elders may possess and administer the substance, Canadian study groups require additional authorization from the leader of the and would not have access to Daime Tea in the absence of a designated elder.

As study groups grow, they become "points", and when a "point" has at least twelve dedicated

³²The Visitor Information Package provided to Health Canada includes copies of the church Code of Ethics and Tenets of Faith and articles describing the Santo Daime church services. The package also contains practical guidelines aimed at preparing participants for attendance at a drinking ceremony, including applicable dietary restrictions (the Church for example recommends fasting for 12 hours prior to consuming Daime Tea) and medication contra-indications.

DRAFT December 12, 2007
UPDATED February 2008

individuals, it may apply to CEFLURIS in Brazil to become a church in its own right. Because the current assessment is intended to support a request for an exemption from the Cému do Montréal, any exemption resulting from this assessment would not apply to any study groups that move to become their own church.

4. IDENTIFICATION OF OPTIONS

OPTIONS:

1. Issue an exemption under s.56 of the CDSA in the public interest to the Cému do Montréal for the religious use of Daime tea.
2. Refuse the request for an exemption under s.56 of the CDSA in the public interest for religious purposes.
3. Exclude Daime tea preparations from Schedule III to the CDSA, thus allowing the Cému do Montréal to import the tea from CEFLURIS in Brazil.
4. Create new regulations authorizing activities with Daime tea.

5. ASSESSMENT OF OPTIONS

Options 3 and 4 were eliminated from further consideration for the following reasons:

- Excluding a substance from the CDSA would allow its import, export, possession and use for a wide variety of purposes, including but not limited to its religious use, which would introduce uncontrolled access to a product and/or substances with possible serious adverse food and drug interactions and insufficient research on long term effects. Health Canada would have no authority to require that mechanisms be in place to mitigate any of the risks that Daime tea may present to public health and safety.
- Due to the small number of potential users associated with this request, it is not feasible to develop a new set of regulations. Health Canada would be required to set up a licence and permit scheme for Santo Daime churches in Canada, to establish a means of monitoring compliance with the regulations, and to develop a suitable evaluation framework that would ensure the final regulations are in fact meeting their intended public policy objectives.

Option 1: Issue an exemption to the Cému do Montréal under s.56 of the CDSA in the public interest for the religious use of Daime tea.

- Recognizes the rights of Canadians to freely practice their religion and may contribute to their spiritual well-being, while respecting the fact that Daime tea contains substances included in the Schedules to the CDSA.

DRAFT December 12, 2007
UPDATED February 2008

- May avoid further legal action on the part of the Cému do Montréal on the grounds that the Canadian government is preventing them from exercising their freedom of religion.
- This option would be similar to the treatment of peyote within the schedules to the CDSA, which allowed individuals the use of a plant containing the controlled substance mescaline for religious purposes.
- This option introduces access to a substance with possible adverse food and drug interactions and insufficient research on long term effects. While the screening process used by the Cému do Montréal would hopefully eliminate the risk of adverse food and drug interactions, a condition on the exemption can also permit the Minister to suspend or refuse further applications should new evidence indicate a significant harm to public health and safety from the use of the substance.
- The decision to grant an exemption from the application of the CDSA for religious purposes sets a precedent as controlled substances contained in plants and preparations derived thereof have been used for social, cultural and religious purposes throughout history. In this regard, the criteria for analysis of this particular request will set the course for future decisions with the same or a different substance.
- The importation and transportation of Daime tea presents a risk of diversion of the substance for illicit purposes through loss in transit or being stolen; however, a condition of the exemption could be that the Cému do Montreal has to have security and control measures in place to mitigate the risk of diversion. The use of Daime tea for non-religious purposes is viewed as sacrilegious by members of the Cému do Montréal.

Option 2: Refuse the request for an exemption under s.56 of the CDSA in the public interest for religious purposes.

- Avoids possibility of serious adverse health effects, should Daime tea be ingested with certain foods and/or medications. the public health and safety risks associated with the sociated with the use of Daime tea in individuals who may be subject to certain food/drug interactions.
- Does not increase the potential for abuse and diversion.
- Likely to be perceived as discriminatory as interferes with the ability of a specific group to freely exercise their right to religious freedom.
- A decision to refuse may result in a legal challenge [REDACTED]
[REDACTED]

6. CONSULTATIONS

s.23

- Health Canada Legal Services

DRAFT December 12, 2007
UPDATED February 2008

- Health Canada Drug Analysis Services (DAS)
- Royal Canadian Mounted Police (RCMP)
- Canada Border Services Agency (CBSA)
- International Narcotics Control Board (INCB)
- Therapeutic Products Directorate (TPD), Health Canada
- Marketed Health Products Directorate (MHPD), Health Canada
- Health Products and Food Branch Inspectorate (HPFBI), Health Canada

The INCB has indicated via written correspondence that it does not consider Daime tea to be controlled under the 1971 Convention. However, it has indicated that signatories must consider their own drug control regimes in assessing this issue. Because the issuance of an exemption to the **Information removed by agreement of requester**

TPD, HPFBI or MHPD did not have any specific input on the issue, although TPD commented on the importance of ensuring that safety information relating to Daime tea (especially potential interactions with drugs) be communicated to the people who will consume it. They also suggested that the safety information provided to persons ingesting Daime tea should be based on a thorough literature review.

7. CONSIDERATIONS

Precedence

The issuance of an exemption in the public interest to the Céu do Montreal his case may lead to other individual requests associated with other Charter protections (freedom of conscience, thought, belief). Persons charged with the importation and/or trafficking of a controlled substance may claim that they intended to use the illegal substance for religious purposes and may site previous exemptions as precedents. While Health Canada may be able to defend a decision to refuse these requests based on a complete assessment of the substance in question against the factors applied in making scheduling decisions, including the risk the substance presents to public health and safety, it should be noted that the courts have ruled in favour of the Santo Daime Church in other jurisdictions (USA and The Netherlands) where public health and safety concerns were used to deny access to Daime tea for religious purposes.

Obligations Under the *Convention on Psychotropic Substances, 1971*

DMT is listed in Schedule I of the Convention on Psychotropic Substances, 1971. Signatories of the Convention are required to "...prohibit all use except for scientific and very limited medical purposes by duly authorized persons...". Signatories are also expected to prohibit manufacture, distribution, import and export except under special license or authorization.

DRAFT December 12, 2007
UPDATED February 2008

While stringent controls apply to DMT under the 1971 Convention, the discussion on pages 386-387 of the Commentary on the 1971 Convention states that neither infusions nor the roots of such plants as the Mimosa Hostilis or Psilocybe mushrooms are covered by the Convention:

“Neither the crown, fruit, mescal button of the Peyote cactus nor the roots of the plant Mimosa Hostilis nor Psilocybe mushrooms themselves are included in Schedule I, but only their respective active principals Mescaline, DMT and Psilobyne (Psilocine, Psilotsin). (.....). An infusion of the roots of the Mimosa Hostilis is used (.....) and (.....) beverages made from such mushrooms are used”³³

Furthermore, the Commentary goes on to state:

“It may be pointed out that at the time of this writing (1971) the continued toleration of the use of hallucinogenic substances (... does not) require reservation (.....). Schedule I does not list any of the natural hallucinogenic materials in question, but only chemical substances which constitute the active principals contained in them”³⁴

Article 32(4) of the Convention contemplates making reservation for plants for religious reasons; in particular the Convention allows signatories to make "reservations" exempting a Schedule I substance from the provisions of Article 7 under the following circumstances:

“A State on whose territory plants are growing wild which contain psychotropic substances from among those in Schedule I and which are traditionally used by certain small, clearly determined groups in magical or religious rights, may, at the time of signature, ratification, or accession, make reservations concerning these plants, in respect of the provisions of article 7, except for provisions relating to international trade.”³⁵

Given that the plant from which Daime tea is sourced is not grown wild in Canada, Article 3(1) of the Convention (regarding preparations of substances controlled under the Convention) applies and Canada has an obligation to control Daime tea as it controls DMT.

Jurisprudence in Other Countries

United States of America

While Daime tea is listed in Schedule I to the CSA in the United States, but further to a legal challenge from the *O Centro Espirita Beneficiente Uniao Do Vegetal* (UDV), the US Drug Enforcement Administration is not allowed to restrict the importation and/or use of Daime tea by the UDV.

³³Commentary on the Convention on Psychotropic Substances, Vienna 21 February 1971, Article 32, p.386.

³⁴Ibid

³⁵Commentary on the Convention on Psychotropic Substances, Vienna 21 February 1971, Article 34, p.386.

DRAFT December 12, 2007
UPDATED February 2008

France

In France, DMT is included in Schedule I to the French controlled substances legislation. In 2005, the Santo Daime Church won a court case allowing them to use the tea on the grounds that they were not performing chemical extractions to end up with pure DMT and harmala and the plants being used were themselves not scheduled. Four months after the court decision however, the common ingredients of Daime tea as well as harmala were added to Schedule I, making the tea and its ingredients illegal to import, use or possess³⁶.

Netherlands

In the Netherlands, DMT is included in Schedule I to the Dutch controlled substance legislation. Nevertheless, the Santo Daime Church in Amsterdam was acquitted on charges of possession on the grounds that there was a lack of evidence that the use of the tea was a threat to public safety, public order, health or good manners. The court also determined that the Church had a right to profess its religion.

Legal Statues in other Countries

The Ceu do Montréal have indicated that the governments of Portugal, Spain and the Netherlands have granted permission to import Daime tea for religious use.

Import of Daime tea

In Brazil, regulations set by the National Antidrug Council (CONAD) prohibit the export of Daime tea. This is an important factor to consider as the Minister would have to determine whether it would be in the public interest to permit the importation of Daime tea when Brazil does not permit its exportation.

Risk to Public Health and Safety

Whereas the public health and safety risks associated with the use of DMT, harmaline and harmalol are significant enough to warrant control under the CDSA, the situation with Daime tea is not as clear. First, there is very little evidence of risk, even in countries where Daime tea has been used for centuries. Potential food or drug adverse reactions, while possible, appear to have been avoided by different Santo Daime churches, possibly as a result of the screening processes adopted, and the fact that they consider the ingestion of Daime tea to be part of a sacred ritual, and a privilege not to be abused.

As mentioned previously, there is little evidence of abuse or diversion of this preparation in North America and as long as appropriate security measures are in place by those involved in transporting and storing Daime tea, the likelihood of future abuse, diversion and/or extraction of

³⁶ Source: www.legifrance.gouv.fr/WAspad/UnTexteDeJorf?numjo=SANP0521544A%20#

DRAFT December 12, 2007
UPDATED February 2008

active ingredients from the preparation imported for religious purposes appears minimal.

There has been an incident of a death in Canada as a result of the ceremonial use of Daime tea. An Ecuadorean Shaman administered Daime tea containing harmaline and tobacco to a First Nations group on a Manitoulin Island Reserve in October 2001, during a three-night ceremony involving fasting and use of the tea. An elderly native woman died the third night from nicotine poisoning. The Shaman was sentenced to a one-year conditional sentence in 2003 on a charge of administering a noxious substance and trafficking in an illegal drug.

A 25 year old man also died after the recreational use of an ayahuasca-like preparation containing 5-MeO-DMT, DMT, harmine, harmaline, and tetrahydroharmine. Further investigation revealed that the individual had ingested a preparation from a South American tree bark and then four hours later ingested tryptamines.

In both of these cases however, the abuse of Daime tea occurred in the absence of the strict protocols that the C eu do Montr eal has in place and is proposing will avoid such adverse events. The Daime tea consumed in these two cases also involved the addition of other substances, such as nicotine and tryptamines.

8. SELECTED STRATEGY

It would appear that the C eu do Montr eal has demonstrated that the sacramental drinking of Daime tea is central to the practice of the Santo Daime religion and that its members should have the right to consume Daime tea because of their right to religious freedom as provided under the Charter of Rights and Freedoms.

That said, while the risk to public health and safety presented by the religious use of Daime tea is not substantial enough to justify impeding the C eu do Montr eal's right to freedom of religion, access to the Daime tea must remain under a certain level of control, as its use still presents some risks, and users who are unaware of the serious adverse food and drug interactions associated with its use could suffer serious health consequences.

It is therefore recommended that a s.56 exemption in the public interest (religious purposes) be issued to permit the import, possession, and administration of DMT, harmalol and harmaline in the form of Daime tea with conditions to mitigate the risks of misuse, abuse, and diversion. A proposed list of conditions can be found in Appendix I. No exemption will however be issued until CONAD (the Brazilian competent authority) permits the export of Daime tea from Brazil.

9. IMPLEMENTATION AND EVALUATION

In order to continue to collect information on the public health and safety risk profile of the active ingredients of Daime tea, Health Canada is proposing to make it a condition of the exemption for C eu do Montr eal to keep records of lab results regarding the concentrations of active ingredients in Daime tea. The C eu do Montr eal will also be required to keep a record of all adverse reactions, including adverse food and drug reactions, associated with the

DRAFT December 12, 2007
UPDATED February 2008

administration of Daime tea in the course of their services.

APPENDIX I: PROPOSED CONDITIONS FOR INCLUSION IN THE SECTION 56 EXEMPTION

- Daime tea is not to be used for medical purposes;
- Daime tea can only be made with *p. viridis*, *b. caapi* and water. It will be shipped in its final tea form in leak-proof 10-12 liter plastic containers;
- The Daime tea for use by the Céu do Montréal must be imported directly from CEFLURIS in Brazil, through Action Customs Services;
- All importations of Daime tea are to be clearly labelled, including the name of the Church of origin, the date and phase of moon that the Daime tea was made, and the address and contact number of the shipping and recipient church;
- Only the designated elders of the Céu do Montréal may claim the Daime tea at customs, and transport the Daime tea from storage to Church services;
- Only the designated elders of the Céu do Montréal can possess and administer Daime tea as part of the Santo Daime sacrament;
- Only persons over the age of eighteen may consume Daime tea;
- All participants must do so freely of their own will and be fully informed of the risks associated with the use of Daime tea;
- All prospective participants must first register with the Céu do Montréal, be given a Visitor's Information Package, and be interviewed by a member of the Céu do Montréal prior to being allowed to consume any Daime tea;
- Health and safety screening processes are to be in place addressing underlying medical conditions, other medications, and foods containing tyramine. A medical information form must be completed and a waiver signed before all persons are allowed to consume Daime tea;
- Public safety precautions and risk management processes are in place to deal with possible medical emergencies and to prevent members from operating a motor vehicle or machinery while under the influence of Daime tea;
- The Daime tea will be kept in a cool area in air tight containers.
- Disposal of any unused Daime tea must follow provincial and municipal guidelines.
- Procedural and physical safety measures are implemented to prevent and minimize risk of diversion, loss or theft of Daime tea, including storing the Daime tea under lock and key in a secure area;
- Only designated elders will have access to the secure area
- The Céu do Montréal will be responsible for recording the concentrations of DMT, harmaline and harmalol in each batch of Daime tea imported for a minimum of two years, and submitting results of said laboratory tests to Health Canada when requested;
- The Céu do Montréal is responsible for reporting any adverse reactions to the Office of Controlled Substances within Health Canada;
- Any loss or theft of Daime tea should be reported to the Office of Controlled Substances, within 10 days of discovery;
- The Céu do Montréal will report, on a monthly basis, the dates of arrival of each import that occurred during the preceding month, the quantity of Daime tea imported for each shipment, the quantity/concentration and dates when Daime tea was consumed by members of the Church;

DRAFT December 12, 2007

UPDATED February 2008

- The Céu do Montréal is responsible for advising Health Canada should any of the circumstances in which it imports, transports, stores and administers Daime tea change, in the case that it may affect these conditions and/or the exemption requires modification;
- The Céu do Montréal must abide by all other federal, provincial, and municipal legislation applicable to the activities authorized pursuant to this exemption.

The exemption may be immediately suspended and/or revoked if:

- Any authorized members violate any of the terms and conditions of the exemption (noting that any such violation may also constitute an offence under the CDSA);
- A designated elder of the Céu do Montréal is found guilty of any other offences under the CDSA;
- There is new evidence that, when assessed along with the evidence upon which this exemption is based, supports a finding that the exemption no longer serves the public interest.

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DRAFT December 12, 2007

UPDATED February 2008

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DRAFT December 12, 2007
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Videos developed by the Santo Daime Church and provided by Céu do Montréal within their application include:

- A 17 Minute History of the Santo Daime Church of Brazil
- The Wisdom of the Serpent NTSC, and
- Santo Daime NTSC

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